

**Competition and Innovation in the
EU Regulation of Pharmaceuticals:
The Case of Parallel Trade**



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Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade

Mededinging en innovatie in de Europese regulering
met betrekking tot geneesmiddelen met betrekking
tot parallelle import

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List of abbreviations

ABPI = Association of the British Pharmaceutical Industry
AEP = Average European Price
AG= Advocate General
AIFA = *Agenzia Italiana Farmaco* (Italian Medicines Agency)
ATC = Anatomical Therapeutic Chemical Classification System
CEPS = *Commission d'Evaluation des Médicaments* (Economic Committee for Health Care Products)
Commission = European Commission
CPMP = Committee for Proprietary Medicinal Products
CPR = *Comitato Prezzi e Rimborso* (Italian Committee for Pricing and Reimbursement)
CTS = *Commissione Tecnico-Scientifica* (Italian Technical Scientific Committee)
DKMA = Danish Medicines Agency
DTP = Direct-to-Pharmacy distribution schemes
EAEPC = European Association of EuroPharmaceutical Companies
EC = European Community
ECJ = European Court of Justice
EFPIA = European Federation of Pharmaceutical Industry and Associations
EFTA = European Free Trade Association
EMA= European Medicine Agency
FTC = Federal Trade Commission
GC = General Court
GDP = Good Distribution Practices
GMP = Good Manufacturing Practices
HE = Health Economics
IO = Industrial Organisations
IP = Intellectual Property
IPRs = Intellectual Property Rights
LFN = *Läkemedelsförmånsnämnden* (Swedish Pharmaceutical Benefits Board)
LIF = *Lægemiddel Industri Foreningen* (Danish Pharmaceutical Industry Association)
MPPA = Dutch Medicinal Product Prices Act
MRS = Dutch Medications Reimbursement System
MSD = Merck Sharp & Dohme
NAS = New active Substance
NCE = New Chemical Entity
NHS = National Health Service
NME = New Molecular Entity
OTC = Over-The-Counter
PPI = Proton Pump Inhibitors
PPRS = Pharmaceutical Price Regulation Scheme
PRO = Pharmaceutical Price Ordinance
PRU = Pricing and Reimbursement Unit
QP = Qualified Person
R&D = Research and Development
ROC = Return on Capital
RP = Responsible Person

SPC = Supplementary Certificate Protection
SSNIP = Small but Significant and Non-Transitory Increase in Price
SPC = Structure-Conduct-Performance
TEU = Treaty of the European Union
TFEU = Treaty on the Functioning of the European Union

The term 'EU' refers to a multiplicity of meanings within the present work: depending on the context, it is used to refer to the territorial space of the European Economic Area, to the European Union as the political and economic union of the 27 Member States, or just as a synonymous of 'European'.

The terms 'European Courts' and 'EU Court' refers to the General Court and the European Court of Justice jointly.

Table of equivalence

This work has been completed after the Lisbon Treaty came into force. The enactment of this Treaty determined the suppression of the European Community and, consequently, it also entailed substantial amendments in the structure of both the Treaty on the European Union and the Treaty establishing the European Community (which is now named ‘Treaty on the Functioning of the European Union’). Numeration also greatly changed. In the text I use the new numeration introduced by the Lisbon Treaty, except for quotations. Also, when I cite papers and books or I refer to legislations and official documents enacted before the Lisbon Treaty came into force, or to interpretative issues based on the wording of Treaty provision that have been changed, I keep the old numeration.

In order to help the reader in getting acquainted with the structure of the new Treaties, I hereby provide a table of equivalence between the old and the new numeration, in relation to the provisions that have been cited in the text.

Old numeration	New numeration
Art. 2 EC	repealed and replaced in substance by Art. 3 TEU
Art. 3 EC	replaced in substance by Articles 3 to 6 TEU
Art. 5 EC	replaced in substance by Art. 5 TEU
Art. 14 EC	Art. 26 TFEU
Art. 28 EC	Art. 34 TFEU
Art. 30 EC	Art. 36 TFEU
Art. 81 EC	Art. 101 TFEU
Art. 82 EC	Art. 102 TFEU
Art. 86 EC	Art. 106 TFEU
Art. 95 EC	Art. 114 TFEU
Art. 113 EC	Art. 284 TFEU
Art. 234 EC	Art. 267 TFEU
Art. 251 EC	Art. 294 TFEU
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Introduction

1. *Background*

Pharmaceuticals are an essential part of modern life. They help satisfy our everyday nutritional, sanitary and medical needs, and represent a primary method for preserving health and treating many diseases and conditions. Their spread, fostered by the progress of pharmaceutical research, created a 'health revolution', increasing human life expectancy and improving quality of life.

Compared to surgical procedures, drugs represent a very cost-effective means for governments to protect the public health of their citizens. This should help reduce total health care expenditure. However, the cost of pharmaceuticals is accounting for an ever-greater proportion of that expenditure. This in turn means that there is increasing scrutiny by governments to tighten budget controls on drugs.

These elements have recently generated a renewed interest in the pharmaceutical industry's practices, and especially in companies' pricing policies, from both the public and regulators. They frequently claim that drugs are priced too highly and that this may undermine patients' access to medicines, as well as their right to health.

In the absence of effective market mechanisms capable of controlling excessive prices, governments have resorted to a wide variety of different policy tools to help them cap the rise of drug prices and of their health care expenditures.

It is the difference between the tools used that has contributed to the presence of large price gaps across countries. Such differences in prices are the basis of what is called 'parallel trade'.

Parallel trade is a form of arbitrage that consists of the cross-border selling of a product protected by an intellectual property right (IPR) without the authorisation of the IPR owner. Parallel trade is an entirely EU phenomenon, because it is based on the principle of free movement of goods, as developed by the jurisprudence in the principle of regional exhaustion of IPRs. Under this principle any protected good that is first marketed in the EU by the IPR owner, or with his consent, shall freely circulate along the supply chain.

As I will explain better *infra*, the European Commission (hereinafter sometimes referred as the 'Commission') and the European Court of Justice (hereinafter, 'ECJ') have always strictly enforced this legal principle against any opposition coming from Member States or private entities to this form of cross border trade. Such a favourable legal environment helped the growth and development of parallel trade.

Whilst at the beginning parallel trade in pharmaceuticals was essentially economically driven by price gaps, as the EU internal market developed, governments began to realise the important potential savings they could make for their health care systems by reimbursing cheaper products, and, indeed, using these lower prices to exert pressure on the prices of original products.

The rapid increase of parallel trade triggered the concern of pharmaceutical companies, who were worried about their profits. They argue that parallel trade, first may not be capable of bringing savings for patients, because regulation on prices would drive out competition, and second it is likely to undermine the investment pharmaceutical companies would make in the development of new drugs.

Therefore it is clear that stakeholders have competing and different interests. Patients want to get their medicines at the cheapest price possible, especially when pharmaceutical expenditures come out of their pockets. Similarly, governments and health care agencies need to control their health care budget and have every interest in lower prices that parallel imported medicines can bring. However, governments also want to grant the most innovative and effective drugs to their citizens, in order to secure their health status. Finally, pharmaceutical companies want to protect their profits and their competitiveness, whose key driver is given by innovation.

Essentially there is a trade off between two clashing objectives: the static efficiency (productive and allocative) achieved through competitive pressure from parallel trade that brings lower prices, and the dynamic efficiency realised through the innovative activity financed by higher prices that lead to the development of new products. According to the first policy goal, parallel trade is potentially beneficial for consumers, as long as it reduces prices of original products, whereas according to the second one, parallel trade is potentially detrimental, because the decline in profits may

determine a reduction in the research and development (hereinafter, 'R&D') activity and consequently stifle innovation.

2. *Past solutions and new challenges*

The tension between static and dynamic efficiency has been subject to a lengthy investigation both in the economic and legal literature.

IPRs are inherently monopolistic, and this appears to be in conflict with competition policy purposes to ban every market power capable of lessening competition to the detriment of consumers' welfare and hampering the freedom of economic initiative.

However, the way IPRs are designed provides a second best solution to this trade off. Being shaped in a fashion that distinguishes them from traditional property rights, i.e. they are limited in time and scope, short run deadweight losses due to monopoly should be offset in the long run by the gains generated by competition, in terms of lower prices, after the expiring of the patent.

Although IPRs embody the balance between the two competing objectives, the way this is concretely struck depends on how IPRs are actually exercised.

For instance, a question that has been pervading the relevant EU case law and the economic literature is whether IPRs can be legitimately used to prevent competition, also in the form of parallel trade.

Traditionally, both the Court of Justice of the European Union and the European Commission regarded restrictions to parallel trade negatively for two concurrent reasons: by impeding *intra-brand* competition, they harmed consumers, and, by putting obstacles to cross border trade, they acted against the completion of the internal market.

This firm conclusion is supported by a robust and well-established strand of case law, and may persuade the reader to believe that the issue of parallel trade is exhausted and sufficiently defined in its legal and economic aspects. However, the so-called 'process of modernization of European competition law', whose supporters strongly claim that the formalistic application of competition law provisions should be overruled in favour of a more economic approach, has, *inter alia*, cast several doubts about the appropriateness of the policy on parallel trade.

The development of certain jurisprudence shows a trend towards this direction.

From the *Bayer* judgment, a jurisprudential *revirement* on parallel trade in pharmaceuticals has been taking place. From then on the attitude of the Commission and of European Courts started diverging. In particular, the judges, educated by the findings of economic theory, doubted that in a highly regulated environment parallel trade on pharmaceuticals could be beneficial for consumers. Also, they feared that parallel trade, by eroding profits, could stifle the innovation incentives of pharmaceutical companies to the detriment of consumers. Under these grounds, it was claimed that restrictions of parallel trade might be permitted.

These developments suggest that there may be scope for improvement in the current policy towards parallel trade. However, how this 'more economic approach' should be performed it appears far from clear.

The reason for such uncertainty in the case of parallel trade in pharmaceuticals is, in my view, twofold: firstly, the way legal proceedings developed left many questions unanswered, with little guidance for handling future cases; secondly, the economics on which the departure from previous case law is based hardly fits the structure and the rationale of EU competition provisions.

This background suggests that the boundaries between IPRs and competition law are still uncertain and that there are new unanswered questions that challenge the current policy pursued at a European level towards parallel trade. For instance, the presence of regulation in the pharmaceutical market poses new conditions of analysis of the effects of parallel trade on prices, especially in relation to the constraints that such regulation may put on market functioning and on firms' pricing strategies.

It thus appears that investigating the current policy pursued at a European level towards parallel trade in pharmaceuticals, in order to assess whether this is informed to economic theory, has policy and academic relevance.

Moreover, this research has additional significance in the present context of reform of EU competition law. The analysis performed has policy implications at two different but interrelated levels: at a '*micro*' level, it suggests potential solutions to the mentioned uncertainty created by the jurisprudential developments in the field of parallel trade of pharmaceuticals; at a '*macro*' level, it may also represent a paramount of

integration of economic reasoning into the legal assessment that can be used to guide the process of modernization of EU competition law.

For this reason, this work appears to be very timely, too.

The presented issue is also important from a societal standpoint. The fundamental role that drugs have in the health of individuals necessarily implies that pharmaceutical policies have very important social implications. The need to discover new medicines and therapies that improve quality and length of life in society is necessarily coupled with the duty for governments to make them affordable to the public. It follows that any change in the way the rules underpinning parallel trade in pharmaceuticals are enforced may have a significant impact over patients' welfare, in terms of access to new and better medicines.

3. *General scope*

This thesis investigates the impact that parallel trade in pharmaceuticals has on consumer welfare, both in a static and in a dynamic sense. The ultimate goal of this analysis is, however, not to say whether parallel trade in pharmaceuticals is good or bad for society. It rather aims at examining from a Law&Economics perspective whether the current legal treatment of parallel trade is optimal and reflects economic theory, whether there is scope for a change, and, if so, on what basis the latter should take place.

In order to comply with this objective, the analysis is going to be developed first on a positive level, and along a normative perspective. Thus, first the principles of law that fund the current policy on parallel trade are going to be examined and then confronted with the findings of economic theory. Last, it will be evaluated whether these findings provide an appropriate ground for a change in this policy.

Inevitably, this thesis is not going to deal with all the antitrust issues related to parallel trade of pharmaceuticals. In particular, as indicated above, the 'macro' implications of a change in the policy on parallel trade of pharmaceuticals in the present context of reform of the European competition law are evident. However, the significance and denseness of the issue of giving practical significance to the 'efficiency defence' now emerging in EU competition law require the formulation of an articulated

proposal that at this stage is impossible to provide, without enlarging too much the scope of the present work. This issue will be thus left for future research.

4. *Product and geographic scope*

The present work concerns reimbursed prescription medicines for human use. Medicines sold over the counter (hereinafter, 'OTCs') are referred to only to a limited extent, when the analysis requires it. Medicines for animal use, medical devices and health services are out of the scope of this research.

Its geographic scope is the 27 Member States currently part of the European Union. In certain sections the analysis is limited to a narrower group of Member States, though.

Reference to the US market is also going to be made. First, the pharmaceutical companies operate worldwide and many big pharma operating in the EU are also present in the US market, and *vice versa*. Secondly, from the regulatory point of view, the US represent the polar opposite of the EU, given that pharmaceutical prices are unregulated and freely established by companies. Thus, for the purpose of legal and market analysis, a comparison between the EU and the US pharmaceutical regulations and markets will be carried out from time to time, when considered appropriate for a more exhaustive and thorough analysis.

Still, this thesis and its findings have mainly relevance for the EU and, as such, they cannot be extrapolated to other areas of the world with diverging regulatory regimes, e.g. on IPRs, on trade policies, or on pharmaceutical regulations.

5. *Methodology*

In conducting the present research, different methodologies are going to be used.

As with regard to the positive part, involving mainly an overview of the case law and the analysis of the relevant principles of the Treaty, the analysis will rely on purely legal research. All the relevant jurisprudence and literature published so far on the related subjects are going to be discussed and examined.

In the normative part, the legal analysis will be supported by the discussion and by the assessment of the findings of the relevant economic literature in the fields of

Industrial Organisations (hereinafter, 'IO'), Economics of Innovation (hereinafter, 'EI'), and Health Economics (hereinafter, 'HE').

6. *Theoretical baseline*

Finally, the reader should be aware of the theoretical baseline underlining this thesis. The balance of the trade off between different policy objectives will be driven by the assumption that consumer welfare is the main goal of EU competition policy. The concept of 'consumer welfare' certainly includes efficiency, in its static features as well as in its dynamic facets. However, efficiency is not going to be considered as a goal in itself here, but it is relevant as long as it concretely contributes to the wellbeing of consumers.

The goal of competition, understood in the sense described above, under EU law must nevertheless be balanced against other non-competition goals that permeate the enforcement of antitrust law at a European level. Among them, market integration is the most important and will be included in large part of the analysis.

7. *Structure of the thesis*

Against this backdrop, the presented work is divided as follows.

Chapter I provides an overview of the pharmaceutical legislation at a European level and up-to-date figures about of the European pharmaceutical market in terms of generated surplus, R&D investment, and units of employment. Despite the fact that this is a large and growing market, it appears that the EU pharmaceutical market is lagging behind its main competitors (US and Japan). One of the causes of this lack of competitiveness is attributed to the fragmentation of the market.

Even if the European Commission has set up some centralized regulatory functions, still drugs pricing and related decisions are under the exclusive competence of Member States, given that national governments finance the largest part of pharmaceutical private expenditures. Budget concerns, in fact, induce them to refrain from relinquishing their sovereignty on health. This creates a fragmented market, especially at the level of prices.

The persistence of price gaps has generated the economic opportunity for arbitrage, or parallel trade. The birth, the growth and the maturity of this form of cross-border trade are discussed at length through the analysis of the related figures and in light of the changes that took place in the relevant legislation.

The economic and legal features characterising the pharmaceutical market have an important implication in antitrust: they render the definition of the relevant market quite complex, due to the distortion created by regulation and patients' insensitivity to price in the mechanisms of interchangeability among drugs. The solutions proposed by scholars and adopted in the case law are provided. In particular, it is examined how the relevant market has been defined in parallel trade cases.

Chapter II presents a comprehensive overview of European case law dealing with the trade off between the protection of IPRs and the rules of the internal market. It describes how judges defined the compromise between these two policy objectives over time, thereby developing the concepts of *existence* and *exercise*, of *subject matter* of an IPR, and establishing the principle of *regional exhaustion* of an IPR.

Such principles have been guiding also the European policy towards parallel trade in all sectors, until the end of the nineties.

The analysis shows how the mentioned developments in case law question these principles in the field of pharmaceuticals. Unfortunately, the history of the analysed cases does not offer the possibility of clearly envisaging the boundaries of this criticism: convoluted wording, procedural obstacles, unambiguous evidence, not to mention the partisan debate often animating the dispute between counterparts, created some loopholes that deserve further investigation.

The fact that Courts opened the way to economic reasoning in a more explicit fashion pays tribute to the right need of modernising European competition law. Yet, the need to reconcile these developments with well-established principles built in forty years of case law arises.

To this purpose, it appears essential to review and assess the economics underlining the new judicial scepticism about parallel trade of pharmaceuticals.

Accordingly, the following two macro-questions are analysed:

1. whether the pharmaceutical sector is a 'special' one where regulation is so pervasive that parallel trade does not have any competitive effect on prices of original products;
2. whether parallel trade is detrimental for pharmaceutical innovation.

These two questions are at the centre of Chapters III and IV respectively.

In order to disentangle the first question, the latter has been divided in three sub-questions:

- a. whether regulation on prices is such that competition cannot take place;
- b. whether parallel trade on pharmaceuticals brings benefits to consumers and national health care systems,
- c. and how large are these savings.

The answer to these questions is provided through the examination of the characteristics of national pharmaceutical regulations and of their economic rationale, through a survey that covers the main EU Member States, with special attention for the countries where imports take place: Sweden, Denmark, UK, Germany. Particular consideration is given to the mechanisms driving the negotiation procedures between health care authorities and pharmaceutical firms, in order to ascertain the role that parallel trade plays with respect to the bargaining power of parties. This overview is complemented with the analysis of the theoretical and empirical literature that studied the effect of parallel trade on prices of pharmaceuticals, both in importing and in exporting countries.

The antitrust implications of these issues are then explored: if drug price formation is not entirely shielded from competitive mechanisms, it is reasonable to presume that parallel trade entails savings. If, on the contrary, competitive mechanisms are overruled by price controls, parallel trade cannot be presumed to put pressure on the price of original products.

If parallel trade of pharmaceuticals can be presumed to bring savings notwithstanding regulation, restrictions of parallel trade could be alleged as anticompetitive under Article 101 TFEU, even if their effects are not concretely proven. In this case, there would be ground to uphold the traditional legal assessment of the

anticompetitive effects caused by restrictions to parallel trade, also in the pharmaceutical sector.

If, on the contrary, the regulatory environment is such that parallel trade cannot be presumed to bring savings, any restriction should be caught only when harm to consumers is concretely ascertained. In this case, there is scope to support a change of the current legal assessment.

However, the change cannot take place only by looking at the effects that parallel trade has at a static level, but it should also look into the impact it has from a dynamic perspective. Chapter IV is devoted to this latter aspect: it analyses the link between parallel trade and the incentives of pharmaceutical companies to innovate.

Economic theory suggests that the level of expected profit may have an impact on the intensity of the R&D activity, namely on the amount of resources invested in innovation, and in turn on the firm's output. The question of whether and how these findings apply to parallel trade did not find any practical application in the considered judgements. It follows that the issue of the impact of parallel trade on pharmaceutical innovation is still open.

This Chapter contributes to the debate that this topic is currently undergoing by placing it in an antitrust context.

To this purpose, Chapter IV reviews the economic literature, starting from the Schumpeterian theory of constructive destruction, until the most recent developments in the Industrial Organisation (IO) theory and in the empirical literature in Health Economics, predicting that there exists a positive correlation between the expected return from drug innovation and the level of investment in R&D.

On this basis, the innovation pattern in the drug industry is further examined, with particular regard to the relationship between patents, profits and firms' incentive to invest in innovation. The literature that focuses on the link between parallel trade, profits and innovation is also analysed and discussed.

Such analysis aims at ascertaining the appropriateness of the presumption that more financial incentives in the form of a broader exclusive right always lead to an increased innovation activity.

The answer to this question has an important implication from an antitrust point of view. In the context of modernisation of Article 102 TFEU, it helps respond the question of how dynamic efficiency considerations enter the antitrust assessment of unilateral restrictions to parallel trade: whether it is sufficient to affirm them to legitimize the abusive conduct, or whether they should be proved, and measured.

The last part of the thesis starts from the acknowledgement that only when the overall effect of parallel trade in the market is clear, policy indications about changes in the legal treatment can be formulated. In considering the welfare implications of a conduct restricting parallel trade, two dimensions are, therefore, weighted: the losses in static efficiency and the gains in dynamic efficiency.

This theoretical analysis is confronted with the literatures that claim that this balancing entails a full-blown market analysis whose complexities Courts may not be able to manage, especially when the examination is prognostic (as it is for efficiencies).

Chapter V deals with these issues. In particular, it attempts to craft a legal standard that help judges apply an effect-based approach to competition law enforcement, especially in relation to restrictions to parallel trade. Also, it proposes a test for efficiencies that it is not too demanding for undertakings, nor too costly for antitrust agencies and judges.

To this purpose, the Chapter looks into procedural instruments, and especially into presumptions and inferential reasoning, that may help Courts getting away from the *impasse* created by a forward-looking market analysis. The aim is to set out a legal standard that is clear, flexible enough to account for market reality and workable at the same time.

CHAPTER I

The European pharmaceutical market

Introduction

This Chapter aims at providing the reader with a good grasp of the economic and legal features that characterise the European pharmaceutical market, in order to place the following analysis into an appropriate context.

Section 1 is a very general platform, where the industry is described in its main elements: economic and financial performance, degree of concentration, competitiveness, level of investment in R&D, regulatory traits, etc. Also, the basic notions of health economics applied to pharmaceuticals are introduced: supply and demand features are discussed, together with their implications for pharmaceutical policies in the EU.

Section 2 looks into the state of health of the European pharmaceutical industry, especially in terms of competitiveness with respect to the US industry. Such comparison provides an occasion to discuss the current crisis in innovation that the sector is experiencing.

Section 3 starts from the premise that one of the reason for the lack of competitiveness of the EU pharmaceutical sector is the fragmentation of the market. To explain the roots of the present situation, the history of the harmonising efforts by EU institutions is reviewed, from the measures tackling marketing authorisation to those attempting to reduce the distortion associated with price controls.

Section 4 focuses on drug price controls and analyses how the jurisprudence reconciled their existence with the principle of free movement of goods.

The legitimacy of drug price controls under EU law established by the European Courts has provided the basis for the existence and growth of parallel trade of pharmaceuticals. Section 5 is devoted to the definition and analysis of this typically EU phenomenon, from its earliest to the latest market developments, as well as in relation to the regulatory provisions disciplining it at a European level.

Section 6 finally discusses the definition of the relevant market in the pharmaceutical market, and what is the impact of price controls on this definition. Specific examination is dedicated to the market definition in parallel trade cases under Article 102 TFEU.

Section 7 concludes.

1. The economics of the pharmaceuticals

Prescription drugs and the pharmaceutical industry have an increasingly important role in modern society. The progress of pharmaceutical research is responsible for the ‘health revolution’ of the last thirty years: thanks to the wider diffusion of more effective drugs, human life expectancy increased and the quality of life improved substantially. Insulin is a meaningful example in this respect: after its discovery in the ‘20s, diabetes does not cause certain death any longer.

Drug therapies have supplemented nutrition, sanitation, and medical care as methods for preserving health. Today, drugs are used to treat many diseases and conditions: chemotherapy for cancer, steroids for skin diseases, psychotropic drugs for mental health problems, beta-blockers for heart disease, protease inhibitors for AIDS, etc. Some of these drugs represent an alternative to more invasive surgical treatments, others are used in conjunction with them, or provide a cure for diseases for which no treatment was available before.

Despite this success, the pharmaceutical industry has come under severe media and legislative scrutiny, especially in US¹.

¹ During the 1960s, the drug industry was subject to two congressional investigations focusing on its business practices and pricing policies. The major concern expressed during the nine-months hearings held by the Senate Subcommittee on Antitrust and Monopoly was that pharmaceutical products were overpriced. Senator Kefauver affirmed: “It is our purpose to inquire into the question of whether the drug manufacturers are setting their price at excessive levels. [...] to determine whether the antitrust laws as applied to this industry are adequate and, if not, to devise specific remedial legislation”. A more harsh statement was made by another member of the Subcommittee, Senator Smathers: “It is readily apparent that the American people [...] share alike

Pharmaceutical firms are among the largest and most profitable businesses worldwide. Led by Pfizer, with sales of \$52.9 billion, five pharmaceutical firms ranked in the top 100 on the *Fortune* list of largest firms in 2004. The profit performance of the pharmaceutical industry is even more remarkable. In 2001, the industry ranked first in rates of return on revenues, assets, and stockholders' equity².

Not only the level of prices charged for drugs has triggered public opinion's disapproval³, but also the magnitude and the nature of these investments have come under criticism, in relation to the type of drugs being produced and for the failure to adequately warn consumers about side effects⁴.

the distinction of paying the world's highest premium for these basic human necessities... This is a shameful condition in our present-day society which spends tremendous sums on research to promote health and increase life-span, and yet the products are placed well out of reach of the average and low-income families". Similar concerns are still raised today by members of the Congress and generated the proposal of allowing reimports of medicines from Canada and Europe into US. See GRAHAM DUKES, *Accountability of the Pharmaceutical Industry*, in *The Lancet*, 2002, no. 360, November 23, 2002. *Contra* COMANOR, *The Political Economy of the Pharmaceutical Industry*, in *Journal of Economic Literature*, 1986, no. 24, p. 1178-1217, and GRABOWSKI and VERNON, *A New Look at the returns and risks to pharmaceutical R&D*, in *management Science*, 1990, no. 36(7), p. 804-821, explaining that without the increase in prices occurred since the '80s the drug industry would have not recovered the cost of the drugs introduced in the '70s.

² The Congressional Office of Technological Assessment (OTA) in February 1990 undertook an extensive study of costs, risks and reward of pharmaceutical R&D. The study found that pharmaceutical manufacturers, on average, earned a net profit of \$36 million from each new drug introduced between 1981 and 1983. On top of a 'normal rate of return' of about 10%, the study found an excess 4.3% profit over a drug's life cycle. Further, profits by pharmaceutical manufacturers exceeded those of companies in industries with similar risks by 2% to 3% in each year from 1976 to 1987. Similarly see SCHERER, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, in *Journal of Economic Perspectives*, 1993, no. 7(3), p. 97-115, who affirmed that the pharmaceutical industry was either the first - or the second - most profitable industry for 24 out 32 years between 1960 and 1991, looking at the median after-tax profit return on stockholders' equity. A 2002 report by Public Citizen cites the fact that US drug company profits increased by 33% in 2001 despite a slowdown in the economy, a drop in employment rates, and the September 11th terrorist attack. *Contra* see GRABOWSKI, VERNON and DI MASI, *Returns on R&D for 1990s new drug introductions*, in *Pharmacoeconomics*, 2002, no. suppl. 3, p. 11-29, where it is shown that pharmaceutical R&D is characterized by a highly skewed distribution of returns and a mean industry internal rate of return modestly in excess of the cost-of-capital.

³ Several studies conducted during the '90s found that drug prices in US were significantly higher than in other countries. Two studies by the US General Accounting Office (GAO) in 1992 found that US prices were 32% higher than in Canada and 60% higher than in the UK. In 1998 the Committee on Government Reform and Oversight of the US House of Representative issues a minority staff report *Prescription Drug Pricing in the 1st Congressional District in Maine: an International Price Comparison*, found that drug prices in US are 72% higher than in Canada and 102% higher than in Mexico. Similarly see the earlier work of SCHUT and VAN BERGEIJK, *International price discrimination: The pharmaceutical industry*, in *World Development*, 1986, no. 14(9), p. 1141-1150. *Contra* see DANZON and CHAO, *Cross-national price differences for pharmaceuticals: how large, and why?*, in *Journal of Health Economics*, 2000, no. 19, p. 159-195; DANZON, *Making Sense of Drug Prices, in Regulation*, 2000, no. 23(1), p. 56-63, who affirms that the findings of these studies are biased because of methodology problems: they do not take into account generic substitution, liability risk, different consumption patterns, and, most of all, they consider wholesale prices and not retail prices. Her findings refute the conventional wisdom that US prices are higher than anywhere else.

⁴ See ANGELL, *The Truth about Drug Companies: How they Deceive Us and what to do about it*, 2004, criticising especially the focus of pharmaceutical companies on 'me too drugs'. For a definition of 'me too' drugs see fn

Other factors have been threatening the performance of the industry: a slowdown of productivity, due to the difficulty of finding new blockbusters, the increasingly pressing cost-containment measures from governments⁵, the development of the generic industry, also encouraged by governments, etc., diminished the outlook for future earnings. As a consequence, share prices of the most important pharmaceutical companies dropped on average about 25% between 2000 and 2005⁶.

The pharmaceutical industry is global, with thousands of firms. Although the largest firms are located in the industrialized countries of Europe, North America, and Japan, pharmaceutical manufacturers are found in nearly every country of the world. These firms are often referred to as 'big pharma' because of the size of individual firms. A relative new segment of the pharmaceutical industry is biotechnology, but firms remain far smaller than big pharma.

The pharmaceutical industry as a whole is characterised by a certain level of fluidity and a good degree of entry of new firms, especially in the areas of biotechnology. While much of the pharmaceutical market is dominated by big pharma, the overall market is highly dynamic, with frequent entry and departure and rapid change in the year-to-year sales ranking of all products⁷.

Despite the fluidity of the pharmaceutical market, however, the degree of competition among firms is decreasing in important respects. The worldwide market for pharmaceuticals is becoming more concentrated because of two factors: the wave of mergers that took place in the nineties and the increased concentration of top selling drugs among fewer and fewer firms.

Four firms accounted for half of the total reported sales of the top 10 firms in 1995, and nearly 50% in 2003, as it is shown in this table.

54 in this Chapter. Also, recall the outcry that accompanied the withdrawal of the \$2.5 billion arthritis drug Vioxx from Merck & Co. Inc. The company took this decision after five days, after data showed that the long-term use of doubled the risk of heart attacks and strokes, confirming concerns raised by earlier studies.

⁵ Also in US, typically a country where pharmaceuticals have been freely priced, congressmen advocated for price controls either through government intervention or market forces. See BLANKEAU, *OTA takes a Closer look at Cost of Drugs, in Hospitals*, 1993, no. 67(7), p. 48-50.

⁶ See BERENSON, *Big Drug Makers See Sales Decline with Their Image*, in *New York Times*, November, 14, 2005; ABOUD, *Stung by Public Distrust, Drug Makers Seek to Heal Image*, in *Wall Street Journal*, August 26, 2005.

⁷ See SCHWEITZER, *Pharmaceutical Economics and Policy*, 2007, p. 24.

Table 1: Worldwide Sales of Pharmaceuticals by 10 Largest Manufacturers

Company	1995 Sales (\$ billion)	Company	2003 Sales (\$ billion)
Glaxo Wellcome	12.5	Pfizer	39.6
Merck	11.3	GlaxoSmithKline	29.8
HMR	8.4	Merck	22.4
Novartis	8.1	Johnson&Johnson	19.5
Bristol-Myers Squibb	7.4	Aventis	18.9
Pfizer	7.1	Astrazeneca	18.8
Roche	6.9	Novartis	16.0
Johnson&Johnson	6.3	Bristol-Myers Squibb	14.9
AHP	6.1	Wyeth (form. AHP)	12.6
SmithKline Beecham	6.1	Eli Lilly	12.5
Combined Sales	80.2	Combined Sales	205

Source: Lehman Bros and company reports, as reported in *The Economist*, July 20, 2002, p. 55.

In the pharmaceutical market, the degree of market concentration changes as one looks more narrowly at specific therapeutic products that actually compete with one another. When the industry is viewed as one market producing all drugs, there are thousands of firms producing pharmaceuticals. Such a market, with so many producers, appears competitive. But when one considers a specific therapeutic class, the number of firms producing these drugs is much smaller. For instance, the world market for statins is dominated by two products, which account for the 80% of the market share.

Table 2: Market concentration of Statins, 2003

Product	Manufacturer	Market Share of Sales (%)
Lipitor	Pfizer	50
Zocor	Merck	30
Pravachol	BMS	15
Lescol	Novartis	1.3
Lescol XL	Novartis	1.7
Others*		2.5

* Comprised of Altocor ad Mevacor, formulations of the generic lovastatin

Source: Adapted from Marketos, 2004.

The number of firms and the competing products vary from a drug family to another and the market concentration index varies for each single therapeutic area. It follows that the competitiveness of the pharmaceutical market depends on the definition of the market, i.e. which family and which therapeutic area are considered⁸.

1.1 *Features of the supply-side of the market*

The introduction of a medicine into the market is the last step of a long procedure that starts with a the activity of research and development (hereinafter, sometimes referred as 'R&D'), continues with clinical trials and ends up with the administrative obligations that lead to the granting of the marketing authorisation.

Once a molecule is invented, pre-clinical trials begin. These tests consist of a pharmacological screening that under European law is regulated by the Directive 2001/83/EC, as amended by Directive 27/2004/EC of the Parliament and the Council (the so called 'Human Use Directive'), which disciplines in detail all the experiments that must be performed. Companies first carry out the tests in vitro: these indicate the therapeutic properties of the molecules and the type of diseases that can be treated. The identified therapeutic characteristics are then tested on animals. These trials aim at ascertaining the level of toxicity, the pharmacodynamic (how the drug works in the body) and pharmacokinetic (how the body processes the drug) properties of the molecules.

Such tests assist pharmaceutical companies to decide whether a drug candidate has scientific merit for further development as an investigational new drug.

At the end of this stage, which generally lasts two or three years⁹, companies are generally granted a patent on the new molecules and clinical trials begin. These are divided in three phases and they aim at ascertaining the efficacy and the safety of the drug on humans. For this reason, it is necessary to obtain the related administrative authorization, before volunteers are recruited.

Under European law, these three phases are regulated by the Human Use Directive.

⁸ For a deeper discussion about the issue of the relevant market definition see *infra* Section 6 in this Chapter.

⁹ Note that patent applications are filed before or meanwhile pre-clinical trials start, because of the length of the procedure to obtain the patent. Companies judge important to start the clinical trials only after the patent has been granted, in order to avoid the risk of another company patenting the innovation before them.

Phase I of clinical trials also does not have any therapeutic objective but only cognitive aims, in order to test (on a small group of around people 20-50) the safety of the drug and to better understand the way the active substance is assimilated by the human body.

Phase II represents the crucial part of clinical trials: it involves a larger group of people (20-300) and serves the purpose of identifying the target disease, establishing the minimum effective dose and the optimal regime of administration.

Phase III represents the last check before the drug is marketed. To this purpose the drug is administered to a statistically significant group of patient suffering the targeted disease (300-3,000). At this stage, it should be ascertained whether the active substance offers advantages compared to existing drugs, in particular with respect to side effects¹⁰.

If Phase III provides positive results, the company applies for the marketing authorisation. This may take up to several years, depending on the chosen procedure and on the State concerned¹¹.

In US, a preceding Phase 0, has been recently added to the three just mentioned. Phase 0 consists of exploratory, first-in-human trials conducted in accordance with the United States Food and Drug Administration's (FDA) 2006 Guidance on Exploratory Investigational New Drug (IND) Studies. Phase 0 trials are also known as human microdosing studies and are designed to speed up the development of promising drugs by establishing very early whether the drug or the agent behaves in human subjects as was expected from preclinical studies. Distinctive features of Phase 0 trials include the administration of single sub-therapeutic doses of the study drug to a small number of subjects (10 to 15) to gather preliminary data on the agent's pharmacokinetics and pharmacodynamics.

¹⁰ However, ANGELL, *The Truth about Drug Companies*, cit., p. 103 *et seq.*, claims that some drugs are tested against a placebo and not against comparable existing drugs.

¹¹ See on this issue SCHWEITZER ET AL., *Is there a United States Drug Lag? The Timing of New Pharmaceutical approvals in the G-7 Countries and Switzerland*, in *Medical Care Research and Review*, 1996, no. 53(2), p. 162-178, who measured the timing of drug approvals in eight developed countries. The authors found that *any* country is lagging behind others in approving many important products: even Switzerland, which is particularly quick in approving new drugs, lags behind other countries. But, on average, US are relatively fast, together with UK, Canada and France. Other countries, like Italy and Germany, are slower.

A Phase 0 study gives no data on safety or efficacy, given that administered doses are too low to cause any therapeutic effect. Drug companies carry out Phase 0 studies to rank drug candidates in order to decide which has the best pharmacokinetic parameters in humans to take forward into further development¹².

Once these hurdles are overcome, 12-13 years have normally passed since the first synthesis of the new active substance¹³. It follows that more or less half of the exclusivity period, starting from the patent application, is not remunerative for the company, because it cannot market the product before the clinical trials are concluded and cannot earn any return on the investment made. For this reason, as from the beginning of the '90s companies were given the possibility of enjoying the Supplementary Certificate Protection (SPC), up to five years from the expiry of the patent¹⁴.

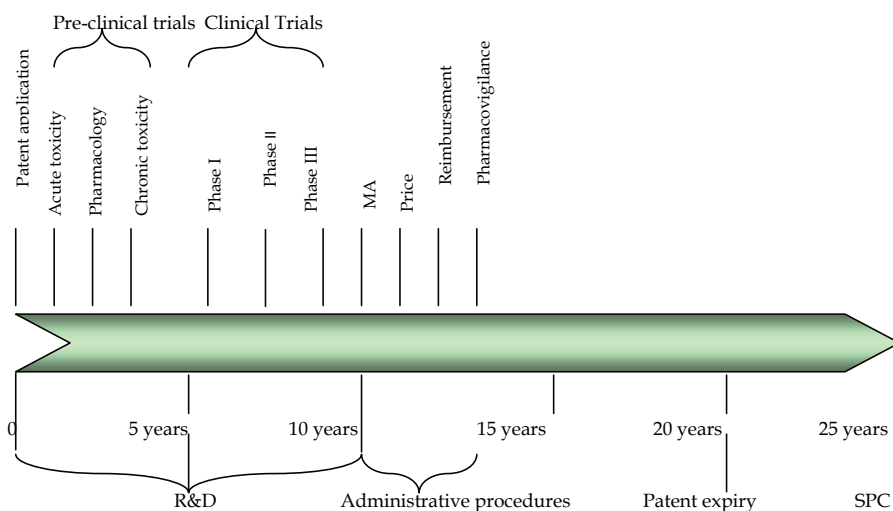
¹² Experts have raised questions about whether Phase 0 trials are useful, ethically acceptable, feasible, apt to speed up the drug development process or save money, and whether there is room for improvement. See CAMPORESI, *Phase 0 workshop at the 20th EORT-NCI-AARC symposium, Geneva*, 2008.

¹³ See LUCIONI, *Le conseguenze delle politiche di contenimento della spesa pubblica nel contesto attuale del mercato farmaceutico*, in *Rass. Dir. Far.*, 1996, p. 358, who affirms that the crisis of the traditional screening model used to select molecules, triggered tighter control over clinical trials. The increased regulatory hurdles increased the length of the procedure, especially starting from the '80s.

¹⁴ In Italy see the Law no. 341/1991. At a Community level see the EC Regulation no. 1768/92.

Graph 1: Phases of the research and development process

Screening of 10.000 molecules



Once the drug is on the market, the stage of the pharmacovigilance (or Phase IV) begins: the company has to comply with the obligation imposed by the Human Use Directive in order to keep under control the effects over the entire population, in order to further test its efficacy and identify possible additional side effects.

The discovering process for pharmaceutical products is not only long, but also costly: it has been estimated that the cost of researching and developing a new chemical or biological entity is €800 million in 2003¹⁵. This investment is allocated along the above indicated phases in the following way: 27.3% of the R&D expenditures are devoted to the pre-human/pre-clinical trials, 7.4% to the Phase I of the clinical trials, 13.1% to Phase II of the clinical trials, 28.5% to the Phase III of the clinical trials, 5.1% to the approval

¹⁵ See DI MASI ET AL., *The price of innovation: new estimates of drug development costs*, in *Journal of Health Economics*, 2003, no. 22(2), p. 151-85. The methodology of the study has been criticised by the consumer advocacy group Public Citizen, which suggests on its web site that the actual cost is under \$200 million, about 29% of which is spent on FDA-required clinical trials: see *Critique of the DiMasi/Tufts Methodology and Other Key Prescription Drug R&D Issues*, available at http://www.citizen.org/congress/reform/drug_industry/articles.cfm?ID=6532.

procedure, 13.4% to the pharmacovigilance and 5.2% to remaining administrative duties¹⁶.

The length of the process that leads to the introduction of a new drug into the market has two effects.

First of all, the costs of innovation are sunk by the time the medicines receive the approval of the health authority and the price is agreed upon. This generates the need for the company to quickly recoup the money invested in order to conduct new research projects¹⁷.

Secondly, there is a high degree of uncertainty. On average only one or two out of 10,000 substances synthesised in laboratories successfully pass all the mentioned stages required by regulation to test the efficacy and the safety of medicines. And only the 23% of the compounds entering clinical trials is eventually approved. The uncertainty over the R&D activity determines the difficulty of foreseeing precisely if and when the product will reach the market and what will be the level of expected profits, which depends on the efficacy and the success of the product. For instance, between 1961 and 1983, only about 1 in 60,000 compounds synthesized by pharmaceutical laboratories were 'highly successful', when success was measured in terms of global sales performance in excess of \$100 million annually¹⁸.

It should be noted, however, that whilst more lenient regulatory controls would diminish this uncertainty, they would also increase the risk to have the toxic products in the market to the detriment of public health¹⁹.

¹⁶ European Federation of Pharmaceutical Industries Associations (hereinafter, 'EFPIA') membership survey conducted in 2009 (percentages calculated from 2007 data). These figures, however, assume that all R&D is entirely conducted in-house. However, pharmaceutical companies rely, to a significant degree, on the acquisition of compounds from third parties. See the Commission Communication of 8 July 2009 on the outcome of the sectoral investigation undertaken by DG Comp in the EU pharmaceutical sector, at p. 8, where it is indicated that in 2007 about 35% of companies' molecules whose application for the marketing authorisation was pending in Europe had been acquired or in-licensed. In ANGELL, *The Truth about Drug Companies*, cit., p. 32-36, the reader will find many examples of fundamental drugs (e.g. AZT, an antiretroviral drug, the first approved treatment for HIV; Taxol, the anticancer most ever sold in medical history; Glivec, the only drug that treats, and blocks, the myeloid leukaemia) that have been first discovered by universities or institutes of research that are publicly financed and only at a later stage developed into marketable products by pharmaceutical companies.

¹⁷ See DANZON and TOWSE, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, in *International Journal of Health Care Finance and Economics*, 2003, no. 3(3), p. 183-205.

¹⁸ See REDWOOD, *New drugs in the World Market: Incentives and Impediments to Innovation*, in *American Enterprise*, 1993, no. 4(4), p. 72-80.

¹⁹ Tighter regulatory hurdles were triggered by the Thalidomide tragedy in the '50s. Thalidomide was developed by Grunenthal in 1954 in Germany. In the mid-1950s there were no guidelines for the

1.2 Features of the demand-side of the market

The demand for pharmaceuticals has unique features.

Demand for pharmaceuticals, like the demand for other health care goods and services, is derived from the demand for health itself²⁰. Medications are important components of health services and are often a crucial element in medical care. Pharmaceuticals can be purchased both separately or jointly from the consumption of other health services. Under some circumstances, they are consumed together with physician office visits and/or hospital stays. In some other circumstances, pharmaceuticals are substitutes for other services, resulting in the reduction of the use of other types of care.

In the market for drugs, as well as of health, patients are not sovereign: they do not choose, nor do they pay for the medicines they consume.

1.2.1 Who chooses drugs: the role of physicians

Patients do not know their present and future need for health and the appropriate level of consumption of medicines. Pharmaceuticals are, in fact, '*post-experience goods*', i.e. goods whose qualities and impact over the personal utility individuals are not perfectly able to judge, even after they consume them²¹.

development, production and marketing of medicinal products, nor a uniform federal pharmaceutical law in Germany. Thalidomide was used to promote sleep and rapidly became the top selling hypnotic and sedative, through TV advertising. In 1958/1959 a significant increase was recorded in the number of newborn babies with congenital deformities. At the beginning of the '60s some surveys raised the suspicion that thalidomide products might possess a teratogenic (defect-causing) effect. On 27 November 1961 Grunenthal withdrew Thalidomide from the market, 12 days after receiving notification of the first plausible suspicions. In 1964, three years after market withdrawal, proof of the teratogenic effect of the drug was obtained in animal experiments conducted in New Zealand on white rabbits. One of the most important consequences drawn from the Thalidomide tragedy was the creation of a wide range of measures to ensure risk minimization in connection with the licensing of newly developed pharmaceutical products. For Germany, the Medicines Act of 1976, which came into force on 1 January 1978, was a landmark event in this context.

²⁰ See SCHWEITZER, *Pharmaceutical Economics and Policy*, cit., p. 116, where a difference between 'demand' and 'need' is made. Need refers to professionally determined requirements and is often little related to demand.

²¹ In economics, an experience good is a product or service where product characteristics such as quality or price are difficult to observe in advance, but these characteristics can be ascertained upon consumption. Experience goods pose difficulties for consumers in accurately making consumption choices. In healthcare, they reward reputation and create inertia. Experience goods typically have lower price elasticity than search goods, as consumers fear that lower prices may be due to unobservable problems or quality issues. Post-experience goods, also called *credence goods*, are goods for which it is difficult for consumers to ascertain the quality even after they have consumed them, such as vitamin supplements. Potential consumers of these goods may require third-party information, provided by private rating agencies or government bodies. See SATTERTHWAITE, *Consumer Information, Equilibrium Industry Price, and the Number of Sellers*, in *Bell Journal of Economics*, 1979, no. 12(2), p. 488-506; NELSON, *Information and Consumer Behavior*, in *Journal of Political Economy*, 1970, no. 78(2), p. 311-329.

The inability of choosing among different therapies induces patients to rely on the expertise of a physician. The latter has primary authority to decide which prescribed medicine should be used, including the method of administration, dosage, and duration of usage.

In the relationship between patients and physicians two problems arise. One is asymmetry of information: on the one hand, patients sense (some of) their symptoms but do not have the necessary skills to analyse them to make a diagnosis; on the other hand, physicians have these skills but do not precisely know all the symptoms suffered by patients²².

The second issue relates to the alignment of the incentives of patients and physicians. On becoming ill, consumers hire health care professionals to act as their agents²³. The perfect agent physician is one who chooses exactly as the patients themselves would choose, if they had the information the physician possesses. In other words, in order to avoid conflicts of interests, the physician should focus on patient's preferences only²⁴.

However, physician is not only an agent but also a provider of care. Like any other rational individual, he, or she, tends to maximize his, or her, own utility, instead of patients' utility. A physician's utility is composed by net income, leisure and inducement²⁵. Inducement is the physician's own effort to induce patients to buy more care. If inducement is profitable, providers would do more inducement²⁶ and patients would buy more medicines, no matter whether this reflects their utility²⁷.

²² For this reason it has been estimated that roughly only one-fourth or more of total personal health-care expenditures can be regarded as 'reasonably informed'. See PAULY, *A Primer on Competition in Medical Markets*, in FRECH, *Health Care in America: The Political Economy of Hospitals and Health Insurance*, 1988, p. 16.

²³ See, for instance, SCOTT and VICK, *Patients, Doctors and Contracts: an Application of Principal-Agent Theory to the Doctor-Patient Relationship*, in *Scottish Journal of Political Economy*, 1999, no. 2(46), p. 111-134.

²⁴ See FOLLAND, *Economics of Health and Health care*, 2007, p. 316.

²⁵ See FARLEY, *Theories of the Price and Quantity of Physician Services*, in *Journal of Health Economics*, 1986, no. 5, p. 315-333. See MCGUIRE and PAULY, *Physician Response to fee Changes with Multiple Payers*, in *Journal of Health Economics*, 1991, no. 10(4), p. 385-410, for a policy proposal to correct physicians' distorted incentives.

²⁶ See SCHWEITZER, *Pharmaceutical Economics and Policy*, cit., p. 123. However, see DE JAEGER and JEGERS, *The physician-patient relationship as a game of strategic information transmission*, in *Health Economics*, 2001, no. 7(10), p. 651-668, who show that there are some situations where the patient is able to constrain the physician in inducing demand.

²⁷ For this reason the demand for pharmaceutical is considered a 'supplier-induced demand' (hereinafter, 'SID'). See EVANS, *Supplier-induced demand: Some empirical evidence and implications*, in PERLMAN, *The economics of health and medical care*, 1974, pp. 162-173, who sees in the fact that demand for drugs is a derived demand the source for possible non alignment of incentives between patients and physicians. See DE JAEGER and JEGERS, *A model of physician behaviour with demand inducement*, in *Journal of Health Economics*, 2000, no. 2(19), p.

1.2.2 Who pays for drugs: the financing of medicines' consumption

With regards to payment, the classical market functioning does not normally apply either: in most of the EU Member States patients use products that another agent – the government – pays.

Pharmaceuticals are, in fact, *merit goods*, i.e. goods that every individual should potentially have at his disposal, even if he or she does not get a concrete utility out of it. It follows that access to medicines is commonly (almost entirely) granted by the State through consumption's financing²⁸.

Drugs play an important role in the field of public health and pharmaceutical spending forms a crucial part of Member State's health and industrial policy and an important share of the social security budget²⁹. For this reason, policy makers face a trade off among overlapping and competing interest.

First of all, they bear the responsibility of guaranteeing that only safe, good quality and effective medicines are marketed. Secondly, given that public or social insurance funds bear a considerable part of the cost of pharmaceuticals, health authorities have a legitimate interest in obtaining good value for money. Equity and efficiency are thus primary objectives of any pharmaceutical policy. Thirdly, in many countries, given the economic contribution of the sector, also the promotion of a regulatory environment conducive to business plays an important role.

231-258, who point that physicians' ability to induce patients may make them better off in some situations. For an evaluation of some aspects of prescribing practices see CHAPMAN, DURIEUX, WALLEY, *Good Prescribing Practice*, in MOSSIALOS ET AL., *Regulating Pharmaceuticals in Europe: striving for Efficiency, Equity and Quality*, 2004, p. 144-157.

²⁸ The governmental intervention in the financing of drug consumption is economically justified by the fact that merit goods are consumed at a suboptimal level if provided through market mechanisms, given that positive externalities generated from consumption are not internalised from consumers. The latter, in fact, are subject to asymmetry of information over the characteristics of the good and consider only individual utility they get from consumption rather than social benefits deriving from it, especially in the long run. To remedy this market failure, the State can choose to encourage a larger production or consumption of these goods through public procurement, regulation, or financial provision. See DELBONO and ZAMAGNI, *Microeconomia*, 1998, p. 794. They underline that "... l'attribuzione di meritorietà ad un bene presuppone che il singolo individuo non sia pienamente in grado di percepire il contenuto di pubblica utilità associato al consumo di particolari beni o servizi se non dopo averne, più o meno a lungo, sperimentato l'utilizzo. Ne consegue che l'autorità pubblica deve garantirne la diffusa accessibilità".

²⁹ The amount for total health care expenditure in Europe is at present divided into three main categories: 17% are represented by pharmaceutical products and other medical non-durables, 35.4% by in-patient care (hospital) and 47.6% by out-patient care and others. See OECD Health Data 2008, *Statistics and Indicators for 30 Countries*, December 2008; EFPIA, *The Pharmaceutical Industry in Figures*, 2009, p. 25.

The separation of the functions of choice and payment, traditionally both pertaining to the consumer, and their attribution to distinct subjects have generated drug consumption patterns unrelated from their cost. This has caused an inflationist trend in the use of medicines and the consequent concern of governments.

It should be noted that also those countries where historically the State did not intervene to cover private health expenditures and citizens (*read*: private insurers) pay for the drugs they are prescribed, experienced an extraordinary growth in pharmaceutical expenditures.

This may be due to the fact that drugs, like any credence good, may display a direct (rather than inverse) relationship between price and demand. That is, a rise in price does not entail a reduction in consumption. In fact, even when patients pay their medicines out of their pockets, to a certain extent they remain insensitive to price. Generally consumers' responsiveness to price is determined by their knowledge and other's people knowledge of a product. But, given that consumers' information over the utility that a drug brings to them is very limited, consumer demand for pharmaceuticals is largely inelastic. Sellers, on the contrary, know the utility impact of such goods on patients' health. It is clear, thus, that there is asymmetric information on the side of patients. This, together with product differentiation within the same therapeutic area³⁰ and the presence of patents, helps companies have influence over prices and strengthens their monopoly power³¹.

For these reasons, and despite cost sharing provisions recently introduced to render consumers more cost conscious³², altogether, spending on health care has been rising at a faster rate than the economies are growing³³.

³⁰ Cf. Section 6 of this Chapter for a discussion about why drugs belonging to the same therapeutic area cannot be always considered perfect substitutes.

³¹ The pharmaceutical market is generally considered to have the structure of monopolistic competition. Monopolistic competition is a market structure where many competing producers sell products that are differentiated from one another (i.e. the products are substitutes, but are not exactly alike), consumers perceive that there are non-price differences among the competitors' products, the demand schedule is downward sloping, there are few barriers to entry and exit, producers have a degree of control over price, and, because of brand loyalty, they can raise prices without losing all of their customers. See CHAMBERLIN, *Theory of Monopolistic Competition*, 1933.

³² These measures generally account for co-payment. Co-payment may work according to four different mechanism: a) fixed fee (per item, per prescription, or according to pack size); b) a percentage of the value of the prescribed drug; c) a deductible up to a certain limit; and d) a combination of the above, usually a fixed fee or a deductible plus a percentage of the value of the drug. It is difficult to assess overall the full economic impact of cost sharing on utilization, health status and income distribution. The first study that investigated

1.2.3 The cost-containment strategies applied by national governments

From 1960 to 2001 total spending on health care as a percentage of GDP (at market prices) in Europe was 3.7% in 1960, 7.1% in 1980, 8.2% in 2000 and 8.4% in 2001³⁴. Between 1995 and 2000 most countries increased their total pharmaceutical expenditures as a percentage of total health care spending from 13.3% to 15.6% on average. Between 1990 and 2000 the unweighted average of per capita pharmaceutical expenditures in the EU Member States (excluding Austria) increased by 79.9%³⁵.

The huge financial constraint such spending is playing on national budgets is illustrated by the following figures:

the effects of cost sharing on patients' welfare is the RAND HEALTH INSURANCE EXPERIMENT (HIE), a comprehensive study of health care costs, utilization and outcomes conducted between 1974 and 1982 in the US. An early paper with interim results (NEWHOUSE, ET AL., *Some interim results from a controlled trial of cost sharing in health insurance*, in *N Engl. J Med*, 1981, no. 305, p. 1501-7) concluded that health insurance without coinsurance "leads to more people using services and to more services per user". However, the experiment also demonstrated that cost sharing reduced "inappropriate or unnecessary" medical care as well as "appropriate or needed" medical care. Later on NEWHOUSE, *Consumer-directed health plans and the RAND health insurance experiment*, in *Health Affairs*, 2004, no. 23(6), p. 107-13, wrote "For most people enrolled in the RAND experiment, who were typical of Americans covered by employment-based insurance, the variation in use across the plans appeared to have minimal to no effects on health status. By contrast, for those who were both poor and sick -- people who might be found among those covered by Medicaid or lacking insurance -- the reduction in use was harmful, on average".

³³ See THOMSON and MOSSIALOS, *Influencing Demand for Drugs through Cost Sharing*, in MOSSIALOS ET AL., *Regulating Pharmaceuticals in Europe*, cit., p. 227-244.

³⁴ In *Eco-Santé OECD*, June 2008, it is reported that in 2006, the latest year for which comparable data are available, health spending on average across OECD countries grew in real terms by just over 3%, the lowest rate since 1997. Looking at the trend during this decade, health expenditure grew rapidly in many countries between 2000 and 2003, with an annual average growth rate of 6.2% over that period. Since 2003, the rise in health expenditure has slowed, however, to an average of 3.6% per year. In several countries, the percentage of GDP devoted to health actually fell slightly between 2005 and 2006, while in others it stabilised. Overall, this marked a pause in a long-term rising trend that has seen health spending rise from 6.6% of GDP on average in OECD countries in 1980.

³⁵ See OECD, *Health Data* 2002, su http://www.oecd.org/document/22/0,3343,en_2649_34631_1935190_1_1_1_1,00.html. It should be pointed out that, unfortunately, most of data on pharmaceutical spending do not distinguish between public and private expenditures, and among the latter the different type of pharmaceutical spending, such as Over-The-Counter products (OTC) or co-payment on reimbursed products; also, methodological problems exist when performing cross-country comparison because of rate fluctuation, price difference and variation in public coverage.

Table 3: Total expenditures in health care in % of GDP (2006)

France	11,1
Germany	10,6
Belgium	10,4
UK	8,4
Spain	8,4
Italy	9,0
US	15,3
Average OECD	8,9

Source: *Eco-Santé OECD*, June 2008, available at www.oecd.org.

Table 4 : Payment for pharmaceuticals by compulsory health insurance systems and national health services (ambulatory care only)

EFPIA 2007	€ million
Austria	1,964
Belgium	2,859
Bulgaria	n.a.
Croatia	349
Cyprus	n.a.
Czech Republic	1,196
Denmark	988
Estonia	62
Finland	1,142
France	21,276
Germany	27,759
Greece	4,298
Hungary	1,194
Iceland	81
Ireland	1,721
Italy	11,493
Latvia	91
Lithuania	n.a.
Malta	n.a.
Netherlands	5,062
Norway	1,077
Poland	1,765
Portugal	1,401
Romania	574
Slovakia	796
Slovenia	209
Spain	10,719

Sweden	1,950
Switzerland	2,683
United Kingdom	10,845
Total	113,554

Source: EFPIA, 2009

Note: Czech Republic, Estonia: 2006 data; France, Greece, Ireland, Netherlands, Norway, Sweden, UK: estimate.

The dramatic increase of health care expenditures and the steady increase of demand for and reliance on pharmaceuticals as a (*read*: the most cost-effective) treatment triggered a wave of cost containment plans at national level in all Member States³⁶.

Governments traditionally targeted the supply-side of the industry, thereby attempting to cap the growth of pharmaceutical expenditures through price control schemes. The latter vary in nature to a great extent from country to country: from price negotiation, to profit cap, to price-volume agreements, to maximum reimbursed prices set by government³⁷.

The impact of these cost-containment policies is often very unclear. In the literature it is often claimed that these legislations did not achieve the goals for which they were enacted. Such failure is due to the fact that reducing pharmaceutical prices does not necessarily lead to a reduction in the total pharmaceutical expenditures, whose amount is determined also by quantities consumed, i.e. by consumption patterns, medical culture, etc.³⁸

Traditional cost containment measures are currently supplemented by new cost-containment measures, based on new methods of accounting the value of a pharmaceutical product. At present the cost of medicines is only one of the sides considered by health authorities; the other one is the benefit generated by the medicine.

³⁶ In two countries, budget systems for pharmaceutical spending existed already before the rising cost of pharmaceutical expenditures became a common problem for policy makers in all European countries. In the UK, between 1991 and 1999, general practitioner fund holders were responsible for prescribing costs, and in Germany an overall expenditure cap for pharmaceutical prescribing has been used since 1993.

³⁷ See better Section 1.1 of Chapter III for an overview of the EU national pharmaceutical regulations.

³⁸ For instance, a controlled price system for drugs may lead to an increase in total drug expenditures, because of a rise in the use of less effective drugs. French drugs have the lowest prices in Europe. Still, pharmaceutical expenditures in France are extremely high: 20% of total health care expenditures, double the US proportion. In Canada, strict government price controls have had little effect on containing total drug spending: the percentage of total health care spending on pharmaceuticals climbed from 11.4% in 1990 to 15.2% in 2000. See SCHWEITZER, *Pharmaceutical Economics and Policy*, cit., p. 149.

Three methods are frequently used to relate these two variables: cost-benefit analysis³⁹, cost-effectiveness analysis⁴⁰ and cost-utility analysis⁴¹.

Together with supply-side measures, demand-side instruments are now increasingly used to contain pharmaceutical expenditures.

All the European governments put a variety of financial incentives on the relevant stakeholders, with the aim of influencing the demand for drugs and containing costs. Such financial incentives may take the form of formularies that restrict reimbursement to a selected list of approved drugs⁴², or generic substitution, or cost-sharing provisions, etc.

These measures determined an increased interposition by third parties payers between patients and their physicians, by deciding which drugs will be better covered than others in order to contain health care costs. Therefore, physicians' professional autonomy is now partially restrained by such measures⁴³. This may determine a reduction of the risk of inducement and change the way pharmaceuticals are demanded⁴⁴.

1.2.4 *The role of pharmacists*

Pharmacists act both as sellers and counsellors for those using drugs and are responsible for ensuring that the patient is informed about the drug's use, its method of administration, indications and contraindications, as well as its side effects. Although they are generally obliged to provide what the doctor prescribed, they are more and

³⁹ Cost-benefit analysis compares the costs of two options giving the same benefit on the basis of the associated costs. The chosen option should entail the lower cost.

⁴⁰ When calculations of monetary value are not possible, outcomes are measured in real terms. In the context of drugs, the comparison between two products is performed by looking at the ratio between the costs and their effectiveness in terms of the cure produced. The less expensive drug per cure is to be chosen.

⁴¹ Cost-effectiveness analysis cannot be performed when two or more outcomes measures are compared. In this case, cost-utility is used, i.e. ratio between the cost of a health-related intervention and the benefit it produces in terms of the number of years lived in full health by the beneficiaries (measured in terms of Quality of Life, hereinafter 'QALY').

⁴² A formulary is a list of drugs covered – positive formularies –, or not covered – negative formularies – by an insurance plan. More complex formularies are used by health plans in the attempt to encourage a more frugal use of expensive drugs. This is accomplished with through tiers within a group of therapeutic equivalents: among them a preferred product is designated. Generally these are generics. The second-preferred drug is normally a branded one and is available with co-payment. The other products are available with higher co-payment rates. See MANDELKER, *Formularies: Balancing Cost and Quality*, in *Business and Health*, 1995, no. 13(3), p. 6-10.

⁴³ See WALLEY and MOSSIALOS, *Financial Incentives and Prescribing*, in MOSSIALOS ET AL., *Regulating Pharmaceuticals in Europe*, cit., p. 177-195.

⁴⁴ See SCHWEITZER, *Pharmaceutical Economics and Policy*, cit., p. 131.

more involved in the campaign to reduce the level of pharmaceutical public expenditures. Thus, for instance, now doctors have the possibility, or the duty, to substitute the prescribed product with a cheaper equivalent.

In sum, the demand for pharmaceuticals has unique features. It is four-tired: the physician prescribes, the patient consumes, and the government pays, and the pharmacists administers. Such fragmentation generates a situation where incentives are not aligned: physicians take decisions on behalf of patients but are not involved in the financial consequences; patients are not decision makers and often do not bear the cost of the physician's decision; payers are not involved in the therapeutic decision either but bear the related cost; pharmacists are often mere executors of physicians' decisions. Each of these actors generally acts in his, or her, own interests but the decisions he, or she, takes may have a negative externality on other stakeholders.

However, in all countries governments are attempting to address these issues and correct these market failures through appropriate measures that help rationalising the use of medicines.

2. The European pharmaceutical market

The pharmaceuticals industry represents an important sector in Europe and plays a critical role in both the industrial and the health field. In terms of production, revenue generation and employment it is one of the best-performing high-technology industries in Europe, amounting to about 3.5% of the total EU manufacturing value-added and 19.2% of the whole EU business R&D expenditures⁴⁵.

According to the latest estimates, the pharmaceutical industry in 2008 provided about 635,000 units of employment in Europe, of which 117,000 are devoted to R&D. It generated a trade surplus of € 52 billion (up from € 7.067 billion in 1990) and involved R&D investment of € 27.2 billion (up from € 7.766 billion in 1990). The estimated total value at ex-factory prices amounted to around € 145 billions⁴⁶.

⁴⁵ See EFPIA, *The Pharmaceutical Industry in Figures*, 2009, p. 10, where it is referred that according to EUROSTAT data, the pharmaceutical industry is the high technology sector with the highest value-added per person employed, well ahead of the average value for high-tech and manufacturing industries.

⁴⁶ See EFPIA, *The Pharmaceutical Industry in Figures*, 2009, p. 10.

These figures pay tribute to the fact that the European pharmaceutical sector is a large and growing market. Factors such as the ageing population⁴⁷, higher life expectancy, advances in biotechnology and a greater reliance on pharmaceuticals as a cure for diseases are opening up this sector.

Although the European pharmaceutical industry is overall performing well, recently the first symptoms of some difficulties have appeared. In particular, it would seem that the European pharmaceutical market is losing competitiveness with respect to the past and in regard to its main competitor, the US.

In 2006 the EU pharmaceutical industry invested about € 24.8 billion in R&D, that is, about 18.5% of its sales. In absolute value, these figures seem to be high enough. However, if compared to previous figures, a declining trend appears. For instance, R&D expenditures represented 1.84% of the European Union's GDP in 2006 against 1.86% in 2000⁴⁸.

This level of investment in R&D, besides being insufficient with respect to the target established at a EU level⁴⁹, is also significantly lower with respect to the expenditures in the US.

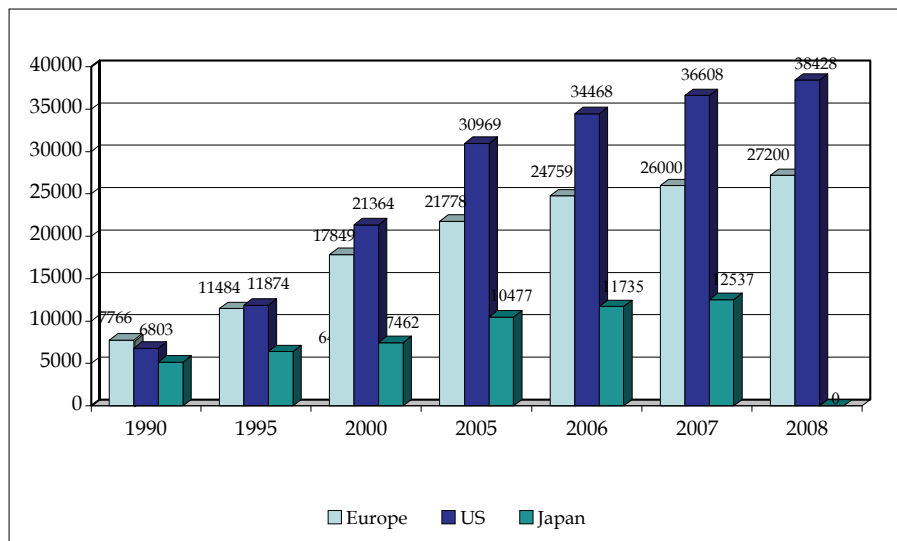
The US pharmaceutical industry leads other industries in the share of sales revenue allocated to R&D. US pharmaceutical manufacturers more than doubled the share of revenue allocated to R&D between 1980 and 2000.

⁴⁷ Total percentage of elderly people, (those aged 65+) in Europe was 21% in 2002 as compared to 10.6% in 1990.

⁴⁸ See EUROSTAT, News release, no. 34, 10 March 2008; *Science, technology and innovation in Europe*, 2008.

⁴⁹ The goal in R&D investments, as set by the Lisbon summit strategy, is to achieve by 2010 an R&D intensity of at least 3% for the EU as a whole.

Graph 2: Pharmaceutical R&D expenditures in EU-US



Source: EPFIA, PhRMA

Note: EU in ml €; US in ml \$

As this graph shows, while in the '90s Europe was investing more than US in R&D, it is now largely lagging behind. Between 1990 and 2008 the R&D growth rate increased 5.2 times in US and 3.3 times in EU. This underpins the claims that there is an uneven distribution of R&D activity between Europe and the US⁵⁰.

Although European pharmaceutical firms are among the leading pharmaceutical groups, they generally obtain results vastly inferior to those of American companies. Also, European companies are, in general, of smaller size than US companies, which therefore benefit of larger amounts of resources to invest in R&D.

This raises concerns about the ability of European pharmaceutical firms to face competition in a globalized environment⁵¹, especially in light of the rapid growth in the research environment in emerging economies such as China and India. This, together

⁵⁰ See GAMBARDILLA, ORSENIGO, PAMMOLLI, *Global Competitiveness in Pharmaceuticals - A European Perspective*, a report prepared for the Directorate General Enterprise of the European Commission, November 2000.

⁵¹ See EFPIA, *The Pharmaceutical Industry in Figures*, 2008, p. 2.

with the lower labour costs, may result in the closure of R&D sites in Europe and the opening of new sites on the Asian continent⁵².

Not only the rate of investment in R&D from European firms has been declining, but also the productivity has been consistently slowing down. Between 1960 and 1965, European companies invented 65% of new active substance (NASs) placed on the world market. Forty years later their share had fallen to 33%.

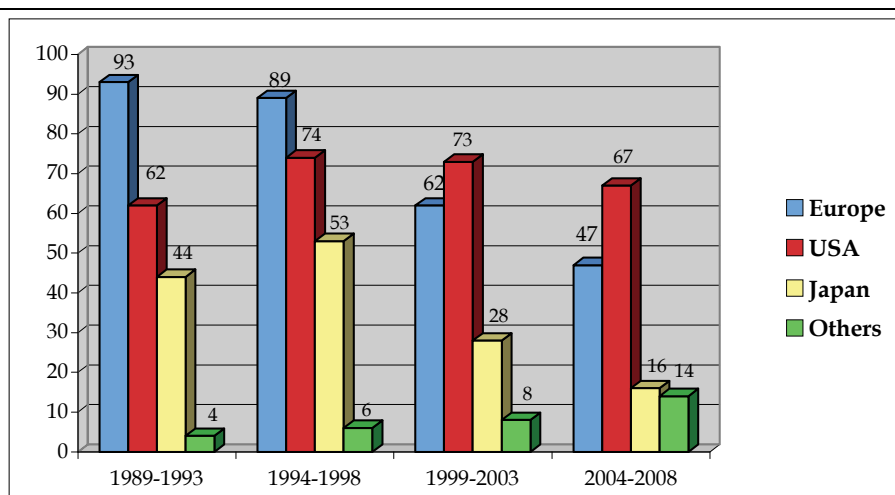
True, the US pharmaceutical firms are not exempt from this negative trend, which has been ascribed by some commentators to a more general crisis of the industry⁵³. Analysts have been claiming, in fact, that also in US to a dramatic increase in R&D expenditures corresponds a decrease in the number of new molecular entities (hereinafter, 'NMEs') put onto the market and an increase in the number of 'me-too drugs' produced⁵⁴. From 1999 to 2003, both the EU and US regulatory authorities have recorded significant reductions in approvals: from 27 to 17 NAS in the EU (through the centralised procedure) and 35 to 21 NMEs in the US.

⁵² This is one of the concerns that triggered the Innovative Medicines Initiative, a Public-Private Partnership between the pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Communities, represented by the European Commission. See http://imi.europa.eu/index_en.html.

⁵³ See GAMBARDELLA, ORSENIGO, PAMMOLLI, *Global Competitiveness in Pharmaceuticals - A European Perspective*, cit., p. 86 *et seq.*

⁵⁴ A 'me-too drug' is a variation of an already existing product, i.e. a re-engineered compound that has similar effects on the human body to the pioneer products. See the study published by CMR International, 2003, describing the increasing trend in the production of 'me toos'. See also *infra* Section 2.2 in Chapter IV for more detailed figures about the number of NMEs produced by US pharmaceutical companies in 2002.

Graph 3: New molecular or biological entities (1989-2008)



Source: Scrip - EFPIA calculations

After 2003, the pharmaceutical productivity seems to have improved, both in US and in Europe: 25 new molecular (chemical and biological) entities, in fact, reached the world market for the first time in 2007. This has somehow relieved the concerns of some experts about the health of the pharmaceutical industry: it has been claimed that the crisis is not structural⁵⁵ and that should be seen in a much wider historical perspective. Past trends show that there have already been fluctuations in drug launches in the history of the industry. However, as of the '50s overall there has been a steady increase in the number of new chemical entities launched⁵⁶. Still, there is disagreement on how to interpret the downward trend and the subsequent improvement in drug launches.

In any case, data available for the period 2003-2007 show the predominance of the United States in terms of R&D investments levels⁵⁷. This fact continues to provide a source of concern from EU institutions for the competitiveness of the EU pharmaceutical

⁵⁵ CRA, *Innovation in the Pharmaceutical Sector*, a Study undertaken for the European Commission, November 2004, where the assessment of European companies' pipelines suggested that the likely number of new active substances to be brought to market or in the process of applying for marketing authorisation was increasing, and therefore the decline did not reflect a structural trend.

⁵⁶ See SCHMID and SMITH, *Is declining innovation in the pharmaceutical industry a myth?*, in DDT, no. 10(1), 2005.

⁵⁷ See EFPIA, *The Pharmaceutical Industry in Figures*, 2008, p. 23; PAMOLLI, *What Happened to the European Pharmaceutical Industry? A European Perspective*, presentation at American Enterprise Industry, Washington D.C., October 7, 2004.

industry.

Such lack of competitiveness of the European industry can be attributed, among other things (like the absence of a federal R&D funding system equivalent to that present in US), to the fragmentation characterising the regulatory environment in Europe⁵⁸.

The latter has been the cause of duplication of costs of marketing, distribution and administration and, in some cases, of excess capacity⁵⁹. In addition, differences in health care systems and regulations, has diminished the attractiveness of the European market as a favourable environment for R&D investments.

For this reason, efforts to build a single market for pharmaceuticals have been made since early ages of the history of the European Union⁶⁰, in the belief that this objective was the fundamental premise for the growth and the competitiveness of the industry and for the effective protection of patients' health. The completion of the single market would, in fact, spur investments from pharmaceutical companies and favour a more efficient allocation of resources.

3. A single market for pharmaceuticals.

The abatements of barriers to integration have been pertaining to three different areas so far: the harmonisation of marketing authorisation procedures and other licences, and the indirect harmonisation of price controls measures; the elimination of national measures of control of public expenditures that create obstacles to free movement of pharmaceuticals; and the harmonisation of national patent systems where the degree of protection was not considered adequate to the logic of the single market⁶¹.

3.1 The harmonisation of marketing authorisation for drugs

Prior to the creation of European Medicines Evaluation Agency (hereinafter, 'EMA') in 1995, medical products were reviewed and approved at national level, with

⁵⁸ See *Il costo della «NON EUROPA» nell'industria farmaceutica*, in *Rass. Dir. Far.*, 1989, p. 526.

⁵⁹ See CURRIE, *European Registration: today, tomorrow, and beyond*, in *Journal of Clinical Pharmacology*, 1990, no. 30(5), p. 386-389.

⁶⁰ See the Commission Communication on the Single Market in Pharmaceuticals. (93)718 Final, Brussels, March, where the Commission expressed concern about the slow development of the European market for pharmaceuticals and suggested that the lost in competitiveness could translate into an economic and social cost for Europe. It outlined an industrial policy that stressed the importance of a single internal market designed to establish a stable environment that would protect patients' health.

⁶¹ In this Chapter, I will focus on the first two mentioned areas.

each country having its own set of policies for drug approval and marketing authorization.

Clearly, such disparities between the national regulations hindered the free movement of goods within the European Common Market and put an obstacle to market integration.

For this reason, the Council, already long time ago started a process of approximation of pharmaceutical national laws, based on the powers that the Treaty attributes to this body to this purpose⁶².

With Directive 65/65/EEC of 26 January 1965⁶³, the Council aimed at harmonising the conditions necessary to obtain a marketing authorisation and a manufacturing licence in each Member State, in order to ensure that the medicine complied with the requirements of quality, safety and efficacy. This first piece of European legislation still provides the foundation of the current regulatory framework for the assessment of medicines.

The primary criterion that guided such harmonisation attempt was the limitation of the discretionary power of national health care authorities, through the adoption of generally accepted scientific standards in marketing authorisation procedures, and the harmonisation of bureaucratic practices with regards to documents, trials, and timelines⁶⁴.

Subsequently, the European Community has introduced a harmonised procedure that allowed the company to obtain a marketing authorisation valid in various Member States.

Directives 75/318/EEC and 75/319/EEC⁶⁵ established a mutual recognition procedure that allowed companies to request a marketing authorization in five or more

⁶² See Article 94 of the EU Treaty: “The Council shall... issue directives for the approximation of such laws... [which] directly affect the establishment or functioning of the Common Market”. See CUVILLIER, *The Role of the European Medicines Evaluation Agency in the harmonisation of pharmaceuticals*, in GOLDBERG and LONBAY, *Pharmaceutical Medicine. Biotechnology and European Law*, 2000, p. 137-156.

⁶³ See Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products.

⁶⁴ See RISTUCCIA, *Il farmaco tra autorizzazioni amministrative e privilegio industriali*, in *Riv. Dir. Civ.*, 1993, no. 1, p. 87.

⁶⁵ See Council Directive 75/318/EEC of 20 May 1975 on the approximation of laws of Members States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products. See also the Second Council Directive 75/319/EEC of 20 May 1975 on the

Member States, after having obtained a first authorisation on the basis of the criteria set by the Directives.

Rules on chemical and pharmaceutical testing, pharmacological and toxicological testing and clinical trials, as already seen, were also harmonised.

In 1977 the Committee for Proprietary Medicinal Products (hereinafter, the 'CPMP') was also founded. It was a scientific review committee designed to ensure the quality, the safety and the efficacy of medicinal products awaiting approval from Member States. Through this body Member States could work together with the Commission in their efforts to harmonise evaluation criteria and co-ordinate the authorisation of medicines. The CPMP was a milestone: it provided the first EU-level pharmaceutical forum for Member State representatives, from which a the current network established among health authorities grew⁶⁶.

Still, companies did not make an extensive use of the harmonised procedure: in the first seven years after the enactment of the Directive only 41 requests were made.

For this reason, and thanks to the major shift in legislative policy going on at that time at a European level⁶⁷, the Commission then decided to introduce a multi-State procedure, disciplined by Directive 83/570/EEC, which had better success among companies.

The goal was to create a unified standard for product review that all countries could use, thereby speeding up the process of authorization in all other EU countries. However, since national authorities were not required to accept the review as final, many States continued their own reviews before authorizing a product for market approval. This duplication of effort undermined the objective of faster market access for manufacturers⁶⁸.

approximation of provisions laid down by law, regulation or administrative action relate to proprietary medicinal products.

⁶⁶ The CPMP now works within EMEA as scientific committee and is composed by two members nominated by each Member State.

⁶⁷ See the EU Commission, *Completing the Internal Market. White Paper from the Commission to the European Council*, 1985. The White Paper contained 300 legislative initiative covering almost all sectors across Europe, of which a dozen were in the pharmaceutical sector, dealing with several issues: from the transparency in national pricing, to the rational use of medicines.

⁶⁸ See EU Commission, *Pharmaceuticals in the European Union*, 2000, available at <http://ec.europa.eu/enterprise/pharmaceuticals.htm>.

In 1993 the Commission expressed its concern about the consequences of the lack of a single market for pharmaceuticals in terms of competitiveness, of social costs and of patients' health protection in Europe. It then outlined an industrial policy program that led to the creation of the EMEA and to the establishment of new harmonised procedures to obtain a marketing authorisation.

EMA's mission statement is *"to promote the protection of human health... and of consumers of medicinal products"*⁶⁹. This goal is to be achieved through a greater level of harmonisation of pharmaceutical regulation within the EU. The evaluation of medicines, post-marketing surveillance and scientific advice, in fact, are major parts of the Agency's work. Also, EMA invests considerable resources in harmonisation activities, particularly in the development of testing guidelines, which generally address specific issues relating to the assessment of quality, safety and efficacy.

The EC Regulation no. 2309/93, as amended by EC Regulation no. 726/2004, enriched the possibilities for pharmaceutical companies to have a marketing authorisation with two additional procedures to the national one. So, at present there are three different procedures to obtain a marketing authorisation for pharmaceutical products⁷⁰:

- the national procedure;
- the procedure of mutual recognition and the decentralised procedure;
- the centralised procedure.

The national procedure allows companies to market their product in a Member State within the EU. Companies have to present the related documentation and information to the competent national health authority, which has to accept or refuse the request within a certain period established by national law.

The second procedure was also introduced in 1993 but it was not implemented until 1998. It is now disciplined by the Directive 2004/27/EC and it is aimed at ameliorating cooperation among Member States. The marketing authorisation request should be presented to each Member State where the company is interested in

⁶⁹ See European Council Regulation No. 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the evaluation of Medicinal Products. OJ L 214, August 24, 1993, p. 1-21.

⁷⁰ See Pharmacos, *Overview of the European Authorisation System*, 2008 available at <http://pharmacos.eudra.org/F2/home.html>

commercialising the drug, on the basis of the same file. The company should then ask one of the Member States to act as referee and prepare an evaluation report. If the State referee accepts the marketing authorisation request, the other States should grant it within 30 days on the basis of the evaluation made by the referee.

When the product has not been authorised anywhere, the decentralised procedure applies. The company asks the State referee to send the documents necessary for the evaluation to the other Member States, which within 90 days should either grant or refuse the authorisation⁷¹.

The third procedure, entirely managed by EMEA, allows companies to have a unique authorisation valid within the whole territory of the European Union. The centralised procedure is fast and generally perceived to be efficient by stakeholders: the EMEA has 210 days to reply to the request of authorisation. Such authorisation is valid in each Member State for a period of five years. After this period the authorisation is renewable for an unlimited period of time.

The centralised procedure is compulsory for orphan drugs, biotechnological products and pharmaceuticals containing new active substance indicated for the treatment of diseases listed in the EC Reg. no. 726/2004. From this point of view, EMEA is also playing an important role in the implementation of the European Union policy on orphan medicines⁷².

Besides the harmonisation of market authorisation procedures, it is important to mention that the action of the European institutions also concerned the standards of quality, safety and efficacy of medicines and aimed at encouraging their free circulation, in order for European patients to have a better and wider choice of products at reasonable prices⁷³. For instance, in all Member States, the Good Manufacturing Practice (hereinafter, 'GMP') is mandatory for manufacturing activities, including quality control.

⁷¹ See PIGNATTI, BOONE and MOULON, *Overview of the European Regulatory Approval System*, in *Journal of Ambulatory Care Management*, 2004, no. 27(2), p. 89-97.

⁷² Recital 9 of the EC Reg. n. 726/2004 reads, "optional access to the centralised procedure should also be provided for in cases where use of a single procedure produces added value for the patient. This procedure should remain optional for medicinal products which, although not belonging to the abovementioned categories, are nevertheless therapeutically innovative. It is also appropriate to allow access to this procedure for medicinal products which, although not innovative, may be of benefit to society or to patients if they are authorised from the outset at Community level, such as certain medicinal products which can be supplied without a medical prescription".

⁷³ The governments have initiated this process in 1964 "convinced that it is desirable and necessary to harmonize specifications for medicinal substances which, in their original state or in the form of pharmaceutical preparations, are of general interest and importance to the peoples of Europe".

This is clearly stated in Commission Directive 2003/94/EC: *"All medicinal products for human use manufactured or imported into the Community ... are to be manufactured in accordance with the principles and guidelines of good manufacturing practice."*⁷⁴

The harmonisation activity of the European Institutions also focused on manufacturing licence, with the Human Use Directive, in order to ensure that production of pharmaceuticals is subject to adequate hygienic and technical requirements. The manufacturing licence is granted by the Member State where the request has been filed, after that the competent authority has inspected the company and ascertained the adequacy of technical machinery and personnel, within 90 days from the request.

As a result, nowadays regulation on marketing authorisation, manufacturing and distribution licences, labelling, leaflet, and advertising is harmonised. What remains in a non-harmonised area are price controls.

3.2 The harmonisation of price control measures

National price controls mechanisms generate the observable price gaps existing for the same drug in different countries, although price discrimination strategies applied by pharmaceutical companies also play an important role in this respect.

On the one hand, pharmaceutical companies price their products differently according to variations in the ability to pay, aiming to obtain the highest price each national market can bear. On the other hand, governments use their authoritative power to moderate pharmaceutical prices pursuant to cost containment objectives and public health protection goals.

Drug prices are thus the result of the interplay between private and public interest. The way this balance between opposing interests is struck necessarily differs from country to country, depending on the health care system, on budget constraints, on the industrial policy pursued, on the type of regulatory tool used to moderate drug prices (profit cap, price controls, reference pricing⁷⁵, substitution policy, reimbursement

⁷⁴ See the Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.

⁷⁵ 'Reference pricing' indicates any mechanism of reimbursement used by national health authorities or insurances, which sets maximum reimbursement price of a drug with reference to the price of a cheaper substitute present in the market. In particular, under a reference pricing system, products are classified in sub-groups with similar therapeutic effects; a maximum reimbursement price is set for all the products

policy etc.), on the health status of the citizens, on medical culture, on the type of medicine, etc.⁷⁶

This creates a wide difference in prices among countries for the same product. Cross-national price differences, in fact, reflect differences in product characteristics and implicit price, which in turn reflect the regulatory regime. Strict price regulation lowers prices for older molecules and globally diffused molecules. Generic competition lowers prices in less-regulated regimes, which also have a more price-elastic demand.

Price disparities are significant also across Member States. Significant differences exist in the terms and conditions under which prescription products are reimbursed by relevant national health funds or social security institutions as well as the number of products accepted for reimbursement⁷⁷. These regulatory differences reflect the dissimilar relations government-industry, which stem from each country's regulatory tradition⁷⁸.

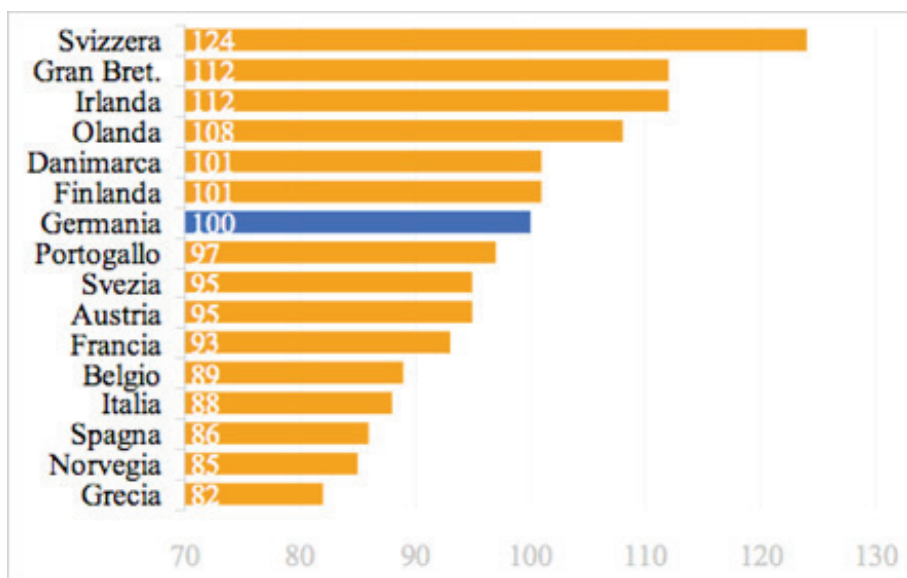
belonging to the subgroups; pharmaceutical companies are free to set prices of their products but if they exceed the reference price, the difference is paid by the patient. A reference pricing system was introduced for the first time in Germany in 1989. Later on other Member States adopted this policy: the Netherlands (1991), Sweden (1993), Denmark (1993), Italy (1996) and Spain (2000). In UK for long time there has been a form of implicit reference pricing given by the rule that provided for compulsory generic substitution at the pharmacy level. See DANZON, *Reference Pricing: Theory and Evidence*, in *The Economics of Reference Pricing and Pharmaceutical Policy*, ed. LOPEZ-CASASNOVAS and JÖNSSON, 2001, p. 86–126.

⁷⁶ The first consideration in explaining international drug price differences is the disparity in tastes and preferences that alter the demand. Significant difference also exists across cultures in the choice of drug, as well as the dosage and the form of administration. In addition, the incentives of the physician are very important. For instance, in Japan doctors tend to prescribe heavily because of the high 'doctor margin', whilst in US doctors do not have this incentive. See SCHWEITZER, *Pharmaceutical Economics and Policy*, cit., p. 186; see also PAYER, *Medicine and Culture*, 1988.

⁷⁷ Differences exist even at the fundamental level of whether to classify a drug as prescription medicine or OTCs or allowed retail outlets: some countries restrict the sale of all medicinal products to pharmacies; some others consent the sale of OTCs also in supermarkets.

⁷⁸ See HANCHER and MORAN, *Capitalism, Culture and Economic Regulation*, 1989, who affirm that, for instance, in UK most of regulatory arrangements were evolved in a political culture marked by a deferential attitude on the part of mass publics towards, and by a preference for informal and private regulation on the part of the 'élite groups'.

Graph 4: Pharmaceutical prices in Europe (2004)



Source: Verband Forschender Arzneimittelhersteller e. V., 2005

The graph above shows that prices are higher in Northern countries, while towards South they are significantly lower.

Historically speaking, Northern European countries, counting on higher income per capita, always opted for health care policies allowing for free pricing of medicinal specialties, in order to foster the growth of in-house pharmaceutical industry; conversely, in Southern European countries, public budget concerns and lower income per capita induced regulators to implement policies that aimed at directly monitoring prices of medicines, in order to keep health care expenses under control, and to promote innovation through other policies (like subsidies to the industry or to universities)⁷⁹.

Although patterns may be changing⁸⁰, what is clear is that significant price differences remain and create fragmentation of the European market at the level of prices. For this reason, as some commentators affirm, at present it is not possible to

⁷⁹ See KANAVOS, *Overview of pharmaceutical pricing and reimbursement regulation in Europe*, p. 13–19, available in <http://pharmacos.eudra.org/F3/g10/docs/synthesis.pdf>.

⁸⁰ On this point see Section 5, p. 42 *et seq.*, in this Chapter.

speak of a single market for pharmaceuticals⁸¹.

The ECJ⁸² and the European Parliament⁸³ called many times the Commission and the Council to action to remedy distortions caused from price differentials. Still, drugs pricing and related decisions are under exclusive national competence and for the time being price gaps appear to be there to stay⁸⁴.

For this reason, the European Institutions has intervened only indirectly on the national measures used by Member States to monitor public pharmaceutical expenditures.

In order to level as much as possible regulatory and price differences, the European Commission introduced two important Directives. Firstly, with the Directive 70/50/EC of the 22 December 1969, the Commission established important provisions aimed at eliminating all the national obstacles of legislative nature to cross border trade, in the belief that the latter was to be encouraged in order to achieve integration⁸⁵. The national measures favouring national products over imports, through discriminatory prices for exports or maximum/minimum prices above/below which exports are blocked, were consequently prohibited as contrary to the goals of the European Union.

Subsequently, with Directive 89/105/EC of the 21 December 1988, the so-called 'Transparency Directive', the Commission established clear and uniform rules for the control of pharmaceutical prices. Articles 2 and 3 of the Directive outline the administrative procedure of price setting for a medicinal specialty, as well as for price increases. Articles 4 and 5 outline the procedure that applies to price freezing decisions

⁸¹ See FARQUHARSON and SMITH, *Parallel Trade in Europe*, 1998, p. 68, affirming that the pharmaceutical industry is a 'sector where the creation of a single European market is highly unlikely to occur even in the medium to long term due to the interest of national governments in controlling spending on pharmaceuticals'. See also HANCHER, *The European Pharmaceutical Market: problems of partial harmonisation*, in 15 ELR, 1990, p. 9, 10-11; BOOER, EDMONDS, GLYNN and OGLIALORO, *Economic Aspects of the Single Market in Pharmaceuticals*, in 5 ECLR, 1995, p. 257 and 261.

⁸² See ECJ, 31 October 1974, in case C-15/74 *Centrafarm v. Sterling Drug*, para. 23.

⁸³ See the EU Parliament's Resolution on the Communication from the Commission on the Single Market in Pharmaceuticals [1999] OJ C279/79.

⁸⁴ Para. 1 of Art. 168 TFEU, reads as follows: "The Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them." See the EU Commission Communication on Single Market in Pharmaceuticals COM(98)588 final, p. 7-8, 12, 18, where the Commission affirms that these matters are mostly within the exclusive competence of the Member States and, pursuant to the principle of subsidiarity, should be left to national authorities.

⁸⁵ Art. 2 of the Directive prohibits measures hindering imports, and Art. 3 forbids measures governing the marketing of products if their effect is to restrain free movement of goods.

and measures that impose direct or indirect controls over companies' margins.

Despite this effort, however, the European pharmaceutical market is still characterised by an appreciable degree of fragmentation and heterogeneity among Member States, especially with regards to pharmaceuticals' prices, health care systems and reimbursement mechanisms.

Given the 'political' impossibility to further use other instruments of harmonisation in the field of pharmaceuticals, the Commission recently switched to soft law tools⁸⁶.

One of the last initiatives undertaken by the European Commission to remedy the market fragmentation and improve the performance of the European pharmaceutical industry in terms of competitiveness and contribution to social and public health objectives, is the establishment of the High Level Group on Innovation and the Provision of Medicines (called "G10 Group") on March 2001. The G10 Group presented its report in May 2002, setting out a framework of 14 wide-ranging recommendations⁸⁷. Tracking these recommendations the Commission created the Pharmaceutical Forum⁸⁸ in 2005, in order to take the process forward around three key themes: information to patients on pharmaceuticals, pricing policy and relative effectiveness.

Surprisingly, both the G10 Medicines Group and the Working Group on pricing of the Pharmaceutical Forum suggested that such disparities in prices should not be regarded necessarily negatively: given that at present economies of Member States are too diverse to support a policy of uniform prices across Europe⁸⁹.

⁸⁶ As a matter of law, the Commission has the possibility to use Art. 95, in order to approximate national pharmaceutical legislation and remedy to market fragmentation. However, already from the Bangemann Three Round Tables that took place from 1996 it was clear that this choice was not feasible, because both the Member States and the industry were not in favour of this option. Also, the Commission itself feared that a 'European price' would have diminished too much the contribution to R&D. See better Section 4.2 in Chapter III.

⁸⁷ See <http://ec.europa.eu/enterprise/phabiocom/g10home.htm>.

⁸⁸ The Pharmaceutical Forum is a high-level ministerial platform for discussion between Member States, EU institutions, industry, healthcare professionals, patients and insurance funds. The Ministerial Forum is supported by a Steering Committee and three expert Working Groups, whose work is coordinated and supported by DG Enterprise. The website of the Pharmaceutical Forum is at http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm.

⁸⁹ This suggestion can be inferred from the minutes of the meeting of November 7-8, 2006, where it is affirmed that new medicines are launched at more or less similar prices all over Europe, without taking into account whether the price was aligned with the per capita wealth of the country. See http://ec.europa.eu/enterprise/phabiocom/comp_pf_wg_min.htm. Similarly see HANCHER, *The European Community Dimension: Coordinating Divergences*, in MOSSIALOS ET AL., *Regulating Pharmaceuticals in Europe*, cit., p. 56, where he affirms that the G10 may mark a departure from the traditional approach of Community-led

4. Price controls and free movement of goods

The ECJ has been called many times to decide upon the validity according to European law of the cost containment measures adopted by several Member States in the pharmaceutical field. In particular, the compliance of drug price controls with Article 34 TFEU has been questioned several times.

In application of the wording of Article 3 TEU, which sets the establishment of the internal market as one of the main goals of the European Union⁹⁰, this provision prohibits quantitative restrictions to free movement of goods and measures having equivalent effect.

While the notion of 'quantitative restrictions' has been easily defined by the ECJ⁹¹, the notion and the scope of 'measures having an equivalent effect to quantitative restrictions' proved to be more difficult to interpret and required some refinement.

The Court first interpreted it as capturing national measures capable of hindering trade "directly or indirectly, actually or potentially" (the so called '*Dassonville* formula')⁹².

This formula was used in *Cassis de Dijon*⁹³ to tackle a national measure that prevented a product manufactured and marketed for the first time in another Member State to enter the domestic market because it did not correspond to the requirements of the latter. This was considered an obstacle to trade because it entailed a double burden for the imported product and indirectly discouraged intra-EU trade. In this way the

harmonization of national rules and regulations. The G10 recommends a preference for coordination of national results, not of the underlying rules themselves.

⁹⁰ The provision states that: "*The Community shall have as its task, by establishing a Common market... and by implementing the Common policies or activities referred to in Articles 3 and 3a, to promote throughout the Community a harmonious and balanced development of economic activities*".

⁹¹ See ECJ, 12 July 1973, in case C-2/73 *Geddo v Ente Nazionale Risi*, para. 7, where the Court defined them as '*measures which amount to a total or partial restraint of, according to the circumstances, imports, exports or goods in transit*'.

⁹² See ECJ, 11 July 1974, in case C-8/74 *Procureur du Roi v. Dassonville* (hereinafter, '*Dassonville*'): the case concerned Scotch whisky imported from France to Belgium in 1970. Belgian law required a certificate of authenticity issued by British customs authorities, while France did not demand such certificate. Clearly, it was difficult to obtain the certificate for imports from a third party. Only direct importers were able, whilst parallel importers were not. See STEINER, *Drawing the Line: Uses and Abuses of Article 30 EEC*, in CMLR, 1992, no. 29, p. 768-771.

⁹³ See ECJ, 20 February 1979, in case C-120/78, *Reuwe-Zentral AG v Bundesmonopolverwaltung für Branntwein* ('*Cassis de Dijon*'). The case concerned a German rule setting a minimum alcohol content for fruit liqueurs. French '*Cassis de Dijon*' liqueur did not meet this requirement and therefore its marketing was prohibited by the German authorities. The Court held that the German rule was a measure having equivalent to quantitative restriction within the meaning of Art. 28 EC.

Court created a presumption that a product lawfully produced and marketed in a Member State has to be admitted to the markets of all other Member States⁹⁴.

The *Dassonville* formula was initially interpreted very widely and only at a later stage the rule was further refined to cover those measures judged *unreasonable*. For instance, a national measure that concerns the intrinsic characteristics of a product (such as shape or composition), i.e. a product rule, is generally considered capable of hindering intra-EU trade. Thus, it automatically falls within Article 34 TFEU⁹⁵. By contrast, when the national measure concerns selling arrangements, i.e. issues extrinsic to the product, it falls within the prohibition only if it discriminates against goods from other Member States⁹⁶.

The examination of the existing cases also illustrates that the enlargement of the scope of the free movement rules went hand in hand with the development of the doctrine of justification. In fact, building on the concept of 'reasonable restraints' elaborated in *Dassonville*, the ECJ in *Cassis de Dijon* created a category of 'mandatory requirements' that could be used to justify a national measure falling within the scope of Article 36 TFEU⁹⁷. Subsequent case law, especially in the field of health, further refined the notion of 'mandatory requirements'.

The first relevant case where these issues were discussed in the context of pharmaceuticals was *Roussel*⁹⁸ in 1983. The Netherlands had adopted in 1982 new rules in response to the substantial profits made by companies importing pharmaceuticals from low price countries and subsequently selling them in the Netherlands at higher prices with respect to those applied in sourcing markets. While the pre-1982 price system applied indistinctly to all pharmaceutical products, the new system of price controls applied only to imports. In particular, prices of imported products should have been priced maximum at a price equal to that applied in the exporting country where

⁹⁴ See CRAIG and DE BÜRCA, *EU Law*, 1998, p. 569-570.

⁹⁵ See ECJ, 24 November 1993, in cases C-267 and 268/91 *Criminal Proceedings against Bernard Keck and Daniel Mithouard*.

⁹⁶ This distinction is very useful in this context, since pharmaceutical price controls are selling arrangements between the government and the pharmaceutical company, as it was held by the ECJ, 11 August 1995, C-63/94 *Belgapom v. ITM Belgium*. See OLIVER, *Some further Reflections on the Scope of Articles 28-30 (ex 36) EC*, in CMLR, 1999, no. 36, p. 783, 794.

⁹⁷ See ECJ, 30 November 1995, in case C-55/94 *Reinhard Gebhard v. Consiglio dell'Ordine degli Avvocati e Procuratori di Milano*, where the Court spoke of 'overriding requirements of general public interests'.

⁹⁸ See ECJ, 29 November 1983, in case C-181/82, *Roussel Laboratoires B.V. and Ors v. État Nèerlandais*.

they were coming from. In practice, the Dutch government was applying a *dual pricing* system, namely a price mechanism varying on the basis of the provenience of the drug⁹⁹.

The Court began its judgment by affirming that price controls applied to imports were not in principle contrary to free movement of goods¹⁰⁰. However, it then noted that the Dutch legislation did not apply to domestic and imported products alike, but, on the contrary, it discriminated between them, rendering the sale of imported products more difficult. Thus, the Dutch system, being a measure of equivalent effect to a quantitative restriction, contravened Article 34 TFEU.

The Court in this way clarified that national price controls were not in themselves contrary to the free movement of goods, unless they fixed prices at a level that rendered the sale of imports more difficult than it was for domestic products.

Not only directly discriminatory systems, such as the Dutch one in issue, fell within the scope of Art. 28 EC, but so did price controls that discriminated in a more indirect manner. For example, the imposition of a single maximum price for both domestic and imported products could have a discriminatory effect, in particular if the maximum price was fixed at such a low level that imported products could not be profitably marketed at all.

In *Duphar*¹⁰¹ the Court analysed a Dutch list of drugs that did not qualify for reimbursement out of social security due to excessive costs. In that occasion, the Court made it clear that, because of the special nature of the products, the blacklisting of drugs was governed by the same principles as price controls and that it was outside Article 34 TFEU, as long as it was based on objective and verifiable criteria, and it was not discriminatory against imported products. But the Court affirmed that if there was discrimination, even a budgetary purpose could not justify the cost containment measures.

Some years later, the ECJ faced again the issue of legitimacy of price controls for pharmaceuticals in the case *Commission v. Belgium*¹⁰². The Belgian government signed with pharmaceutical manufacturers and importers a system of program contracts. The

⁹⁹ For a discussion of the effects of dual pricing see *infra* Section 5.1 of Chapter II.

¹⁰⁰ See *Roussel* at para. 17.

¹⁰¹ See ECJ, 7 February 1984, in case C-238/82, *Duphar BV and others v The Netherlands State*.

¹⁰² ECJ, 19 March 1991, *Commission of the European Communities v. Kingdom of Belgium*.

contract provided for specific commitments about the level of investments in R&D, of employment and of export to be maintained by the companies in exchange for the authorised reimbursement prices. The European Commission contested this system of program contract, because it constituted a measure having equivalent effect to a restriction of free movement of goods. The ECJ confirmed this view and held that such a system obviously put at disadvantage the importers, while Belgian companies would have benefit of higher reimbursement prices.

This negative attitude towards discriminatory measures, however, was partially and indirectly overturned in *Decker*¹⁰³, where the Court indicated that even if price controls fall within the scope of the prohibition, they might benefit from a justification. Luxembourg rules provided that medical treatment abroad would only be reimbursed if the competent social security institution has given prior authorisation. These rule were found to run against Article 34 TFEU, because they encouraged to buy products in Luxembourg rather than in other Member States. Nevertheless, the Court accepted that the rules might be justified by the risk of seriously undermining the financial balance of the social security system.

Altogether, it is clear from the line of the case law that differences between national health care systems are not considered as obstacles to the free movement of goods¹⁰⁴. Provided that they were not discriminatory, the ECJ found various *escamotages* either to consider them out of the scope of Article 43 TFEU, or to justify them on the basis of public policy.

True, the fact that the competence on health is set at a national level can be perhaps a valid reason to explain the willingness of the Court to leave intact national measures entailing price controls. Where Member States remain solely or primarily responsible, it is legitimate the discharging of such responsibility that may involve the adoption of measures that are restrictive of free movement. Given that such measures have an immediate, but intermediate, economic aim, but an ultimate public interest aim, it would be unreasonable to ask Member States to achieve it through means less restrictive of free movement, if the latter require massive public finance, such that

¹⁰³ See ECJ, 28 April 1998, in case C-120/95 *Decker v. Caisse de Maladie des Employés Privés*, para. 36 and 39.

¹⁰⁴ See SNELL, *Free Movement of Pharmaceutical Products: an Overdose of Cheap Drugs?*, in EBLR, 2003, p. 508; KANAVOS, *The Single Market for Pharmaceuticals in the European Union in Light of European Court of Justice Rulings*, in *Pharmacoeconomics*, 2000, no. 18(6), p. 523-532.

Member States would abandon the policy entirely. In sum, such policies are justified on the fact that these measures are strictly part of national economic policy¹⁰⁵.

Still, this clashes with the principle that restrictions to trade cannot be justified for purely economic reasons.

Nevertheless, the Court solved this contradiction by indirectly allowing economic aims as justification either by interpreting narrowly the concept of restriction (like in *Duphar*¹⁰⁶), or linking the economic aims with other public policy considerations (like in *Evans Medical*¹⁰⁷, where the profitability of an undertaking was considered to be necessary for the achievement of a public interest, i.e. public health) or simply denying or ignoring the economic nature of the justifications (like in *Decker*¹⁰⁸).

One could argue that the EU legislative process could have removed the problem by repealing all the legislative disparities creating the price gaps. However, the history of the EU's action in this respect proved to be a failure. Lacking Member States' consensus on this point, the EU has not been able to undertake this task, nor in the past¹⁰⁹ and neither today¹¹⁰.

For this reason, the ECJ has built a case law that allows the Treaty to tolerate a patchwork of national measures controlling the pricing of pharmaceutical products.

That is why the EU pharmaceutical market is currently experiencing a transition phase where the policy of price harmonisation is indirectly pursued through trade liberalisation, while keeping regulation at a national level. The differences in regulatory

¹⁰⁵ Cf. SNELL, *Economic Aims as Justifications for Restrictions on Free Movement*, in SCHRAUWEN, *Rule of Reason: Rethinking Another Classic of European Legal Doctrine*, 2005, p. 49; OLIVER and JARVIS, *Free Movement of Goods in the European Community*, 2003, p. 193-204.

¹⁰⁶ The Dutch rules clearly amounted to a restriction in need of a justification, as the Advocate General Mancini affirmed. However, the Court did not follow his advice, probably in order to avoid going into the issue of justification and to safeguard the doctrine that economic grounds cannot act as justifications.

¹⁰⁷ See ECJ, 28 March 1995, in case C-324/93 *The Queen v. Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith Ltd.*, where the Court rules that the refusal to grant import licence of narcotic drugs could not be justified if the reason was simply the need to safeguard the survival of an undertaking, but the survival of the undertaking was necessary to ensure reliable medical supplies, justification would be available, subject to proportionality.

¹⁰⁸ See *Decker*, para. 39: "it cannot be excluded that the risk of seriously undermining the financial balance of the social security system may constitute an overriding reason in the general interest capable of justifying a barrier to free movement". It should be noted that while in *Duphar* the need to preserve the financial balance lead to consider the national measure entirely out of the scope of Art. 34 TFEU, the same reason provided a justification to the restriction under Art. 36 TFEU in *Decker*. Cf. SNELL, *Economic Aims as Justifications*, cit., p. 43-44.

¹⁰⁹ See ARMSTRONG, *Regulating the Free Movement of Goods: Institutions and Institutional Change*, in SHAW and MORE, *New Legal Dynamics of European Union*, 1995, p. 578-580.

¹¹⁰ See better *infra* Section 4.2 in Chapter III.

measures used by Member States to control pharmaceutical expenditures generate price gaps and the consequent possibility to arbitrage, or to parallel trade.

5. What is parallel trade?

In the literature, parallel trade emerges either because of the possibility for arbitrageurs to free ride on the investments of authorized distributors at various levels of the distribution chain¹¹¹, or because of price differentials, i.e. as a consequence of currency exchange or international price discrimination practices from manufacturers¹¹². In the pharmaceutical market parallel trade is the result of price differentials determined by manufacturers' pricing policies, currency fluctuation, as well as governmental price controls.

The price differential creates scope for parallel import, as long as shipping costs are lower than such price disparity.

Parallel trade consists of the importation of legitimately produced goods into a country without the authorization of the trademark, copyright, or patent holder.

In its Communication of 1998 the European Commission re-affirmed that pharmaceuticals are fully governed by the rules that oversee the functioning of the

¹¹¹ See LEXECON, *The Economics of gray-market imports*, 1985; BRANDER and KRUGMAN, *A reciprocal dumping model of international trade*, *Journal of International Economics*, 1983, no. 15, p. 313-321, where parallel trade flows occur profitably in both directions, contrary to what happens under the price discrimination-hypothesis, where flow is always from low-price countries to high-price countries.

¹¹² *Ex multis*, see TARR, *An Economic Analysis of Grey Market Import*, mimeo, Federal Trade Commission, September 1985, who found that differentials in manufacturers' prices to the United States versus their domestic markets exceeded plausible estimates of the differential marketing costs, thereby concluding that free riding was an important factor determining parallel trade only in some industries, like perfumes, while price discrimination was the main explaining factors in other sectors like German cars and Japanese cameras; HILKE, *Free-trading or free-riding: an examination of the theories and available empirical evidence on grey market imports*, in *World Competition*, 1988, no. 32, p. 75-91, who found that the fact that import prices in the destination currency were not reduced in the same proportion as the appreciation of that currency (so called 'incomplete pass-through') was the most convincing explanation to emerging of parallel import; MAULEG and SCHWARTZ, *Parallel Imports, Demand Dispersion, and International Price Discrimination*, *Journal of International Economics*, 1994, no. 37, p. 167-195, 174, recalling different cross-sectional comparisons on luxury cars, pharmaceuticals and books, acknowledges that in general, there is widespread evidence of international price discrimination from manufacturers; SCHUT and BERGEIJK, *International Price Discrimination: The Pharmaceutical Industry*, *World Development*, 1986, no. 14, p. 1141-1150.

internal market¹¹³, and subsequently in 2003 recalled that parallel trade as a legal form of trade among Member States¹¹⁴.

The term derives from the fact that such a form of trade occurs 'in parallel' to manufacturers' channel of distribution¹¹⁵, albeit within the same legal and regulatory framework ensuring patient safety.

Parallel trade has developed more or less consistently in all sectors¹¹⁶. However, in the pharmaceutical market the economic driver of this business is particularly strong: indeed, price differentials for drugs may be significant, up to 30% and more.

The flow of goods originally occurred from southern European countries to northern European countries, as Member States of the Mediterranean area applied direct cost containment policies that kept prices down, whereas northern countries always allowed free pricing.

However, market analysis suggests that some of the traditional patterns are changing. Tougher recent cost-containment measures have been imposed in the traditional free markets of Denmark, Germany, the Netherlands and the UK, while some former low-price countries are introducing higher prices. This has somewhat reduced price gaps.

Also, currency fluctuations, not only determine a cyclical widening of price gaps among countries, but also generates trade routes previously not existing or not enough profitable. For instance, the UK has always been an importing country, due to the high prices charged there. But under the present economic conditions, the Pound lost very much compared to Euro. As a result, the UK is starting exporting into Scandinavian

¹¹³ See Communication from the Commission on the single market in pharmaceuticals, COM(1998) 588, Brussels, 25.11.1988

¹¹⁴ The Commission also underlined that these products are not identical but essentially similar to the products that have already received a marketing authorisation in the Member State of destination. See Communication from the Commission on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, COM(2003) 839, Brussels, 30.12.2003.

¹¹⁵ See WARWICK, *Parallel Imports*, 1993, p. 1, who defines parallel trade as having 'two vital, distinguishing features. They are lawfully put on the market in the place of export, the foreign country. But, an owner of the intellectual property rights in the place of importation, the domestic country, opposes their importation (usually because the goods are sold in the two different countries at quite disparate prices) and, taking advantage of the lower price, some enterprising middleman buys stocks in the cheaper, foreign country and imports them into the dearer, domestic country. Hence, the imports may be described as being imported in 'parallel' to the authorized distribution network.'

¹¹⁶ See the *International price comparisons. A survey of branded consumer goods in France, Germany, Sweden, the UK and the US*, research report for the UK Department of Trade and Industry and the Swedish Ministry for Foreign Affairs, 2001.

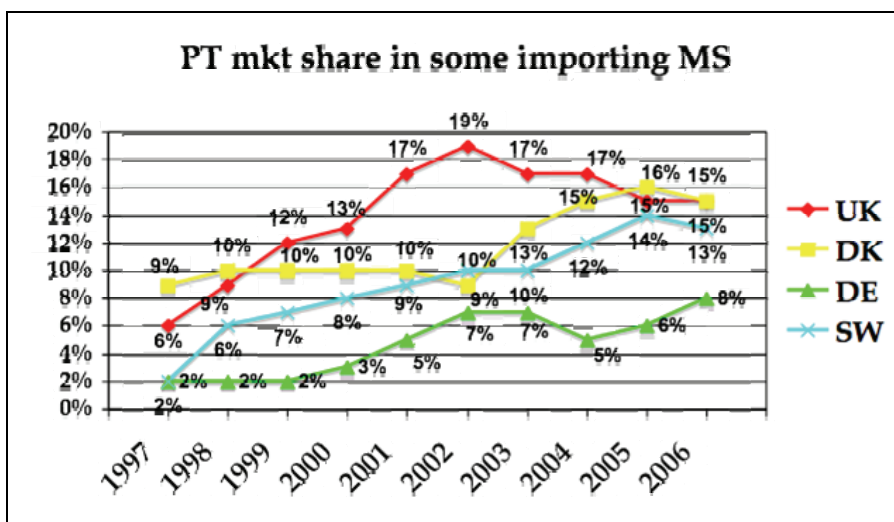
countries and into Germany.

Thus, it is no longer possible to speak of traditional low-price and high-price countries, as the prices for specific products may be the exact opposite in certain cases. Parallel trade seems no longer to be a simple south-north route, or even a one-way flow, but instead many countries act as suppliers and importers at the same time, albeit for different products.

Accordingly, price variation is becoming more and more diverse, and countries that historically were exporters are now also importers. This is the case, for example, with both France and Italy. Furthermore, the EU enlargement in 2004 contributed to the integration of new markets and the expansion of the concept of parallel import to the accessing countries (see *infra*).

Parallel trade on pharmaceuticals started in '70s but it increased significantly with the maturing of the internal market. From the half of the '90s the share of parallel trade grew up to 7-17%, especially in countries like Denmark, Sweden, United Kingdom, Germany and the Netherlands.

Graph 5: PT market share evolution along time in some importing Member States



Source: IMS Health, EFPIA, and EAEPC.

The UK market has one of the highest level of penetration among the four countries mentioned. In the years 2000–2002, the UK market for parallel imports was one of the largest in Europe and was worth around \$1, 700 million, that is, about 15% market share and 14% of the National Health Service expenditures¹¹⁷. In 2003 parallel imports were estimated to account for 17% of the pharmacy market sales. After a period of stagnation in 2004, the business is now expanding again¹¹⁸.

Likewise, the German market for parallel trade experienced a rapid growth. Over the period 1998-2003 the market shares of total pharmacy market sales increased from less than 2% to around 7%. In 2002, parallel imports penetration increased significantly, as legislation required pharmacists to source at least 5% of the sales from parallel imported products. In 2003 such percentage was incremented to 7%. In 2004 the reversion to 5% of the mandatory quota reduced parallel import market share again to around 5%. However, it increased again to around 8.5% by the end of 2006. The average market share for the 20 drugs with largest turnover is around one third.

In the Netherlands, parallel imports reached about 13% of the market in 2006.

In Denmark, the first approval for parallel import of a drug was given in 1990 and since then marketing authorisation has been granted for 6-8, 000 products. Over the period 1998-2004 the share of total drug expenditures spent on parallel imported products has remained more or less constant at slightly above 12% of total sales of prescription and non-prescription drugs in the primary health care sector. The expenditures on parallel imported medicine in the hospital sector amounts to 2% of total expenditures on drugs in the hospital sector.

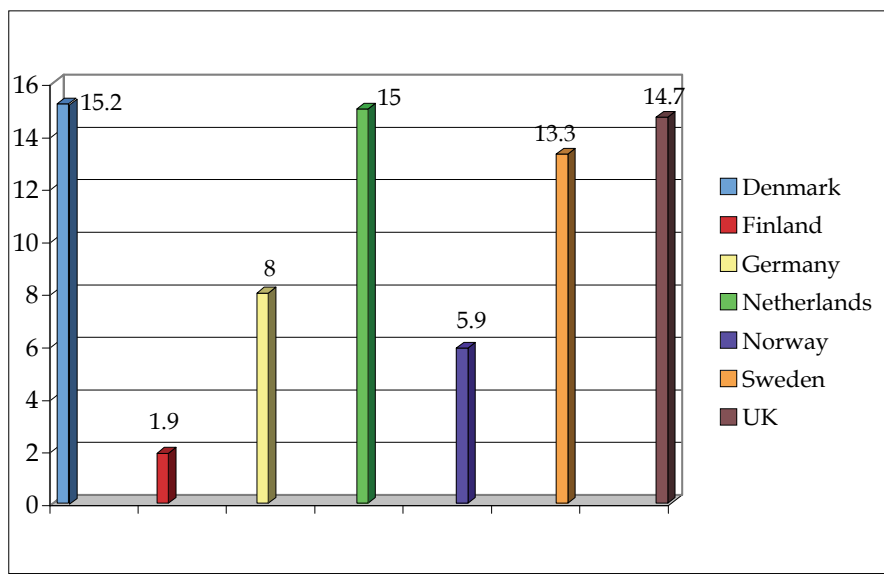
The first parallel imported drug was available on the Swedish market in 1997. The parallel import increased rapidly also in Sweden. The market share of 1.9% in 1997 increased to 6.1% in 1998. By 2000 the market share was 8.6% and reached 12.1% in 2006.

Here below a graph illustrates the parallel trade market penetration for the year 2007 in those European countries where imports mainly take place:

¹¹⁷ Data are even more significant in specific cases: Merck & Co. Inc. estimated that parallel imports for Timoptic (an anti-glaucoma) reached at that time 56% and for Renitec (a cardiovascular drug) 50% of the UK market sales.

¹¹⁸ This is the outcome of market analysis performed by IMS Health, and presented at Management Forum, London, February 2006, by Janice Haigh.

Graph 6: Parallel trade market penetration in 2007 in importing countries



Source: EFPIA, The Pharmaceutical Industry in Figures, 2008

Germany is currently the top destination country for incoming parallel trade, with sales approaching €2 billion and 8% retail penetration, having overtaken the UK for the first time ever in 2007. According to IMS, parallel trade market penetration in Germany increased by 75% over the past three years whilst the UK has recorded a 14% decline¹¹⁹.

One of the main drivers of German growth has been the switch from traders to speciality products. Though often categorised 'hospital only' in other European countries, these are retail market products in Germany due to the high number of office based specialists there. High price speciality products provide the best opportunity for importers to deliver the amount of saving (15% with respect to the original product) required by law, which allows parallel imported products to be preferred to an original

¹¹⁹ I obtained this information from Mondher Toumi (IMS) at the SMi conference on Pharmaceutical Parallel Trade, in London, on February 2009.

product in the dispensing¹²⁰, and for pharmacists to meet the mandatory quota (5% of sales) of parallel imported products to be dispensed most easily¹²¹.

In the UK parallel trade experienced a slump for several reasons.

First of all, patent expiries had a marked negative impact on parallel imports.

Secondly, the price reduction renegotiated in 2005 within the Pharmaceutical Price Regulation Scheme (hereinafter, the 'PPRS') scheme¹²² have reduced the scope for parallel trade, and this trend is going to be strengthened by the price reduction decided by the Department of Health¹²³. As a result, exports from the UK into other countries, like the Scandinavian ones and Germany, grew.

Thirdly, it has now become more expensive to source from the Eurozone due to a steadily weakening Pound (-20% against Euro in 2007). The only encouragement for the trade is that parallel imports remain popular with pharmacists, who see them as a way of recouping dispensing losses resulting from the government's generic reimbursement pricing policy and the claw-back not taking into account lower wholesaler discounts after three major manufacturers switched to direct-to-pharmacy distribution¹²⁴.

The Netherlands has become Europe's third largest parallel import market, recording a penetration of 15% (it's been 13-18% throughout the past decade) and 2007 growth of 10%. Discounts retained by pharmacists and vertical integration between the leading parallel trader, the largest wholesaler and the largest pharmacy chain, are the main drivers.

Requirement on pharmacists to substitute the cheapest equivalent version has favoured parallel imports usage in Sweden and Denmark. Penetration of the retail

¹²⁰ See fn 480 in Chapter III for an exhaustive description of the financial requirements mandated by law for parallel traded products dispensation in Germany.

¹²¹ See better *infra* 3.1 of Chapter III.

¹²² The PPRS is the Pharmaceutical Price Regulation Scheme is described *infra* Section 1.1 in Chapter III.

¹²³ Provision is made for two separate price cuts (a price cut of 3.9% in February 2009 and a further price cut of 1.9% in January 2010) and the introduction of generic substitution in the NHS. It is intended that the initial price cut and the introduction of generic substitution will have the combined effect of reducing NHS expenditure on branded medicines by an average of 5% per annum over the lifetime of the scheme compared to expenditure on 31 December 2008 on products on the market on that day (with an additional 1% price cut being applied from 1st January 2010). Date Price adjustment are established as following: February 2009: -3.9%; January 2010: -1.9%; January 2011: +0.1%; January 2012: +0.2%; January 2013: +0.2%.

¹²⁴ Direct-to-Pharmacy (hereinafter, 'DTP') distribution has been implemented firstly by Pfizer in the UK market in 2007. DTP schemes enable the manufacturer to control distribution of its products until the point of sale: in fact, the manufacturer does not sell its products to wholesalers any longer but to an agent, which supplies pharmacies against a fixed fee agreed on a contract. The DTP has been under the scrutiny of the OFT, which in April 2007 affirmed that no particular competition concerns were arising for the time being.

market in both countries is about 12%, with 9% growth in Sweden in 2007 and 4% in Denmark. In particular, changes in pharmacy remuneration are planned in Sweden alongside the abolition of Apoteket's monopoly, with dispensing fees adjusted in line with the discounts that pharmacies are expected to obtain with purchases of parallel imported products.

In Norway and Finland parallel imports are, instead, declining.

Overall, in the period between June 2005 and June 2007 the turnover in all import markets increased of the 11.8%, reaching the level of 4600 million Euros. In 2007, parallel imports represent roughly the 9.1% of the sales in import markets and the 3.2% of the total pharmaceutical sales of the EU 27¹²⁵.

Contrary to a widespread belief, the 2004 EU enlargement has not caused a rise in parallel trade. The main reason behind this is related to the derogation to the rules of the internal market that prevents parallel exportation from the new countries provided by the Specific Mechanism¹²⁶. However, the expiry of the derogation may not trigger a large rise in parallel trade, because – surprisingly – some new accession countries, like Poland, are experiencing quite high launch prices of new products, so that overall they are importing more than exporting.

¹²⁵ See IMS Health, MIDAS at MAT/JUN/07. Germany, UK, Netherlands, Sweden, Norway, Finland, Denmark, Belgium, Austria are the considered countries. Values are at standard purchase price in importing markets. Transaction can be pharmacy sell-in or sell-out.

¹²⁶ When new countries where patent protection does not exist or is weaker to European standard, access the EU, there is a temporal interregnum (the so called 'Specific Mechanism') when parallel exports and imports towards the other Member States are not allowed. The Act of Accession of Spain and Portugal contained provisions that were temporarily freezing the provisions on free movement. According to Articles 42 and 202 respectively of the Act of Accession of the Kingdom of Spain and the Portuguese Republic to the European Communities, quantitative restrictions on imports and exports and any measures having equivalent effect were to be abolished on 1 January 1986 between the Community and Spain and Portugal. However, pursuant to Article 47 regarding Spain and Article 209 regarding Portugal, the entry into force of Article 36 TFEU was postponed for the patented products in the following terms: *'Notwithstanding Article 42 [Article 202], the holder, or his beneficiary, of a patent for a chemical or pharmaceutical product or a product relating to plant health, filed in a Member State at a time when a product patent could not be obtained in Spain [Portugal] for that product may rely upon the rights granted by that patent in order to prevent the import and marketing of that product in the present Member State or States where the product enjoys patent protection even if that product was put on the market in Spain [Portugal] for the first time by him or with his consent.'* The Act of Accession contained parallel provisions providing transitional provisions subject to the introduction of effective patent laws by those two Member States. Ten new countries joined the EU on 1 May 2004. Among these, eight countries (Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia) did not previously have the same level of intellectual property protection as it could be found in the former EU-15. This was particularly the case with medicines. As such the Accession Treaties signed between the EU and each new country introduced the 'Specific Mechanism', effectively suspending the principle of the free movement goods in this sector to prevent parallel trade in pharmaceutical products that lack equivalent IPR protection.

5.1 *The current regulatory environment*

Parallel distribution involves the transfer of genuine, original, branded products, authorised in accordance with EU legislation, marketed in one Member State (source country) to another Member State (destination country) by ‘exporting’ wholesalers and ‘importing’ parallel distributors. The parallel distributed product is placed on the market in competition with an essentially similar product already marketed there at a higher price by or under licence from the owner of the brand’s intellectual property (the directly-distributed product).

Such a transfer cannot take place without several specific authorisations and licences. Parallel trade is regulated at several levels:

1. at the level of the *exporting wholesaler* (hereinafter, the ‘*exporter*’) to be authorised to store and distribute medicines;
2. at the level of the *parallel distributor* (hereinafter, the ‘*importer*’) with respect to three aspects:
 - a) wholesaling - authorisation to store and distribute medicines;
 - b) manufacturing - activities of repackaging and re-labelling;
 - c) individual products - marketing authorisation/EMA parallel distribution notice (see below).

The exporters are required to hold a pharmaceutical wholesaling authorisation issued (in accordance with Article 77 of the Human Use Directive) by the competent authority in the Member State in which they are located. In accordance with the wholesaling authorisation, the exporters are obliged to follow Good Distribution Practice (hereinafter, ‘GDP’) guidelines pursuant Article 84 of the mentioned Directive, to employ a Responsible Person (hereinafter, ‘RP’) and are subject to periodic inspection by the competent authority. Separate and additional authorisation must be obtained from the relevant competent authority in order to handle and distribute controlled drugs.

Medicines, when parallel distributed, are subject to a second process of approval: the first time when the manufacturer applies for the marketing authorisation in the originating Member State; subsequently a second regulatory assessment takes place before the distribution in parallel can start. It follows that the parallel distributors in the

country of destination need to have in the first place a marketing authorisation (or licence) to be able to commercialise imported products. However, the type of licence needed depends on the adopted approval process.

If the directly distributed product has been subject to the national approval process, pursuant the Human Use Directive, then the parallel distributor must obtain a parallel import marketing authorisation from the same competent authority for the product to be distributed in parallel. Together with any applicable fee, the applicant must indicate the source country and the product's marketing authorisation number there. The competent authority then conducts checks, in conjunction with the competent authority in the source country, to assure itself that there are no differences of therapeutic significance from the directly-distributed product covered by a full marketing authorisation in the country of destination. The general principles to be considered by national competent authorities when granting simplified marketing authorisations for parallel-distributed products were first outlined in a 1982 Communication from the European Commission¹²⁷.

If the directly distributed product has been approved centrally by the European Commission, following a positive opinion from the EMEA and in accordance with EC Regulation no. 726/2004¹²⁸, then no further regulatory approval is necessary as the product on the market is, by definition, authorised and identical in every Member State. However, a linguistic compliance check on the pack labelling and patient package leaflet of the parallel-distributed product by the EMEA is required in accordance with Article 57.1(o) of Title IV of the Regulation, resulting in the issue of a Parallel Distribution Notice.

In accordance with Article 76(3) of Directive 27/2004/EC, importers are required to notify the full marketing authorisation holder and the competent authority in the Member State of destination of their intention to parallel distribute a product. In addition, under trademark law, the importer must also notify the trademark owner.

¹²⁷ See Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, 30.12.2003, COM(2003) 839 final, p. 5.

¹²⁸ It is the Reg. (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

Moreover, importers also have to adapt the packaging/labelling of every incoming batch to access the local market, in accordance with the marketing authorisation, national law and decisions of the ECJ¹²⁹. To this effect, they need a manufacturing authorisation¹³⁰ issued by the competent authority in the country of operation. Holders of manufacturing authorisations are obliged to follow GMP guidelines, to employ a Qualified Person and are subject to periodic inspection by the competent authority. The Qualified Person (hereinafter, 'QP') has to be a person who has received the relevant education and training (in accordance with Article 48 of the Directive 27/2004/EC), usually a pharmacist with industry experience, or a chemist, with responsibility to personally ensure that a quality system is implemented and maintained.

If a parallel distributor does not repack or re-label goods in his own facility, he will have to subcontract these processes to an authorised re-packer, who will have to demonstrate that he is in possession of a manufacturing authorisation and operates under GMP conditions. In these cases, all legal and technical requirements that must be observed by the parallel importer/distributor will be laid down in a technical agreement between him and the re-packer. This ensures full compliance with all legal and technical requirements under GMP.

6. The definition of the relevant market for pharmaceuticals

The presence of price controls has a significant impact also in the way the relevant market for pharmaceuticals is defined in competition cases. In parallel trade cases this task involves specific interpretative issues that are going to be analysed in this final Section.

In order to perform this analysis, I will first introduce some basic notions in relation to the tools used to define the relevant market in competition cases. Such notions are going to be later on applied to the pharmaceutical market, and specifically in parallel trade cases.

6.1. The definition of the relevant market

As it will be illustrated in Chapter II, strategies intended to hinder or prevent

¹²⁹ See *infra* Section 3.1 in Chapter II.

¹³⁰ In UK the licence for repacking/re-labelling is called a 'manufacturers (assembly only)' licence.

parallel trade may fall under the scope of Article 102 TFEU, if put in place by dominant companies¹³¹.

A prerequisite for any assessment of unilateral conducts under the mentioned provision is the identification of the relevant market on which the undertaking may have a dominant position¹³². The concept of relevant market is, in fact, functional to the objective of preventing the creation or the reinforcement of a dominant position that may impede effective competition in a substantial part of the common market¹³³.

For this reason, the operation of the definition of the relevant market serves the purpose of establishing the boundaries of the competitive constraints that the undertakings face, in order to ascertain whether they are capable of disciplining their behaviour¹³⁴.

In *Continental Can*, in fact, the ECJ said: “... the definition of the relevant market is of essential significance, for the possibilities of competition can only be judged in relation to those characteristics of the products in question by virtue of which those products are particularly apt to satisfy an inelastic need and are only to a limited extent interchangeable with other products.”¹³⁵

¹³¹ See KOENIG and ENGELMANN, *Parallel Trade Restrictions in the Pharmaceutical Sector on the Test Stand of Art. 82 EC: Commentary on the Opinion of Advocate general Jacobs in the Case Syfait/GlaxoSmithKline*, in ECLR, 2005, p. 338; VAN KERCKHOVE, *Parallel trade in pharmaceutical products following the ECJ's Bayer judgement: Can a case be made under Article 82 EC?*, in *The European Antitrust Review*, 2005.

¹³² Under European case law, a dominant position is a “position of economic strength enabling to behave to an appreciable extent independently of competitors, customers and ultimately of consumers”. See ECJ, 13 February 1979, in case C-85/76 *Hoffman-La Roche & Co. AG v. Commission*, para. 38. Community Courts and the Commission have interpreted this definition for long time in a rather formalistic way. The first criterion used by the Commission to assess dominance is, in fact, the market share of the undertaking in a given market, followed by other factors such as entry barriers, customers' capacity to react, etc. See the EC Commission notice on the definition of the relevant market, of 9 December 1997 (hereinafter the ‘Commission's notice on market definition’), para. 10. Note also that Community approach to dominance does not match the concept of market power referred by economic theory. The latter is the ability of an undertaking to set prices above marginal costs, measured by the Lerner index $P_m - P_c / P$. Such index is based on the inverse of the demand elasticity and it indicates the profit-maximizing price for a monopolist. See LERNER, *The concept of monopoly and the measurement of monopoly power*, in *Review of Economic Studies*, 1993, no. 1, p. 157; LANDES and POSNER, *Market power in antitrust cases*, in *Harvard Law Review*, 1981, no. 94, p. 937.

¹³³ See Commission's notice on market definition, para. 2. The Director's Guideline on Market Definition OFT 403, March 1999, para. 1.5, follows the same approach: “Market definition is not an end in itself, but rather a step which helps in the process of determining whether undertakings possess, or will possess, market power”. See also PITOFKY, *New Definitions of relevant Market and the Assault on Antitrust*, in *Colum. L. Rev.*, 1990, no. 90, p. 1805, at 1806-1807, where the author acknowledges that the definition of the relevant market is the most important, and often the most difficult, issues in enforcement actions.

¹³⁴ See LUTZ and STIROH, *The Relevant Market in Intellectual Property/Antitrust Litigation*, in 658 *Practising Law Institute – Patents, Copyrights, Trademarks, and Literary Property Course Handbook Series*, 2001, p. 75, at 86.

¹³⁵ See ECJ, in case C-7/62 *Continental Can v. Commission*, para. 32, where the ECJ quashed the Commission's decision, because it failed to define the relevant product market.

In general, the market analysis focuses on two dimensions of the relevant market: the product and the geographic market.

The former has been described as *“the market for all the products and/or services in question which are regarded as interchangeable, or substitutable, by the consumer by reason of their use, price and characteristics”*¹³⁶.

Therefore, the exercise of the product market definition consists of identifying effective alternative sources of supply for the consumer.

In *Hoffman-La Roche*, the ECJ held: *“The concept of the relevant market in fact implies that there can be effective competition between the products which form part of it and this presupposes that there is a sufficient degree of interchangeability between all the products forming part of the same market in so far as a specific use of such products is concerned”*.¹³⁷

A first step that helps in limiting the field of investigation of possible substitutes is the analysis of the product characteristics and its intended use.

However, functional interchangeability and similarity in characteristics are insufficient to know whether two products are demand substitutes, because the responsiveness of customers to changes in price may be determined by other considerations as well. Stated differently, differences in product characteristics are not in themselves sufficient to exclude demand substitutability, since this depends on how customers value different characteristics¹³⁸.

Following the developments in the jurisprudence along this trend¹³⁹, the

¹³⁶ See the Commission's notice on relevant market, para. 7.

¹³⁷ See *Hoffman-La Roche*, para. 28.

¹³⁸ Products' characteristics was the only criterion guiding the definition of the relevant market in *United Brands*, where the ECJ at para. 22 held that bananas constituted alone a market because of the *“special features distinguishing it from other fruits that it is only to a limited extent interchangeable with them and is only exposed to their competition in a way that is hardly perceptible”*.

¹³⁹ See GC, in case T-83/91, *Tetra Pack v. Commission*, para. 63: *“... the definition of the market in the relevant products must take account of the overall economic context, so as to be able to assess the actual economic power of the undertaking in question. [...] it is necessary first to define the products which, although not capable of being substituted for other products, are sufficiently interchangeable with its products, not only in terms of the objective characteristics of those products, by virtue of which they are particularly suitable for satisfying constant needs, but also in terms of the competitive conditions and the structure of supply and demand on the market.”* See also GC, in case T-504/93, *Tiercé Ladbroke v. Commission*, para. 84: *“According to settled case law, for the purposes of applying Article [82] of the Treaty, the relevant product or service market includes products or services which are substitutable or sufficiently interchangeable with the product or service in question, not only in terms of their objective characteristics, by virtue of which they are particularly suitable for satisfying the constant needs of consumers, but also in terms of the conditions of competition and/or the structure of supply and demand on the market in question”*. Similarly, ECJ, in case C.31/80 *L'Oreal*, para. 25; ECJ, in case C-322/81 *Michelin v Commission*, para. 37; ECJ, in case C-62/86 *AKZO Chemie v Commission*, para. 51; GC in case T-30/89 *Hilti v Commission*, para. 64, and in case T-83/91 *Tetra Pak v Commission*, para. 63.

Commission notice on market definition has rendered the analysis of substitution more flexible and enriched it with criteria other than physical identity of products. For instance, substitution may not be symmetrical: a mid-quality product does not necessarily compete with a more sophisticated product. Nevertheless, the existence of the latter may exert pressure on the price of the mid-quality product, as consumers may switch to the superior product for certain levels of price¹⁴⁰.

A comprehensive analysis of the demand's side possibility of substitution, hence, has to take into account the economic context, including the objective characteristics of the product and the degree of inter-changeability between the products, having regard to their relative prices and intended use; but also consumers' preferences, consumption patterns, the competitive conditions (like barriers to entry, switching costs, network effects, etc.), the structure of supply and demand, the existence of consumers groups that facilitate price discrimination¹⁴¹.

However, this checklist is neither fixed, nor exhaustive, nor is every element mentioned in the case law necessarily mandatory in every case. Each case will depend on its own facts, and it is necessary to examine the particular circumstances in order to establish whether the supposed dominant product competes with others and to what extent the latter exert a competitive constraint on the former, and consequently on the conduct of the allegedly dominant firm.

6.1.1. The product market and the SSNIP test

The competitive constraint to which a given good may be subject to is generally considered threefold and consists of demand substitutability, supply substitutability and potential competition¹⁴².

The main theoretical instrument to find alternative sources of supply from the consumers' perspective is the hypothetical price increase test, based on the assumption that consumers' reaction to a change in price signals the presence of suitable alternatives

¹⁴⁰ See BRUZZONE, *L'individuazione del mercato rilevante nella tutela della concorrenza*, 1995.

¹⁴¹ See BELLAMY and CHILD, *European Community Law of Competition*, 2001, para. 9-011 until 9-064; FAULL and NIKPAY, *The EC Law of Competition*, 1999, chapter 1; WISH, *Competition Law*, 2003; *Hoffmann-La Roche*, para. 28; ECJ, 14 February 1978, in case C-27/76, *United Brands Company and United Brands Continentaal BV v Commission of the European Communities*, para. 30 *et seq.*; ECJ, 9 November 1983, in case C-322/81, *Nederlandsche Baden – Industrie Michelin v Commission*, (*Michelin I*), para. 37. Finally see the decision of the Commission of the 18 July 1988, in case No. IV/30.178 *Napier Brown-British Sugar*.

¹⁴² See Commission's notice on market definition, para. 13.

(the so-called ‘SSNIP test’, acronym for Small but Significant and Non-transitory Increase in Price)¹⁴³.

This test consists of a mental experiment, postulating a hypothetical small (in the range of 5 % to 10 %) but permanent change in prices and evaluating the reaction of consumers to it. The question to be answered is whether they would switch to other substitute products, i.e. whether the increase in price is profitable or not. If substitution were enough to make the price increase unprofitable because of the resulting loss of sales, additional substitutes and areas are included in the relevant market.

In other words, starting from the type of products that the undertakings involved sell, additional products will be included in, or excluded from, the market definition, depending on whether competition from these other products and areas affect or restrain sufficiently the pricing of the parties’ products in the short term. The relevant market therefore consists of a basket of goods and/or services that are considered substitutes by consumers. Such a basket is considered “worth monopolizing” provided that the undertaking could profitably increase its price without its customers turning away and choosing other goods and services from other suppliers^{144 145}.

¹⁴³ The original concept founding the SSNIP test probably has been proposed first in 1959 by economist Morris Adelman of the Massachusetts Institute of Technology. See ADELMAN, *Economic Aspects of the Bethlehem Opinion*, in *Virginia Law Review*, 1959, no. 45, p. 686. Several other researchers formulated, apparently independently, similar conceptual approaches during the 1970s. See WERDEN, *The 1982 Merger Guidelines and the Ascent of the Hypothetical Monopolist Paradigm*, in *Antitrust Law Review*, 2003, no. 71, pp. 253-269. The SSNIP approach was then implemented in three antitrust cases: in a 1972 Justice Department attempt to enjoin the merger of *Associated Brewing Co.* and *G. W. Heileman Co.*, in 1975 during hearings on the U.S. government’s monopolization case against IBM, and in a 1981 proceeding precipitated by *Marathon Oil Company’s* effort to avert takeover by *Mobil Oil Corporation*. In 1982 the U.S. Department of Justice Merger Guidelines introduced the SSNIP test as a new method for defining markets and for measuring market power directly. In EU law it was used for the first time by the Commission Decision 92/553/EEC of 22 July 1992 related to the proceeding No. 4064/89 (Case No IV/M.190 - *Nestlé/Perrier*) and has been officially recognised by the European Commission in its notice on Relevant Market.

¹⁴⁴ The test has been for the first time applied in the *Tetra Pak I* case, where the Court found the two types of milk, apparently perfectly substitutable, were instead in different relevant markets. Such rigidity in the determining substitution between products has been tempered in *Hoffman-La Roche* and *Michelin*.

¹⁴⁵ A relevant problem with the application of this test is the so-called “*cellophane fallacy*”. The test uses competitive price as benchmark, and if the undertaking is already charging monopoly prices, any further increase in price looks unprofitable. In this case, the SSNIP test is likely to fail in correctly assessing the relevant market. The *cellophane fallacy* arises from the fact that economic theory predicts that any profit-maximizing firm sets its prices at a level where demand for its product is elastic. Therefore, when a monopolist sets its prices at a monopoly level it may happen that two products appear to be close substitutes whereas at competitive prices they are not. This may cause a too broad definition of the relevant market, including products that are not substitutes. The *cellophane fallacy* takes its name from the well-known case *United States v E.I. Du Pont de Nemours & Co.*, No. 5 Supreme Court of the United States, 351 US 377 of 11 June 1956. In this case, Du Pont (a cellophane producer) argued that cellophane was not a separate relevant market since it competed with flexible packaging materials such as aluminum foil, wax paper and

This 'thought experiment' can be implemented through the use of several methodologies that help the understanding of buyer substitution patterns.

First of all, past buyer responses can be very informative. This data can, for instance, be inferred by interviewing consumers about their buying decisions. Interviewing executives may be instructive too, given their knowledge of rivals' strategies.

Econometric and statistical estimates of cross-price elasticities for the demand of a product, the examination of price movements over time, and the analysis of causality between price series and similarity of price levels and/or their convergence, are useful tools to determine the degree of substitutability among products¹⁴⁶.

Supply-side substitutability is also taken into account when defining the relevant market. This criterion looks at whether suppliers are able to switch production to the relevant products in the short term without incurring significant additional costs or risks in response to small and permanent changes in prices. If such switch takes place, the additional production that is put on the market will have a disciplinary effect on the competitive behaviour of the dominant undertaking¹⁴⁷. The third source of competitive constraint, potential competition, is not taken into account by the Commission when defining the relevant market, since conditions under which potential competition actually displays an effective competitive constraint occur only when entry is favoured. But this element is generally part of the analysis on dominance¹⁴⁸.

polyethylene. The problem was that Du Pont, being the sole producer of cellophane, had set prices at the monopoly level, and it was at this level that consumers viewed those other products as substitutes. Instead, at the competitive level, consumers viewed cellophane as a unique relevant market (a small but significant increase in prices would not have them switching to goods like wax or the others). In the case, the US Supreme Court failed to recognize that high own-price elasticity might mean that a firm is already exercising monopoly power.

¹⁴⁶ See BAKER and BRESNAHAN, *Economic Evidence in Antitrust; Defining Markets and Measuring Market Power*, Stanford Law and Economics Olin Working Paper No. 328, 2006 available at <http://ssrn.com/abstract=931225>; BAKER and RUBINFELD, *Empirical Methods in Antitrust Litigation: Review and Critique*, in *American Law & Economics Review*, 1999, no. 1, p. 424-427.

¹⁴⁷ See the Commission notice on relevant market, para. 20.

¹⁴⁸ See the Commission notice on relevant market, para. 24. If required, this analysis is only carried out at a subsequent stage, in general once the position of the companies involved in the relevant market has already been ascertained, and when such position gives rise to concerns from a competition point of view. Cf. WHISH, *Competition Law*, 2003, p. 25, where he affirms that the definition of the relevant market is based only on the constraints coming from actual competitors.

6.1.2. *The geographic relevant market*

The geographic relevant market has been defined as *'the area in which the undertakings concerned are involved in the supply and demand of products or services, in which the conditions of competition are sufficiently homogeneous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those area'*¹⁴⁹.

What matters, therefore, is the possibility for consumers to have an alternative source of supply of a given product located elsewhere within the same territory¹⁵⁰.

The Commission's approach to geographic market definition starts from the overview of the distribution of market shares of the undertaking(s) and their competitors, and continues with the analysis of price differences at national and EU level. This should give a preliminary view of the weight that the undertakings enjoy both in their domestic markets and abroad. Then the examination of national or local preferences, current patterns of purchases of customers, product differentiation/brands will serve the purpose of establishing whether other companies in other areas constitute a real alternative source of supply for consumers, and in this way determining whether the working hypothesis is consistent with the finding of national or regional geographic markets.

Also, it is very important to determine the geographical distribution of trade flows, in order to ascertain whether the price policy applied in a certain area is influenced by the policy applied in a neighbouring area¹⁵¹.

Finally, obstacles and additional costs, like expedition costs, labour and raw material costs, difficult access to the distribution chain and differences in the legal system, are relevant to determine the easiness for consumers to reach another geographical area where consumers can purchase the same good. The presence of chains

¹⁴⁹ See the Commission Notice on Relevant Market, para. 8.

¹⁵⁰ See FRIGNANI, *Abuso di posizione dominante*, in *Diritto Antitrust italiano*, ed. FRIGNANI, PARDOLESI, PATRONI GRIFFI, and UBERTAZZI, 1993, p. 332.

¹⁵¹ The absence of imports does not necessarily signal the presence of distinct markets, since the threat of potential coming from abroad disciplines domestic manufacturers's behaviour. See BRUZZONE, *L'individuazione del mercato rilevante*, cit., p. 40.

of distribution that link distant areas to the same market can, conversely, facilitate the possibility for consumers to find an alternative supplier¹⁵².

6.2 The definition of the relevant market in the pharmaceutical sector

6.2.1 The limits of the SSNIP test

It is acknowledged both in the economic and legal literature that defining the relevant market in the pharmaceutical industry is not straightforward¹⁵³.

First of all, the analysis of the characteristics of the products is not conducive to any result, because products with the same pharmaceutical form are often destined to target different diseases. At the same time, there exist medicines of different forms that are therapeutically equivalent. It follows then that the market analysis should focus on the intended use of the products rather than on their physical characteristics.

Secondly, most of the assumptions that underline the SSNIP test do not hold, due to the particularity of the market mechanisms characterizing drug price formation and consumer choice.

As previously explained, patients are to a large extent insensitive to price, because the financial resources for their pharmaceutical expenditures does not come out of their pockets but they are provided either by the national health care system, or by private insurance, or by both.

Not only consumers do not pay the drugs they consume, but also they do not choose them, as they have to rely on the therapy prescribed by physicians on the basis of the anamnesis made. In other words, prescribing doctors are the main determinant of demand in pharmaceutical prescription markets. The latter, as already indicated, is a derived demand generated by the interaction of different stakeholders in a pluralistic decision-making process.

¹⁵² For instance, in the retail markets the distribution of the population is such that, even if consumers purchase their products from a given area, the latter can compete with other that are geographically distant and may seem to far to reach. See, for instance, the Commission decision in the case No. IV/M.0026 *Cargill-Unilever*, of 29 December 1990, related to the distribution and sale of agricultural products where the geographic relevant market was defined as corresponding to the entire UK.

¹⁵³ See MORSE, *Product market definition in the pharmaceutical industry*, in *Antitrust L.J.*, 2003, no. 71, p. 633; COSCELLI and OVERD, *Market Definition in the Pharmaceutical Sector*, in *ECLR*, 2007, no. 25(3), p. 294- See also the *Indagine Conoscitiva nel settore farmaceutico* performed by the Italian antitrust authority in 1997, available at [http://www.agcm.it/agcm_ita/DSAP/DSAP_IC.NSF/0/3a250fe3093bed4ac12564c3004594a7/\\$FILE/Ic14.pdf](http://www.agcm.it/agcm_ita/DSAP/DSAP_IC.NSF/0/3a250fe3093bed4ac12564c3004594a7/$FILE/Ic14.pdf).

Actual trends in the consumption of medicines prescribed therefore constitute important indicia of the degree of substitutability among medicines. Still, the assessment of the competitive constraints between categories of medicines cannot be based on price. In fact, there is usually very limited price sensitivity on the part of the physicians, too¹⁵⁴. And albeit cost containment measures on physicians are increasingly playing an important role in the choice of the therapy, the decision process is more often dominated by considerations about the effectiveness and the appropriateness of the therapy in relation to physical characteristics of patients. This may cause some inertia in doctors' prescribing behaviours, which often tend to crystallize after a certain period of time.

Such limits are exacerbated by the fact that pharmaceutical companies do not normally compete on price but resort to other means to gain larger market share: detailing activity to doctors, advertising in medical journals, funding of clinical studies, mailing doctors, general marketing, diversifying pharmaceutical forms and widening the indications for which a product can be prescribed.

These features explain the presence of low cross price elasticities among branded products and undermine any attempt to apply the SSNIP test in a traditional manner to a given pharmaceutical product.

From the supply side, the analysis of the possibility of alternative supplies is not easier. In fact, the pharmaceutical industry is sometimes characterized by many market segments of small dimension, especially for highly specialized products that treat particular diseases only. The high level of investment necessary to discover, develop and commercialize these products may constitute a powerful barrier to entry for competitors. In this case, the possibilities of substitution for patients who suffer of a given illness are reduced to zero.

In light of these remarks, it appears that the traditional principles that guide market analysis under European competition law may not be suitable for antitrust analysis in the pharmaceutical sector, as they may not provide any useful insight about competitive dynamics. This does not mean that market definition in the pharmaceutical industry should be different from that in other industries. Notwithstanding the

¹⁵⁴ The trial court in *SmithKline Corp. v. Ely Lilly & Co.*, 427 F. Supp. 1089, 1117, affirmed that price has little to do with physicians prescribing practices.

ambiguous opinions of Courts at this regard¹⁵⁵, it seems that the same rules should apply, but they should be adapted to the features that characterise the industry¹⁵⁶.

Notably, in US the Federal Trade Commission (hereinafter the 'FTC') applies the substitutability principles and the SSNIP test, with a certain dose of flexibility that leaves some scholars with the impression of lack of transparency in the procedure¹⁵⁷.

This method has led to find disparate product market definitions for prescription drugs, ranging from narrow markets including a single chemical compound in non-merger cases¹⁵⁸, to broader markets including various drugs having the same mechanism of action¹⁵⁹, and to even wider products markets that consider all the drugs that cure a particular disease, generally in merger cases¹⁶⁰.

6.2.2 *The criteria used by the antitrust authorities in EU and in US*

Both the FTC and the European Commission usually distinguish among prescription pharmaceuticals, OTC products and 'pipeline products', i.e. products that are not yet in the market but that are at an advanced stage of development, that is to say at Phase II or III of clinical trials.

Normally OTCs are considered together with branded products, but in some cases, the FTC alleged OTC markets only¹⁶¹. In other cases, both the FTC and the Commission considered together marketed drugs and pipeline products, alleging 'innovation markets'¹⁶².

¹⁵⁵ See *United States v. E.I. du Pont de Nemours & Co.*, 1956, 351 U.S. 377 supporting the view the usual principles apply also to the pharmaceutical market. *Contra* see *In re Cardizem CD Antitrust Litig.*, 2001, 200 F.R.D. 297.

¹⁵⁶ See MORSE, *Product market definition in the pharmaceutical industry*, cit., p. 676.

¹⁵⁷ See MORSE, *Product market definition in the pharmaceutical industry*, cit., p. 633.

¹⁵⁸ For instance, the FTC used the dosage form, the dosage frequency or the dosage strength of products to narrow markets. See e.g. *Baxter Inc. & Wyeth*, FTC Docket No. C-4068, 3 February 2003, available at www.ftc.gov/os/2002/12/Baxter_wyethcomplaint.pdf; *GlaxoWellcome plc & SmithKline Beecham plc*, FTC Docket No. C-3990, 26 January 2001, available at www.ftc.gov/os/2000/12/glaxosmithklinecmp.pdf.

¹⁵⁹ See *Amgen Inc. & Immunex Corp.*, FTC Docket No. C-4053, 3 September 2002 available at www.ftc.gov/os/2002/07/amgencomplaint.pdf.

¹⁶⁰ See *Pfizer Inc. & Pharmacia Corp.*, FTC Docket No. C-4075, 27 May 2003 available at www.ftc.gov/os/2003/04/pfizercmp.pdf. The FTC in that case alleged a market of 'research and development, and the manufacturing and sale of prescription drugs or the treatment of Erectile Dysfunction'.

¹⁶¹ See *Pfizer Inc. & Pharmacia Corp.*

¹⁶² See GLADER, *Innovation markets and competition analysis*, 2006, p. 114. Notwithstanding the scepticism of some scholars to the use of 'innovation markets' in antitrust, still the latter appear to be very important in market analysis for pharmaceuticals. The industry is, in fact, characterized by a continuous and intense R&D activity. For this reason, especially in merger cases, the examination of future products that are present in the pipeline plays a key role in determining the relevant market. See MORSE, *The Limits of Innovation Markets*, ABA, Antitrust and Intellectual Property Newsletter, 2001, p. 22-35, available at

In Europe, each of these three mentioned segments is subsequently divided into groups that present similarity in therapeutic indications and clinical effects through the WHO Anatomical Therapeutic Chemical Classification system (hereinafter, the 'ATC')¹⁶³ for market definition purposes. The ATC groups pharmaceutical products according to the organ or system in which they act and their chemical, pharmacological and therapeutic properties¹⁶⁴. The ATC system differentiates between five different levels, starting with the anatomical group, followed by the therapeutic group and three subgroups.

According to this taxonomy there are 14 anatomical groups, 92 therapeutic groups, 222 therapeutic subgroups, 560 chemical/therapeutic groups and 1597 chemical subgroups.

The first and the second level identify the system (digestive, nervous, etc.) targeted by the medicine and the type of drug (anaesthetic, anti-asthmatic, etc.) respectively. These levels are generally considered not enough to find substitute products from the demand side, because the first one identifies the anatomical part of the human body affected by the disease, while the second one groups medicines that have different therapeutic uses.

That is why the European Commission, as well as national authorities and Courts, mainly use the third level of the ATC to establish a market definition. The ATC 3 is the therapeutic/pharmacological sub-group. Therefore, it groups medicines with the same therapeutic properties for a given disease or family of diseases. In other words, the ATC 3 indicates the intended use of a given product.¹⁶⁵

www.abanet.org/antitrust/mo/premium-at/ip/559817_2.pdf, who affirms that the use of innovation markets to challenge some mergers in US generated substantial controversy. See also GILBERT, *Comments on the Use and Misuse of Innovation Market Analysis*, en banc testimony before the Federal Trade Commission Hearings on Global and Innovation-Based Competition, Washington, D.C., October 25, 1995.

¹⁶³ The ATC classification has been drawn up by EphMRA (European Pharmaceutical Marketing Research Association). The second ATC level corresponds to therapeutic main groups, whereas the third ATC level reflects therapeutic/pharmacological subgroups.

¹⁶⁴ The ATC system was originally intended to provide a useful method of pharmaceutical product categorization for statistical, population-based analyses and evaluation of health policy.

¹⁶⁵ Note that the future products do not have an ATC collocation because they do not have a marketing authorisation yet. Therefore, the innovation markets are defined in relation to the intended use of the future products. See Commission Decision of 8 May 2000, Case COMP/M.1846 – *Glaxo Wellcome/Smithkline Beecham*, para. 198. For a detailed analysis of the case law and the criteria used by the European Commission and the FTC in defining innovation markets for merger cases see GLADER, *Innovation Markets and Competition Analysis*, cit., pp. 114-124 and pp. 208-213.

The clusters at the ATC 3 level form distinct market segments. And given the relatively low cross price elasticity of demand between them, products belonging to different therapeutic classes are commonly not considered to be substitutes, even though the pharmaceutical form is the same.

However, this is not always the case, as there are products that belong to several clusters, since they can be used to cure more than one disease¹⁶⁶. At the same time, all the products included in the same cluster are not always directly competing. Stated differently, it is not possible to rigidly isolate clusters, as sometimes the definition of the relevant market may require the aggregation of different clusters, or, on the contrary, further narrowing the ATC 3 down to the ATC 4 level (see better *infra*).

6.2.3 The limits of the ATC for Article 102 TFEU cases

There are a number of merger decisions on Article 101 TFEU cases in which the ATC classification has been used to discuss the market definition in the pharmaceutical sector¹⁶⁷. But, so far, there is almost no case law on product market definition in the pharmaceutical sector under Article 102 TFEU¹⁶⁸.

It is suggested by several commentators that, given that the market analysis conducted for merger cases has a different objective from the analysis under Article 102 TFEU, the use of the ATC classification may not be entirely appropriate¹⁶⁹.

First of all, in merger control cases the concern of the authorities is whether horizontal concentration will in the future lead to a reduction in the competitive

¹⁶⁶ As MORSE, *Product market definition in the pharmaceutical industry*, cit., p. 639 notes, there are disease that can be treated with one product only, and there are other diseases that can be treated with various drugs that may compete among each other. On this last point see DI MASI, *Price trends for Prescription Pharmaceuticals 1995-1999* prepared for the U.S. Department of Health and Human Services Conference on Pharmaceutical Pricing Practices, Utilization and Costs, 8-9 August 2000, available at <http://aspe.hhs.gov/health/reports/drug-papers/dimassi-final.htm>. Alternative therapies may be chemically similar or very different, and may have the same mechanism of action and still be functionally similar. In this case, other factors like safety and efficacy profiles help in determining the degree of substitutability among them.

¹⁶⁷ See Commission Decision of 16 July 1996, Case IV/M.737 – *Ciba-Geigy/Sandoz*; Commission Decision of 27 February 2003, Case COMP/M.2922 – *Pfizer/Pharmacia*; Commission Decision of 29 April 1993, Case IV/M.323 – *Procordia/Erbamont*; Commission Decision of 6 September 1994, Case IV/M.464 – *BMSC/UPSA*; Commission Decision of 13 September 1996, Case IV/M.781 – *Schering/Gehe-Jenapharm*; Commission Decision of 22 May 2000, Case COMP/M.1878 – *Pfizer/Warner-Lambert*.

¹⁶⁸ The Commission, in fact, ruled for the first time on this issue in the *AstraZeneca* case. See Commission decision of 15 June 2005, COMP/A. 37.507/F3 – *AstraZeneca*.

¹⁶⁹ See also the CAT in the *Genzyme* case, where the Tribunal held at para. 198 that neither the ATC classification, nor the Commission's previous decisions applying that classification in merger cases, are determinative of the issue of market definition in Art. 102 TFEU cases.

constraints on the merged entity. Enforcement actions aim at preventing the establishment of a dominant undertaking in the future, rather than controlling the behaviour of a dominant undertaking as such. Therefore, market definition in merger control consists in a dynamic analysis that combines current market information with a prognosis of the future development. In contrast, the market definition in an Article 102 TFEU case aims at assessing the past and present effects of a specific corporate conduct. It is, therefore, a retrospective analysis of the market that is solely based on market information at the time of the anticompetitive behaviour and, thus, it is more stringent than the one in merger control cases¹⁷⁰.

Secondly, the application of the ATC in an Article 102 TFEU case may be too simplistic. Merger cases often involve a large number of products and the use of the ATC 3 level aims at verifying where overlaps between the two undertakings' pipeline exist. That is why the Commission considers also future products: it investigates the competitive state of future markets, and then it studies the competitive situation with respect to products that have reached a level of development such that their competitive impact on the near-future market can be easily predicted¹⁷¹. In other words, the European Commission looks at where the pipelines may coincide in the product development, in order to foresee whether competition in the future product market will be lessened. In fact, such examination is generally aimed at maintaining a sufficient level of R&D competition after a merger.

However, this approach is concerned with issues that have little relevance in Article 102 TFEU cases and, on the contrary, it overlooks other issues that may be determinant¹⁷².

The use of the ATC alone does not always reflect on the substitutability of the pharmaceutical product with all aspects that a doctor takes into account when

¹⁷⁰ See GLYNN, *Article 82 EC and price discrimination in patented pharmaceuticals: the economics*, in ECLR, 2005, p. 135; MORSE, *Product market definition in the pharmaceutical industry*, cit., p. 633.

¹⁷¹ See Case No. IV/M.072 – *Sanofi/Sterling Drug* (1991); Case No. IV/M.323 – *Procordia/Erbamont* (1993); Case No. IV/M.426 – *Rhône-Poulenc/Cooper* (1994); Case No. IV/M.457 – *la Roche/Syntex* (1994); Case No. IV/M.500 – *AHP/Cyanamid* (1994); Case No. IV/M.555 *Glaxo/Wellcome* (1995); Case No. IV/M. 495 – *Behringwerke AG/Armour Dow Pharmaceutical Co.* (1995); Case No. IV/M.587 – *Hoechst/Marion Merell Dow* (1995); Case No. IV/M. 631 *Upjohn/Pharmacia* (1995); Case No. IV/M. *Hoffman LaRoche/Boehringer Mannheim* (1997); Case No. IV/M. 1229 – *American Home Products/Monsanto* (1999); Case No. IV/M. 1403 – *AstraZeneca* (1999); Case No. IV/M. 1378 – *Hoechst/Rhône-Poulenc* (1999).

¹⁷² See PAUTKE and JONES, *Competition Law Limitations for the Distribution of Pharmaceuticals – Rough Guide to the Brave World*, in ECLR, 2005, no. 26(1), p. 27.

prescribing a product. As already underlined above, medicines belonging to the same class may not be substitutes. The replacement of a drug with another one depends on medical culture, gravity of the disease, and physical characteristics of patients. As the WHO notes, the “(...) assignment to different ATC groups does not mean difference in therapeutic effectiveness and assignment to the same ATC group does not indicate therapeutic equivalence.”¹⁷³

That is why the ATC 3 level alone might not be sufficient to define a market in Article 102 TFEU cases.

Therefore, the question remains whether the method used to define the relevant market in a merger control procedure can be equally applied in an Article 102 TFEU case.

The Commission itself acknowledged that the identification of the relevant therapeutic classification is just the opening of the market analysis¹⁷⁴. In fact, it may be appropriate to carry out an analysis at other levels of the ATC system where the ATC 3 does not reflect the reality of the market.

In recent comments on the *Bayer* and the *Glaxo* cases, for instance, it is suggested that narrow market definitions may be used as a tool to help authorities investigate issues that could otherwise escape competition law provisions. This may mean that the ATC 3 level may become just the starting point of the analysis and that the latter may continue further to the ATC 4 level when the previous does not seem to be appropriate to define relevant markets¹⁷⁵. Should demand factors require it, the relevant market could be narrowed even more and potentially arrive to be identified with a single brand¹⁷⁶.

Symmetrically, it may be the case that the ATC 3 is too limited and that other therapeutic groups of the same level need to be included in the relevant market, or that

¹⁷³ See, for instance, the indications about the use and misuse of the ATC provided by the WHO, available at <http://www.whocc.no/atcddd/>.

¹⁷⁴ See para. 134 of the decisions taken by the European Commission adopted in the context of the Regulation (EEC) No 4064/89, where it affirmed that the ATC classification is only ‘starting point’ in the market analysis.

¹⁷⁵ See the Commission decision of 17 May 1999, in the case IV/M.1397 *Sanofi-Synthelabo*, where the Commission defined the relevant market for one of the products at the ATC 4 level. See also the case of the Italian competition authority n. 8916, 23 November 2000, procedimento I337 - *Bracco-Byk Gulden Italia-Farmades-Nycomed Amersham Sorin-Schering*, where the authority started defining the market from the ATC 3 level and then went further down to ATC 4 level.

¹⁷⁶ GYSELEN, *Comments at the EU Pharmaceutical Forum*, Brussels, May 2004.

medications in the same class belong to various markets.

6.2.4 When pharmaceutical product markets are narrow

The trend of defining relevant product markets more narrowly in non-mergers cases emerges from authorities' practice and from the case law both in US and at national level within the EU.

The FTC generally starts market analysis in merger cases with a presumption of narrow markets, limited to a specific therapeutic compound. And then it broadens the market as long as evidence shows that physicians and hospitals use other compounds as substitutes¹⁷⁷.

In non-merger cases, instead, the FTC has alleged very narrow prescription drugs markets limited to a single branded drug and its generic equivalent¹⁷⁸ or even to generics only¹⁷⁹.

For instance, the FTC alleged separate markets for different dosage strength of the same generic hypertension drug, and excluded the branded equivalent (Adalat CC®), because the entry of a second generic at each dosage level caused a significant reduction in price for each single dosage of the first generic¹⁸⁰.

Notably, the claim of narrow relevant market has been extended to merger cases recently¹⁸¹: in that occasion, the FTC defined the market as the manufacture and sale of a

¹⁷⁷ See BALTO and MONGOVEN, *Antitrust Enforcement in Pharmaceutical Industry Mergers*, in *Food and Drugs L.J.*, 1999, No. 54, p. 255, at 259.

¹⁷⁸ In *Abbott Labs. & Geneva Pharm., Inc.*, FTC Docket Nos. C-3945, 3946, 22 May 2000, available at www.ftc.gov/os/2000/05/c3945complaint.pdf, the FTC alleged a market of terazosin hydrochloride used principally to treat benign prostatic hyperplasia or enlarged prostate, bioequivalent to Abbott's Hytrin. The FTC alleged that other drugs are not effective substitutes because they are different in terms of chemical compound, safety, efficacy and side effects, as well as in terms of price sensitivity from consumers. In *Hoechst Marion Roussel Inc. & Andrx Corp.*, FTC Docket o. 9293, 16 March 2000, available at www.ftc.gov/os/2000/03/hoechstsnrxycomplaint.htm, the FTC alleged a market of once-a-day time-release diltiazem in capsule form, designed to be taken once every twenty-four hours. The product belongs to a group of drugs used to treat hypertension and the occurrence of angina but the other products treating the same diseases were not considered substitutes because of difference in efficacy and side effects, as well as risks associated with the switching from a drug to another within the group.

¹⁷⁹ The justification for alleging generic-only markets was in found in the fact that generic version of the branded products varies in price to a large extent. On these grounds consumers may not view the product as equivalent or interchangeable. Accordingly, when the price differential between the branded product and the generic product is large, they are in separate markets. When, conversely, the price gap is narrow, products are more likely to be in the same market. See *Dow Chem. Co & Marion Merrell Dow Inc.*, 24 May 1994, File No. 941-0019, p. 7.

¹⁸⁰ See *Biovail Corp. & Elan Corp.*, FTC Docket No. C-4057, 15 August 2002, available at www.ftc.gov/opa/2002/06/biovailelan.pdf.

¹⁸¹ See *Baxter Int'l, Inc. & Wyeth*, FTC Docket No. C-4068, 3 February 2003, available at www.ftc.gov/od&2002/12/baxter_wyethcomplaint.pdf.

specific general anaesthetic commonly used during surgery and as a sedative for patients on mechanical ventilators, because the product proved to be superior in terms of safety profile and quickness in adjusting the amount of sedation, with respect to other equivalent products.

At national level several European cases confirm this trend: *Napp Pharmaceutical*¹⁸², *Genzyme*¹⁸³, *Glaxo Principi Attivi*¹⁸⁴, *Phoenix-Pharma*¹⁸⁵, *Pharmalab*¹⁸⁶, *Pharmadex*¹⁸⁷, *Sandoz*¹⁸⁸, *Flavelab*¹⁸⁹, and *Syfait*¹⁹⁰. In all these cases Courts and antitrust authorities considered markets composed by the active ingredient.

In *Napp Pharmaceuticals* the UK's Office of Fair Trade (hereinafter, the 'OFT') defined a separate market for 'sustained release morphine tablets and capsules'. The Competition Appeal Tribunal (hereinafter, the 'CAT') later on supported this market definition. Justification for this assessment was found on the evidence showing that the analysed product, MST Continuous®, a sustained release morphine product, was in the market with a similar product, which, however, was a second line treatment, used only when patients were intolerant to morphine. Owing to practical disadvantages related to the administering the substitute product, the latter was not considered to pose substantial competitive constraints on the allegedly dominant product. For this reason, the two products were not regarded as substitutes and the relevant market was confined to oral morphine.

The *Genzyme* case was about the tying conduct put in place by a

¹⁸² See case No. 1001/1/1/01, *Napp Pharmaceutical Holdings limited and subsidiaries*, January 15, 2002, Competition Appeal Tribunal (CAT).

¹⁸³ See *Genzyme v. OFT*, March 4, 2004, CAT.

¹⁸⁴ See case of the Italian Competition authority against GSK, *Glaxo Principi Attivi*, August 2, 2006. The authority defined the relevant market starting from the ATC 3 level where a large cluster composed by molecules and finite products with analgesic properties was identified. Within this cluster the authority focussed on one of three subgroups that included the so-called 'Triptans' (N02CC), antimigraine products. The alleged dominant product, Sumatriptan Succinato, was the first to come into the market and in its injectable version remains the only existing remedy for the cluster headache. The specific characteristics of the product and the way of administering it were considered by the Italian authority enough to distinguish the allegedly dominant product from other antimigraine drugs.

¹⁸⁵ See case No. 04-D-05, *Phoenix Pharma*, February 4, 2004.

¹⁸⁶ See case No. 00-MC-14, *Pharmalab*.

¹⁸⁷ See case No. 01-MC-04, *Pharmadex TDC*, September 24, 2001.

¹⁸⁸ See case No. 03-D-35, *Sandoz*, September 24, 2003.

¹⁸⁹ See case No. 00-MC-16, *Flavelab*, November 7, 2000.

¹⁹⁰ I refer here to the national phase of the *Syfait* case, before the Hellenic Competition Authority asked the ECJ to rule on the referred legal questions: there the authority found GSK to be dominant for Lamictal®, an antiepileptic, because patients could not be effectively treated with other drugs without substantial side effects.

biopharmaceutical company that developed an orphan drug, Cerezyme®, an intravenous infusion aimed at curing the so called Gaucher disease¹⁹¹. The administering of the drug is normally supported by homecare companies who can co-ordinate drug supply and delivery, education and support for patients to self cannulate and infuse, and a long term home infusion service where necessary. Patients suffering from Gaucher disease, therefore, have a constant need for effective treatment, including responsible clinicians.

The defendant argued that the relevant market was constituted by all the LSDs products, because the R&D facilities and marketing activities, as well as the administering method are the same for these products and the allegedly dominant drug.

The Tribunal, however, overturned the defendant's argument and defined the product market definition based on the concept of interchangeability from the demand side.

The CAT acknowledged the fact that biopharmaceutical companies regard themselves as competitors in the upstream research market for orphan drugs, because research techniques leading to the development of drug for Gaucher disease may be transferable to research into possible other drugs based on the same technology for other diseases.

Yet, this approach did not address the issue of substitutability for patients suffering this rare disease and their need to be treated with an effective product. Also, this argument disregarded the fact that a producer possessing a marketing authorisation for a LSD product may not be able, without substantial switching costs due to the separate approval procedures for orphan drugs, to swiftly obtain another marketing authorisation that allows it to sell the same product for other diseases¹⁹².

For this reason, the CAT considered the product market to be constituted by the alleged dominant product and its competitor. The latter were, in fact, the only ones

¹⁹¹ The Gaucher's disease is one of many lysosomal storage diseases (LSDs). It is caused by a hereditary deficiency of the enzyme glucocerebrosidase (also known as acid β -glucosidase), leading to an accumulation of fatty material in the spleen, liver, kidneys, lungs, brain and bone marrow. Symptoms include enlarged spleen and liver, liver malfunction, skeletal disorders and bone lesions that may be painful, severe neurologic complications, as well as other symptoms. It is named after the French doctor Philippe Gaucher, who originally described it in 1882.

¹⁹² See para. 212 of the final decision of the CAT in the *Genzyme* case.

having a marketing authorisation for the Gaucher disease¹⁹³.

Also, the Court affirmed that, given that Genzyme's competitor's product was a second line treatment used for those patients for whom the ERT therapy¹⁹⁴ was not suitable, beside Genzyme's product and a competitor *de facto* there were no other products to treat the disease in the UK market. Thus, the market could be reduced to the allegedly dominant product only¹⁹⁵.

In *Flavelab*, the *Conseil de la Concurrence* in France faced a case of predation where the defendant company produced Céfuroxime®, belonging to the family of cephalosporins, an injectable antibiotic used to prevent the occurrence of infections in the surgery operations, marketed with the name of Zinnat®. The defendant argued that the relevant market included all the antibiotics that have the same indications in the family of the cephalosporins. The complainant, on the contrary, supported a much narrower definition of the market, which was in its view composed by the allegedly dominant medicinal specialty.

The *Conseil de la Concurrence* observed that hospitals specifically ordered GlaxoSmithKline's (hereinafter refereed as 'GSK') product. This, in the view of the authority, indicated that for doctors the product was not substitutable with other molecules belonging to the group of cephalosporins. Moreover, the authority pointed to the fact that hospitals generally carry out the prophylactic policy by purchasing different antibiotics that target different bacteria, which cannot be considered substitutable.

The *Conseil*, therefore, deduced that nothing prevented at that stage to identify the relevant market as composed by the allegedly dominant product and the generic version.

In the *Astrazeneca* case, where for the first time the European Commission operated the assessment of the relevant market for pharmaceuticals in an Article 102 TFEU case, the defendant company was found dominant on the proton pump inhibitors market (hereinafter, 'PPI'), which belongs to the ATC category (AO2BC), with its product Losec® (omeprazole).

The market analysis conducted by the Commission started from ATC 3 level

¹⁹³ See para. 209-210 of the final decision of the CAT in the *Genzyme* case.

¹⁹⁴ Some forms of Gaucher's disease may be treated with enzyme replacement therapy (ERT), i.e. the direct replacement of the missing enzyme.

¹⁹⁵ See para. 205-206 of the final decision of the CAT in the *Genzyme* case.

where the cluster of 'drugs for the treatment of peptic ulcer' was first identified, including omeprazole and histamine antagonists (hereinafter, 'H2 blockers'), widely used for the treatment of ulcers before the launch of omeprazole. The Commission narrowed the market to the mere omeprazole, because of its different mode of action with respect to H2 blockers. The latter, in fact, have only indirect effects on the treatment of acid related diseases, while the former has a direct effect on the proton pump in the stomach's cells.

In the appeal against the Commission decision, Astrazeneca argued that, although it was true that PPI are therapeutically superior to H2 blockers, and despite such superiority was accepted by the scientific community from the early 1990s¹⁹⁶, doctors did not recognise it immediately. The increase in use of PPIs was gradual, because the H2 blockers exerted a competitive constraint on the former and because doctors were concerned with the possible side effects of PPIs, being the latter much stronger drugs with respect to H2 blockers. This prescribing pattern showed, according to the applicant, that H2 blockers and PPIs are prescribed for the same medical treatment and are therefore in the same relevant market. This was confirmed by the significant percentage of use that H2 blockers had in several countries and by the fact that they were not entirely replaced by the PPIs in any country¹⁹⁷.

However, the Commission invalidated these argument by pointing at the fact that PPIs were superior products with respect to H2 blockers, as well as to other medicines in the field of acid-related gastrointestinal disease, because of the direct effect on the proton pump in the stomach's cell, whatever the cause of the acid secretion into

¹⁹⁶ Due to their singular mode of action, the therapeutic effectiveness of PPIs is considered to be superior to that of other categories of medicinal products used for the treatment of gastrointestinal diseases related to conditions caused by acid production, including the H2 blockers. PPIs' superior characteristics with respect to H2 blockers show up in terms of healing rate, symptom relief, eradication rates and the prevention of relapse. Indeed, AZ states in its 1994 annual report: "*Losec (omeprazole) offers significant clinical advantages compared with H2-receptor antagonists. Comparative clinical studies of these pharmaceuticals have shown that patients treated with Losec become symptom-free earlier and more patients get their ulcers healed. This applies to peptic ulcer as well as to reflux oesophagitis. In the case of RO and [duodenal ulcer], long-term therapy with Losec is effective in preventing recurrence*". In its 1996 annual report AZ notes that "*Astra's success with Losec is due in large part to the product's good clinical effect and specific mode of action: It inhibits the final stage in the formation of hydrochloric acid in the stomach. This means that Losec is more effective than previous drugs in the treatment of peptic ulcer, and it has essentially no side effects*".

¹⁹⁷ These arguments were opposed by the Commission, in particular by referring to the fact that the Court in the case T-340/03 *France Télécom v. Commission* acknowledged that when consumers migrate from one product to another, and when they have similar functions but substitutability is asymmetric, these products are do not belong to the same market.

the stomach. This differentiates PPIs from H2 blockers, which targeted only one of the factors stimulating the acid-production proton pump without any direct impact on the pump itself. Such characteristic was one of the factors that induced the Commission to exclude the H2 blockers from the relevant market.

As for the price substitution, the Commission noticed that in the relevant period of time the H2 blockers did not exert any competitive pressure on Losec, whose market share kept growing steadily and fast, though Losec was priced three times higher than H2 blockers.

Thus, the Commission affirmed that therapeutic superiority, prescribing patterns, lack of correlation of prices of the two groups led to place them in two distinct product markets

6.2.5 *How to properly define the relevant market for antitrust cases in the pharmaceutical sector?*

The examination of the recent Commission's enforcement action in the *AstraZeneca* case provides a good indication of the criteria used to define markets in non-merger cases.

Great weight is attributed to differences between medicines' modes of action, i.e. the way they produce their therapeutic effects¹⁹⁸. For instance, quickness of the relieving effects and lack of substantial side effects may prove the superiority of a product over the other equivalents. This can first help in understanding whether confronted products are similar or one of them is therapeutically superior.

This does not mean that to be in the same markets drugs should be identical. But the presence of sufficiently unique features and significant differences may lead to identify discrete markets.

The fact that a product is priced at a higher level with respect to predecessors also indicates therapeutic superiority that may induce to consider the former to belong to a separate market with respect to the latter. That means that also cost-effectiveness information contributes to the market analysis.

With regards to the 'functional interchangeability', generally considered the pivotal criterion that determines the boundaries of the relevant market, it is necessary (but not sufficient) to check whether different medicines are prescribed for the same

¹⁹⁸ Cf. the Commission decision in the *AstraZeneca* case, para. 373-374.

disease, as degrees of efficiency and appropriateness may determine separate and possibly narrower product markets¹⁹⁹. The evidence of a higher rate of efficacy provided by scientific literature and medical publications, in fact, may lead to distinguish products that are *prima facie* equivalent.

Also, gradual but steady process of replacement of an old product with an emerging one in medical prescriptions generally lead to deduce that they do not belong to the same relevant market. Indeed, the fact that two products are prescribed for the cure of the same symptoms or illness, but one follows an increasing pattern, while the rate of prescription of the other one is decreasing, signals the absence of competitive constraints between them and leads to consider them as belonging to different markets.

In the economic literature the application of a four-pronged test has been suggested in order to properly assess the relevant market for pharmaceuticals and to determine, for instance, whether the allegedly dominant drug and the supposed competitors belong to the same relevant market.

First of all, evidence of therapeutic substitution should be used to narrow down the number of products that according to physicians can be considered interchangeable in the treatment of a disease. All the products that are not considered to be suitable substitutes from doctors should be excluded by the relevant market, unless it appears from the indications that they are specifically designed to treat the same physical condition, despite doctors' perception.

This information can be inferred from medical literature, as well as from labelling information.

Secondly, it is important to look at prescribing patterns. This information indicates the actual use of a medicinal product. If there is evidence that two or more products are prescribed for the same disease over time, this indicates that they are in the same product market.

This evidence is also important to understand how quickly a product has started to be prescribed by doctors, how much they have been influenced by advertising in switching to the new product, and how patients react to it.

Third comes the commercial evidence. Internal documents of both undertakings

¹⁹⁹ See *Sanofi/Synthelabo*, para. 31.

may give good insights of the commercial and marketing strategies they adopted to compete with the rival and gain market share over it.

Finally, if data are available, it is critical to look at an econometric estimation of the effect that advertising, entry of competing products, introduction of new presentation forms and conducted clinical studies, have on the substitution pattern among different drugs²⁰⁰.

6.3 *The relevant market definition in parallel trade cases*

It is a well-established principle in the law that relevant markets cannot be limited to a single manufacturer's product²⁰¹. However, as already pointed, some case law suggests that in some instances one good alone can constitute a separate market²⁰². The tendency to identify relevant market composed by a single product particularly emerged for parallel trade cases under Article 102 TFEU in the field of pharmaceuticals.

The particular perspective required, namely the wholesalers' standpoint, provided the occasion to address one feature of the pharmaceutical market that only few Courts have considered until now: the degree of substitutability among medicines for wholesalers.

It has been argued that the mechanisms of substitution among pharmaceuticals cannot be determined by the product analysis alone, but it is necessary to take into account the distribution and the dispensing process.

As opposed to a normal demand and supply chain, the buying and selling of a prescribed pharmaceutical product involves various actors with different decision-making functions at different stages of the process. In particular, among the latter, the physician appears to play a key role in the choice of the product to be administered to the patient. After pharmacies receive the prescription from the patient, they often have very limited possibility of substitution of that product and they generally order from

²⁰⁰ See COSCELLI and OVERD, *Market Definition in the Pharmaceutical Sector*, cit., p. 295.

²⁰¹ See ABA Section of Antitrust Law, *Antitrust Law Developments* 566, 2002. In *DuPont* the Supreme Court explained that whenever manufacturers have power over price and production of its own product, they cannot be considered to have a power that amount to an illegal monopoly.

²⁰² Cf. *Kodak*, 504 U.S. at p. 482, where the Court said that the relevant market could be limited to parts and services for Kodak machines because once customers bought the equipment they were locked into buying only Kodak parts and services. It follows that the outcome of the case was very much fact-specific and cannot be extended through analogy to any case.

wholesalers those indicated by doctors²⁰³. Equally, wholesalers do not have any other choice but provide exactly the requested product from manufacturers. The prescribed product then goes down along the distribution chain back to the patient.

In light of the rigidity of the pharmaceutical supply distribution chain and of the binding constraint posed by the medical prescription, one may argue that often no – or very limited – possibility of substitution exists for the pharmaceutical wholesaler when it comes to the satisfaction of the order of the pharmacist²⁰⁴. It follows that the definition of the relevant market in the relationship between pharmaceutical manufacturers and their customers may in certain cases be limited to the prescribed pharmaceutical product ('one product-one market' definition).

This may be the case when wholesalers must necessarily have one of the specific medications from this pharmaceutical company in their range, failing which they would lose a substantial part of their clientele, not occasionally for the delivery of this single medication, but for all the services it can offer to their pharmacist customers.

Not only the refusal to supply of a non otherwise substitutable product from the manufacturer would endanger the commercial relationship between the wholesaler and the pharmacy, but also it would prevent the wholesaler from complying with the legal obligation that in certain Member States – like Italy or France - requires him to keep in stock at least 90% of the products marketed in the domestic market²⁰⁵.

The 'one-product-one market' definition has been subject to criticism in the literature from both commentators and industry stakeholders²⁰⁶.

Pharmaceutical industry representatives argue, in fact, that narrow markets should be applied only when assessing the market power at the stage of manufacturing

²⁰³ In *In re Cardizem CD Antitrust Litigation* the district Court suggested the once a physician prescribes a particular drug, a patient may only purchase that drug or its FDA-approved AB-rated bioequivalent. It also added that *de facto* there are no other choices available for consumers, because they cannot obtain any other product than the one prescribed by the doctor. Similarly, in *Schering Plough Corp., Upsher-Smith Labs. & Am. Home Prods Corp.*, FTC Docket No. 9297, 21 October 2002, the complaint counsel suggested that the requirement that a physician must approve switching a prescription significantly prevents interchangeability.

²⁰⁴ This criterion has been applied from the Court of Appeal of Milan, decision of 12 July 2005, case 2056/2005, *Farmacia Petrone v Pharmacia Italy and Pfizer Italy* (not published).

²⁰⁵ In Italy, the Decree no. 538 of 30 December 1992, which translated into national law the principle contained into the Directive 92/25/EEC ("*Attuazione della Direttiva 92/25/CEE riguardante la distribuzione all'ingrosso dei medicinali per uso umano*"), established at art. 7(1) that, *inter alia*, pharmaceutical wholesalers should keep in their stock the 90% of medicinal specialties marketed in Italy.

²⁰⁶ See JENNY, *Pharmaceuticals Competition and Free Movement of Goods*, EU Competition Law & Policy, 2002, p. 82; EFPIA, *Article 82 EC: Can it be applied to control sales by pharmaceutical wholesalers?*, 2004, p. 31.

of molecules, or at the stage of direct sale of medications by pharmaceutical companies to dispensaries and hospitals²⁰⁷.

When there is a direct sale to the customer, i.e. hospitals and pharmacists, the therapeutic use of the product is certainly relevant, because this is the feature in which these subjects are interested.

Conversely, when sales are directed towards distributing wholesalers, the therapeutic criterion seems to be less relatable. Indeed, in this case, neither the physician nor the patient is involved and the wholesaler seeks no therapeutic indication. It follows that the therapeutic criterion may not be adequate in parallel trade cases²⁰⁸.

These stakeholders thus allege that the relevant market should be determined not from the perspective of the final consumers but from the point of view of wholesalers.

Such approach has been justified on the following grounds.

Wholesalers rationalise distribution, make use of economies of scale and scope, and use resources (space, stores, transport means and workers) to obtain the maximum profit from the capital invested in infrastructures, given the regulatory constraints on margins they are subject to.

From this point of view, the rigidity of choice among products deriving from the doctor's prescription does not have any influence on wholesalers' assortment. On the contrary, the fact that wholesalers can freely choose the composition of the residual unregulated 10% of their stock gives them a sufficient degree of discretion. In choosing the composition of that part of their stock, wholesalers rely, for instance, on the dimension of boxes, on price and on the intensity of demand. The account of these variables allows wholesalers to calculate the expected average revenue of each product and to consequently plan the assortment and the quantities of that product to be kept. Therefore, the worsening of the sale conditions of a product is likely to trigger the

²⁰⁷ EFPIA, *Article 82 EC: Can it be applied to control sales by pharmaceutical wholesalers?*, cit., p. 31.

²⁰⁸ Confirmation to this approach comes from the French case on 'small hand equipment' where the Paris Court of Appeal criticized the construction of the relevant market, identified with the single tool, done by the Competition Council as liable of artificially fragmenting the market. See the case *Sifco Stanley SA*, May 17, 1994, Paris Court of Appeal. See also the letter from the Minister of the Economy of January 20, 2003, concerning the concentration in the pharmaceutical distributing wholesalers sector: "[...] the market test did not make it possible to clearly delineate a segmentation of the wholesaler distribution market as a function of products distributed by wholesaler-distributors. In this case, and for the needs of this analysis, we shall be interested in the overall pharmaceutical distribution market."

reduction of wholesalers' demand of that product and the switch to another product.

In light of this, wholesalers' demand may be thought to be very elastic, as compared to consumers' demand. In fact, no matter the therapeutic characteristics of drugs, a wholesaler could consider two products as substitutes, as long as they provide him with the same average revenue.

The reasoning should apply *a fortiori* to wholesalers who engage in parallel importing activities and to pure exporters²⁰⁹: when they sell in importing countries, they are free from any public service obligation. Thus, the therapeutic characteristics of drugs do not represent an issue for them. On the contrary, they base their selling decisions mainly on price differentials across countries, in order to maximise their margins and profits. From this point of view, when for a given product margins are squeezed due to the reduction of its price gap across countries, parallel importers would switch to a more profitable product. In this sense, the medicaments that provide the same margin are 'equivalent' economically speaking²¹⁰.

Accordingly, it has been thus suggested that, for cases under Article 102 TFEU concerning parallel trade, there is a separate product market for all pharmaceutical products capable of being profitably parallel distributed from exporters/wholesalers. It follows that the relevant market in parallel trade cases should include '*all tradable drugs*'.

Criticism against the 'one-product-one-market' definition can be inferred also from the jurisprudence at the national level in other sectors. In France it has been argued, for instance, that such an approach would lead to paradoxically attribute market power also to small pharmaceutical undertakings²¹¹.

However, at present the jurisprudence and the authorities did not express their view on the alternative definition of the relevant market as '*all tradable drugs*'²¹².

²⁰⁹ To my knowledge the difference between exporters and wholesalers, on the basis of their subjection to the public service obligation, exists only in France, where regulation explicitly distinguishes between them, also in terms of the licence released by the authorities.

²¹⁰ I assume here that the costs of purchasing drugs, repacking and reselling them abroad are constant in time and across drugs.

²¹¹ EFPIA, *Article 82 EC: Can it be applied to control sales by pharmaceutical wholesalers?*, cit., p. 25.

²¹² Such approach seems to be accepted by the GC in the *Glaxo* case, where at para. 159 it affirms "It does not appear to be manifestly incorrect to consider that the buyer, that is to say, the Spanish wholesaler who might engage in parallel trade, is less interested, for that purpose, in the therapeutic indication and the pharmacological products of each of the medicines which he buys from GW than in the fact that all of those medicines are reimbursed by the Spanish sickness insurance scheme and that their price is therefore set by the Spanish authorities. Likewise, it does not appear to be manifestly incorrect to consider that the buyer is less interested in the price of each of the medicines as such than in

The reason of this caution may be found on the shaky economic foundations of this criterion. In fact, following this logic, any item or commodity, which gives the same margin, no matter the nature of product considered, should be part of the relevant market. Such criterion, therefore, does not give any real guidance to assess the relevant market in pharmaceuticals.

It rather appears that therapeutic interchangeability should remain the guiding criterion in the assessment of the relevant market also when wholesalers are concerned. Pharmaceutical markets definition should not be any different from that in other industries. Traditional methods and principles generally used to define markets would apply but should be adapted to the particular features of the industry.

The interchangeability principle should be applied also in parallel trade cases, in order to ascertain that they cannot substitute the source of the product requested by the pharmacy with another one. This is consistent with the notion provided by the European Commission, which defined the assessment of the relevant market as an exercise of identification of the substitute sources of supply for consumers²¹³, both in terms of surrogate products and of alternative geographical location of suppliers.

It follows that a narrow definition of the relevant market can be supported only where medicines that may be considered substitutes for patients and doctors, can prove to be complementary for wholesalers. In other words, it should be demonstrated that wholesalers could not resort to other sources of supply for that product requested by the pharmacy.

If the domestic legal framework prevents wholesalers from sourcing supplies from other stakeholders in the pharmaceutical supply chain, like other wholesalers, this means that a wholesaler does not have alternative and legitimate sources of supplies and that is locked-in by the rigidity of the doctor's prescription. In this case the relevant market should be identified on the basis of the commercial relationship between the manufacturer and the single wholesaler. In turn, this would lead to affirm the existence

the fact that there is a sufficient price differential to render parallel trade lucrative, for all of those medicines, between Spain and the Member State of destination. In those circumstances, it is not manifestly incorrect to accept that all the medicines reimbursed by the Spanish sickness insurance scheme which are capable of being sold at a profit owing to the price differential between Spain and the Member State of destination constitute a product market." However, the Court did not explicitly rule on this issue.

²¹³ Note that the notion of 'consumer' under competition law includes also other stakeholders along the distribution chain, hence also wholesalers.

of a relevant market composed by a single chemical compound.

If, on the contrary, wholesalers are able to fulfill their legal and commercial obligations through the replacement of the requested product with another one or, if they manage to offer anyway their services to the pharmacies, there exists a certain degree of substitution among source of products that impedes to consider each of them as a distinct market²¹⁴.

In fact, the presence of alternative sources of supply, even if they are at the same level in the supply chain²¹⁵, has a positive impact on the possibilities of substitution. This reduces the anticompetitive impact of a refusal to supply, because it does not affect the minimum stock required by law to fulfil the public service obligation²¹⁶.

6.4 The geographic market definition for pharmaceuticals

Relevant geographic markets in the pharmaceutical sector are defined as national in scope²¹⁷.

The national nature of pharmaceutical markets derives from a number of factors.

These include in particular the enduring differences in national health care systems, different price and reimbursement rules, e.g. the wide differences between national rules on incentives for cheaper generic and parallel imported products, as well as different brand and packing strategies, different distribution and different prescribing habits of physicians.

As explained in previous Sections, at this stage, harmonisation is mainly limited to rules relating to the authorisation of medicinal products (either nationally or through a centralised EU system), and in particular rules aimed at ensuring that the products concerned fulfil requirements in terms of safety, quality and efficacy. In all Commission decisions regarding pharmaceutical products, the relevant geographic market has been thus defined as national.

However, the mentioned jurisprudential trend suggests that there is a new

²¹⁴ See case No. 04-D-05, *Phoenix Pharma*, February 4, 2004, Competition Council, where the latter concluded that “*Seule une instruction approfondie pourra permettre de mesurer la marge de manoeuvre dont disposent les grossistes-répartiteurs mais il ne peut être exclu, à ce stade de l’instruction, que l’approvisionnement de ces derniers, en chacune des spécialités protégées par brevet, constitue un marché pertinent sur lequel le fabricant est en position dominante*”.

²¹⁵ For instance, art. 6, para. 1, lett. b) of the Italian Law No. 538/1992 provides that the wholesaler can source his supplies from companies who have a legal distribution license.

²¹⁶ See the Court of Appeal of Milano, 20 April 2005, in the case no. 2056 *Petrone v. Pfizer/Pharmacia*.

²¹⁷ See Commission’s decision in *GlaxoWellcome*, para. 114.

approach to market definition in relation to cases on parallel trade of pharmaceuticals. It is advocated that conventional competition law assessment is not appropriate in these cases, because this does not take into consideration the specific features that parallel trade of pharmaceuticals entails. Exporters and exporting wholesalers do not operate only in the exporting countries, where regulatory features determine the narrow geographic limitation of markets, but they take advantage of this regulation to exploit price differences abroad. That means that wholesalers who mainly engage in exporting activities operate in a different market, i.e. outside the exporting countries.

Other scholars confirm this approach through another argument: since R&D is global, the geographic consideration of future markets should focus at least on the territory of the EU and, possibly, on worldwide markets²¹⁸.

Still, differences in the patent system and in pharmaceutical regulations across Member States lead to different market conditions and degrees of competition. And this is why it appears correct to follow the approach adopted by the European Commission, which always defines relevant markets for pharmaceutical products as national in scope.

7. Conclusions

This Chapter has examined the main legal and economic features of the European pharmaceutical industry.

The main lesson to be drawn from the above analysis is that the European market is, despite the harmonisation efforts started already long time ago, still highly fragmented especially at the level of prices. This represents a concern for the competitiveness of the European firms in a globalized environment.

Such fragmentation finds its origins in the different medical culture and health status, but especially in the diverse way Member States conceive and shape their intervention in the market to solve the tripartite trade off they face in the regulation of pharmaceuticals: safety, efficiency and equity.

²¹⁸ See GLADER, *Innovation markets and Antitrust Analysis*, cit., p. 114 and 218; GILBERT and SUNSHINE, *The Use of Innovation Markets: a Reply to Hay, Rapp and Hoerner*, in *Antitrust Law Journal*, 1995, no. 64, p. 81, where they affirm that “the boundaries of innovation markets are typically broad, usually encompassing the world and often including products that, if defined at the goods level, would be in multiple markets. Good markets are often more local because of the need for local distribution assets, regulatory barriers, etc.”

The architecture of the Treaty and the application that EU Courts have provided are such that the ultimate responsibility of the health of European citizens is attributed to Member States, which, concerned by their budget constraints, have generally been reluctant to relinquish their sovereignty to the EU on this matter and to favour harmonisation.

This generated the proliferation of mechanisms of price controls that are very different in nature and that create wide price gaps among countries for the same products.

The EU Courts have been called many times to discuss the validity of such regulation in light of the principle of movement of goods. However, *de facto* enlarging the scope of mandatory requirement that can justify a departure from this principle to economic aims, they have constantly affirmed the validity of national price controls where they aim at stabilising pharmaceutical price expenditures and when they are not discriminatory.

This provided the legal basis that favoured the development of parallel trade on pharmaceuticals.

The latter has been used, together with other instruments, by European institutions to indirectly pursue a policy of price harmonisation in the European pharmaceutical market. One would expect this policy to be temporary, though. In fact, once harmonisation is achieved, there is no scope for parallel trade any longer. Still, after thirty years of parallel trade, drugs prices are not harmonised, though. As I will better illustrate in the following Chapters, regulation on prices, in fact, is acting as a counterbalancing force that from time to time allows price gaps to re-emerge in the market.

These two coexisting forces create a continuous 'push-and-pull' effect, where some price harmonisation is contrasted by the creation of new price gaps due to regulation. For this reason, at present the European pharmaceutical market remains stuck in a transition phase, where parallel trade can still exist.

CHAPTER II

The intersection between intellectual property rights and competition policy goals in the pharmaceutical sector

Introduction

This Chapter reviews an old legal issue that has been subject to abounding theoretical elaboration both from the legal scholars and the jurisprudence: the intersection between IPRs and competition law.

The two bodies of law are complementary components of a modern industrial policy and pursue the same goal: the improvement of consumer welfare, through the promotion of innovation. However, it is apparent that they do it through different means. Industrial property laws offer a period of exclusive rights to the inventor to spur its inventive activity through a monetary reward. On the contrary, competition law attempts to keep markets innovative by maintaining effective free access and preventing foreclosure.

Starting from the *grand arrêt* in Consten and Grundig, this Chapter traces the path followed by the EU jurisprudence to reconcile IPRs and EU competition law.

In the early stages of the EU case law, this clash was thought to be of great concern for antitrust authorities and led to place overly strict limits on the exercise of IPRs. Later on, this misconception of the effects of IPRs was mitigated by the progress of economic understanding. So, for instance, EU competition law does no longer assumes that the legal monopoly conferred by IPRs amounts to an economic monopoly or even confers market power, but it accepted the view that this issue should be established empirically.

Under EU law, the intersection between IPRs and competition law takes an additional feature. In fact, IPRs are inherently national, whilst competition provisions maintain a EU dimension and, for this reason, bear market integration overtones. From this point of view, the exercise of an IPR according to national law can run against Treaty provisions, especially when it provides the IPR owner with absolute territorial protection that limits cross border trade.

In order to solve this friction, European Courts engaged in a lengthy and gradual work of interpretation of the Treaty provisions, which led to the well known, albeit harshly criticised, distinction between ‘existence’ and ‘exercise’ of IPRs. In turn, this provided the basis for the development, through an articulated and tortuous route, of the notion of ‘specific subject matter’ and of the principle of ‘regional exhaustion’ of IPRs.

The result of this evolution is that, whilst competition law intervention is now more limited, as the ‘exceptional circumstances’ test for IP protected products in refusal to licence cases shows, in some cases where IPRs’ use unjustifiably runs against the ‘constitutional’ goals of the Treaty, EU competition law comes into play again as a ‘second tier’ of regulation of IPRs.

This legal environment shaped the current European policy towards parallel trade. On the basis of the above mentioned principles, traditionally the Commission and the EU Courts regarded negatively any attempt to impede parallel trade, either through the refusal to supply wholesalers who engage in exporting activities, or by applying a price policy that renders exports economically uninteresting.

Yet, recently the jurisprudence has been questioning this policy in the field of pharmaceuticals, inspired by the ambiguity of welfare effects of parallel trade professed by economic theory.

This Chapter reviews these developments traced above according to the following structure.

Section 1 sets the theoretical basis of the analysis, by recalling the economic rationale of IPRs – the stimulus to innovation – and explaining where and to what extent the clash with competition law arises. This analysis is applied to the pharmaceutical

sector, in order to understand how legal systems reconciled the generalised access to medicines and the incentive on companies to produce new drugs.

Section 2 reviews the early case law dealing with the use of IPRs that runs against the rules of the internal market, which led to the elaboration by EU Courts of the dichotomy 'existence-exercise' of IPRs and of the notion of 'specific subject matter'.

Section 3 continues the analysis by disentangling the jurisprudence that founded the principle of regional exhaustion of IPRs within the EU and examines all the cases that defined when trademarks and patents are exhausted according to the principles of EU law. A final section is devoted to the exhaustion of IPRs covering products that are first marketed outside the EU.

Section 4 specifically examines the case law dealing with the exercise of IPRs according to European competition law rules. In particular, the jurisprudence on the refusal to licence IPRs to competitors and the related 'essential facility doctrine' are discussed.

The principles elaborated by the analysed jurisprudence guided the legal treatment and the policy of favour pursued by the Commission and the EU Courts towards parallel trade. Section 5 is entirely devoted to the discussion of the case law that consolidated this approach.

Section 6 examines the *revirement* in the jurisprudence's attitude towards parallel trade, which took place around ten years ago.

Section 7 concludes.

1. The structure and the function of intellectual property rights

It is widely acknowledged among scholars that there exists a trade off between IPRs and free competition²¹⁹.

²¹⁹ Classical readings are: BAXTER, *Legal Restrictions on Exploitations of Patent Monopoly: An Economic Analysis*, 76 Yale L.J., 267 (1966); KAPLOW, *The Patent-Antitrust Intersection: A Reappraisal*, in Harv. L. Rev., 1984, no. 97, p. 1813; PRIEST, *What Economists Can Tell Lawyers About Intellectual Property: Comment on Cheung*, in Res. in L. & Econ., 1986, no. 8, p. 19; BOWMAN, *Patent and Antitrust Law: A Legal and Economics Appraisal*, 1973. More recently, we have the works of PTOFSKY, *Antitrust and Intellectual Property: Unresolved Issues at the Heart of the New Economy*, in Berkeley Tech. L.J., 2001, p. 535; NASCIBENE, *Diritto d'autore e abuso di posizione dominante: i rapporti (difficili) tra proprietà intellettuale e disciplina antitrust*, in Foro it., 2002, IV, 338; PARDOLESI, *Di regolazione antitrust e diritti di proprietà intellettuale*, in Mercato Concorrenza Regole, 2004, n. 1, p. 7 et seq. The *Antitrust Bulletin* and the *Minnesota Law Review* devoted monographic volumes to the issue in Fall 2002 and

German-speaking lawyers would speak of *Spannungsverhältnis* (relationship of tension) between the individual right to exclusively benefit from situations of competitive advantage in the market ('property')²²⁰, and the economic freedom of everybody to enter the market and operate in it at the same conditions ('liberty')²²¹.

The economic rationale of intellectual property rights protection rests on the non-rivalry feature typical of knowledge.

Non-rivalry has been described by Thomas Jefferson with the following words: *"If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of every one, and the receiver cannot dispossess himself of it. He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me."*²²²

The non-rivalry characteristics of knowledge-based products, like inventions, impedes the appropriability of the return on investment made by inventors. The possibility of everybody to enjoy and use at zero cost the information on which the product is based does not allow the inventor to recoup the money invested and

in Spring 2003 respectively. See also the Federal Trade Commission report entitled *To Promote Innovation: The Proper Balance of Competition Law and Policy*, released in October 2003.

²²⁰ Intellectual property rights, as a form of private property, are both internationally and nationally protected. Art. 15 (and in particular 15.3) of The International Covenant on Economic, Social and Cultural Rights (ICESCR) protects the right of individuals to enjoy the moral and material fruits of its inventions. The article recognizes "the right of everyone" both "to enjoy the benefits of scientific progress and its applications" and "to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." To achieve these goals, the Covenant mandates that States Parties undertake a series of steps. These include "those necessary for the conservation, the development and the diffusion of science and culture." More specifically, States Parties "undertake to respect the freedom indispensable for scientific research and creative activity." At a European level see Art. 345 TFEU, which states: "The Treaty shall in no way prejudice the rules in Member States governing the system of property ownership."

²²¹ Such general interest is protected at a European level by the provision set forth by Article 3 TEU and Article 3 TFEU, and in particular at Article 3(1)(b) TFEU, which establishes among the exclusive competences of the European Union "... (b) the establishing of the competition rules necessary for the functioning of the internal market". Articles 101 and 102 TFEU are the principal means to achieve such goal. In Italy the freedom of carry out an economic activity, but not the method of interfirm rivalry, as IRTI, *L'ordine giuridico del mercato*, 1998, pp. 47 *et seq.* recalls, is protected at a Constitutional level by Art. 41(1). The principle of free competition is protected from the antitrust Law n. 287/90.

²²² See the letter to Isaac McPherson dated Aug. 13, 1813. In the same letter, Thomas Jefferson also wrote that for these reasons "Inventions then cannot, in nature, be a subject of property". However, note that Jefferson disregarded the fact that knowledge has only some of the features of public goods: in fact, it is excludable, as long as it is not disclosed and remains under the control of the individual, or the firm, behind the discovery.

discourages innovation *ex ante*. That is why appropriability in a knowledge-based economy represents a concern for public policy.

IPRs have been generally identified as a valid policy instrument to overcome such a market failure. They give the inventor the exclusive right to sell his/her invention at a price above the marginal cost, and in this way the possibility to recover the investments made through a sufficient monetary reward. The prospect of these earnings provides an incentive mechanism that spurs innovation²²³.

The exclusionary nature of IPRs appears in contrast with the basic rules of the free market economy, where agents are free to enter the market and carry on economic activities and consumers get their preferred products and/or services at a cost equal to the marginal cost of the producer. These features, assumed to be the best way to serve the collective interest, are guaranteed by competition law.

'Property' and 'liberty', however, are not necessarily at odd. They are rather two sides of the same coin. Two faces, in a continuous dialectic relationship, of the principle of free economic initiative that guides and shapes the economic organization of Western countries²²⁴.

The attribution to individuals of a *ius excludendi alios* has, in fact, primarily a pro-competitive function: notwithstanding the monopolistic features, IPRs spur competition on innovation²²⁵. Patents, in particular, embody the Schumpeterian logic of "constructive destruction"²²⁶. As already indicated, the prospect of monopolistic returns deriving from

²²³ On the economic function of IPRs see, among legal scholars, UBERTAZZI, *Invenzione e innovazione*, 1978; BEIER, *The Significance of the Patent System for the Technical, Economic and Social Progress*, in IIC, 1980, p. 563; GUGLIELMETTI, *Rileggendo Einaudi: giustificazione e scopo della tutela brevettuale per le invenzioni industriali*, Studi Franceschelli, 1983. In the Law and Economics literature see the work of LANDES and POSNER, *The Economic structure of Intellectual Property Law*, 2003. For formalizations see ARROW, *Economic welfare and the allocation of resources for invention*, in NELSON, *The rate and direction of economic activities: economic and social factors*, 1962; NORDHAUS, *Invention, growth and welfare*, 1969. See *infra* Chapter IV for a deeper analysis of the economics of IPRs and further references.

²²⁴ See ASCARELLI, *Teoria della concorrenza e dei beni immateriali*, 1960, p. 41 *et seq.*; FRANCESCHELLI, *Contenuto e limiti del diritto industriale*, in Riv. Dir. Ind., 1952, I, p. 7; ID., *Valore attuale del principio di concorrenza e funzione concorrenziale degli istituti di diritto industriale*, in Riv. Dir. Ind., 1956, I, p. 28; GHIDINI, *Profili evolutivi del diritto industriale*, 2001, pp. 6 *et seq.*, all of them considering the institutions of industrial property as part of the theory of competition. Finally see PARDOLESI and GRANIERI, *Proprietà intellettuale e concorrenza: convergenza finalistica e liaisons dangereuses*, in Foro Italiano, 2003, no. 5, p. 193 *et seq.*

²²⁵ See ASCARELLI, *Teoria della concorrenza e dei beni immateriali*, cit., p. 41 *et seq.*; FRANCESCHELLI, *Trattato di diritto industriale*, 1960, ch. XLII; MARCHETTI, *Sull'esaurimento del brevetto di invenzione*, 1974, pp. 119-120; GHIDINI, *Profili evolutivi del diritto industriale*, cit., pp. 8-9.

²²⁶ The original notion of "creative destruction" is found in the writings of Mikhail Bakunin, Friedrich Nietzsche and in Werner Sombart's *Krieg und Kapitalismus* (War and Capitalism), 1913, p. 207, where he wrote: "again out of destruction a new spirit of creativity arises". The economist Joseph Schumpeter popularized

the exclusivity in the production and commercialisation of patented products induces firms to be pioneers in the market and invent better technologies and new products. Once the market is opened up, new profits expectations are available. This attracts the entry of competitors that developed alternative technologies and products that compete with the first one and eventually replace it.

This positive function, however, comes at a cost: the exclusionary nature of IPRs in fact produces the so-called *dead weight loss*. Although they do not necessarily imply the existence of a monopoly²²⁷, IPRs imply a restriction of competition. In the case of patents, from a “subjective perspective” such restriction is functional to grant the inventor a necessary reward that it is impossible to get in a competitive market (the so-called ‘differential profit’). But from an “objective perspective”, the restriction to competition also implies a restriction to economic opportunities available in the market for other economic agents²²⁸.

That is why IPRs constitute a legal (temporary) exception to the paradigm of competition specifically designed to stimulate innovative activity and economic progress, to the benefit of society²²⁹. Therefore, they are a policy tool intended to solve appropriability problems related to knowledge-based goods, rather than a form of real property²³⁰.

and used the term to describe the process of transformation that accompanies radical innovation. In Schumpeter’s vision of capitalism, innovative entry by entrepreneurs was the force that sustained long-term economic growth, even as it destroyed the value of established companies that enjoyed some degree of monopoly power. See SCHUMPETER, *Capitalism, Socialism and Democracy*, 1942. See further discussion in Section 2.1 of Chapter IV.

²²⁷ It should be noted that an IPR does not confer automatically monopoly power to its owner. The DOJ/FTC IP guidelines at Section 2.0 apply a general rule that market or monopoly power will not be presumed as arising from intellectual property. Some US courts, however, including in recent opinions, have held that in a tying case (as opposed to a monopolization case), if the tying product is patented, there is a rebuttable presumption of market power (which presumption would be the defendant’s burden to rebut). See *Independent Ink, Inc. v. Illinois Tool Works Inc.*, 396 F.3d 1342, 1344 (Fed. Cir. 2005). The same principle applies under EU competition law. See better *infra* Section 4 of this Chapter.

²²⁸ See MARCHETTI, *Sull’esaurimento del brevetto di invenzione*, 1974, pp. 98-99.

²²⁹ Art. 9 of Italian Constitution promotes the stimulus to innovation through scientific research. The latter, normally carried out through private economic activity, is, in turn, embodied in the principle of economic freedom set forth by Art. 41 of the Italian Constitution and of free competition set forth by the EU Treaty. See GHIDINI, *Profili evolutivi del diritto industriale*, cit., p. 8 and 9.

²³⁰ See LEMLEY, *Property, Intellectual Property and Free Riding*, in 83 *Texas Law Rev.*, 2004-2005, p. 1031 *et seq.*, strongly arguing against the idea that IPRs constitute a form of real property. In the same spirit see previous works of scholars reporting a “misappropriation explosion” and the proliferation of overprotectionist trends misinterpreting the original function of IPRs: GORDON, *On Owning Information: Intellectual Property and the Restitutionary Impulse*, in *Va. L. Rev.*, 1992, p. 149; REICHMAN, *Beyond the Historical Lines of Demarcation*:

The limitation in time and scope provides an important device to coordinate the intersection between competition and IPRs. In particular, with patents short run deadweight losses due to monopoly power are offset in the long run by the gains generated by competition, in terms of lower prices, after the expiration. In this way, the legislator found an equilibrium point between the individual interest of innovators and the general interest to the safeguard of competitive conditions of the market²³¹.

1.1 The trade off in the pharmaceutical sector

The pharmaceutical sector represents an area where the portrayed dialectic relationship between competition and IPRs assumes additional features to those present in other markets. In this field the stimulus of innovation through the attribution of IPRs serves a general interest of supreme importance: the protection of health, recognised as everybody's right by the Universal Declaration of Human Rights²³², by the Charter of Fundamental Rights of the European Union²³³, and as a constitutional right, or an *objectif à valeur constitutionnel*, at national level²³⁴.

Competition Law, Intellectual Property Rights, and International Trade after the Gatt's Uruguay Round, in *Brooklin J. of Int. L.*, 1993, p. 75; GHIDINI, *Prospettive "protezioniste" nel diritto industriale*, in *Riv. Dir. Ind.*, 1995, I, p. 73.

²³¹ Patents are, in fact, considered a second best solution to the trade off between IPRs and competition. A first best solution, where a socially desirable level of innovation is associated to the absence of market power and to a global diffusion of goods at accessible prices, would be given by public procurement. Nevertheless, concerns related to the possibility of regulatory capture, moral hazard and asymmetry of information with respect to real costs and benefits of R&D investments, impose to delegate innovation activity to individual agents and to set up a patent system.

²³² Art. 25 of the UDHR states: "Everyone has the right to a standard of living adequate for the health and wellbeing of himself and his family...". The Preamble to the WHO constitution also affirms that it is one of the fundamental rights of every human being to enjoy "the highest attainable standard of health". Inherent in the right to health is the right to the underlying conditions of health as well as medical care. The United Nations expanded upon the "Right to Health" in Article 12 of the International Covenant in Economic, Social and Cultural Rights in 1966. Not only did this document guarantee the "right of everyone to the enjoyment of the highest attainable standard of health", but it also specifically called for the "provision for the reductions of... infant mortality and for the healthy development of the child; the improvement of all aspects of environmental and industrial hygiene; the prevention, treatment and control of epidemic, endemic, occupational, and other diseases; and the creation of conditions which could assure to all medical service and medical attention in the event of sickness."

²³³ Art. 35 of the ECHR states: "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities." The principles set out in this Article are based on Art. 168 TFEU, which states: "Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health. Also see Articles 11 and 13 of the European Social Charter available at <http://conventions.coe.int/Treaty/en/Treaties/Html/163.htm>.

²³⁴ Art. 32 of the Italian Constitution states: "La Repubblica tutela la salute come fondamentale diritto dell'individuo e interesse della collettività, e garantisce cure gratuite agli indigenti." Recital 11 of the Préambule de la Constitution Française of 1946 states: "La Nation garantit à tous, notamment à l'enfant, à la mère et aux vieux

A generalised access to medicines is an essential tool to guarantee the right to health to everybody. It seems, therefore, that the grant of a patent over a pharmaceutical specialty that allows the patent owner to charge high prices for its products would obstacle such a policy objective. At the same time, without the possibility to patent their discoveries, private parties would lose the incentive to invest in research to find new molecules in the first place.

The framework just sketched indicates that in this sector the paradigm of 'consumer welfare' necessarily means 'affordable medicines' and 'new and better medicines' for the improvement of quality of life of individuals, at the same time. Nevertheless, while the two policy objectives appear necessarily complementary, it is undeniable that the means to achieve them are conflicting and need to be balanced.

1.2 *Striking the balance: the Italian case*

A meaningful example of the balancing exercise operated by the legal community to solve this tension is given by the history of patentability of medicinal specialties in Italy.

Initially the Law no. 872 of 12 March 1855 and then the *Legge sulle Invenzioni*, the Royal Decree no. 1127 of 29 June 1939, prohibited the patentability of pharmaceuticals in Italy²³⁵. The rationale of the prohibition was inspired by the concerns related to the creation of a monopoly over goods essential for public health. Pharmaceuticals were considered vital products for individuals and for this reason, everybody, also poor people, should have had access to them. On the contrary, the exclusivity right that pharmaceutical firms would have enjoyed through a patent over their products would have brought an increase in prices and a decrease in the quantity sold in the market, in contrast with the policy objective to grant universal access to health care²³⁶.

The unpatentability of medicinal products, however, would have allowed any competitor of the inventor to freely copy the formula of new invented molecules without

travailleurs, la protection de la santé, la sécurité matérielle, le repos et les loisirs". Articles 43 of the Spanish Constitution states: "*Se reconoce el derecho a la protección de la salud*". Even where the right to health is not considered a subjective right (for instance, in France, in South Africa, in Poland and in Germany), it is anyway regarded as a *objective à valeur constitutionnelle*, which may pose limits on other constitutional rights, like the right to private property.

²³⁵ Art. 14 of the cited Royal Decree established that "*non possono costituire oggetto di brevetto i medicamenti di qualsiasi genere, né i processi per la loro produzione*".

²³⁶ FRANCESCHELLI, Ciarlatani, *specialisti e segretisti*, in *Problemi attuali del Diritto Industriale*, 1977, p. 375.

incurring in substantial sunk costs and to market it a competitive price. It has been argued that the impossibility of recover investments discouraged innovation and the sector remained dominated by small players unable to reach a critical mass, with respect other companies in other European countries: few Italian firms destined their financial resources to the discovery of new products, while the majority of companies (of small size) was mainly basing its activity on the imitation of products discovered and patented elsewhere²³⁷.

The Italian Constitutional Court in 1978 declared the prohibition to patent pharmaceuticals contrary to the Constitution²³⁸. Among other things, such prohibition was contrary to Article 9 of the Italian Constitution, which explicitly promotes scientific development and research.

According to the Court, Article 32, par. 1, of the Constitution could not to be interpreted as if the protection of public health would always automatically prevail over the value of scientific research. On the contrary, the latter was seen as the engine of the progress in the pharmaceutical sector and a means to improve public health through new medicines.

²³⁷ PALLINI, *Invenzioni Farmaceutiche*, p. 427. However, see the work of BOLDRINE and LEVINE, *Against Intellectual Monopoly*, Chapter 9: *The Pharmaceutical Industry*, available at <http://levine.sscnet.ucla.edu/papers/imbookfinal09.pdf>, where the authors support the idea that the productivity of the Italian pharmaceutical industry was not undermined by the impossibility to patent pharmaceutical products. In particular, they affirm “the possibility of freely imitating products patented elsewhere favoured the creation of a large number of Italian imitative firms, which improved upon existing products and, at the same time, allowed for their diffusion at much lower prices. In spite of this, the forty largest Italian firms (out of about 500, until the late 1970s) did not simply imitate but developed their own products and innovated extensively, either by using existing products as ingredients (25%) or by using products which were not patentable or with expired patents (31%)”. During the period 1961-1980 a total of 1282 new active chemical compounds was discovered around the world. Of these, a total of 119 came from Italy (9.28%). During the period 1980-1983 a total of 108 compounds were discovered. Of these, 8 came from Italy (7.5%). SCHERER, *A Note on Global Welfare in Pharmaceutical Patenting*, in *The World Economy*, no. 27(7), 2004, p. 122, confirms this by saying “...research by Sandy Weisburst and mentored by me showed, for example, that Italy, with a vibrant generic drug industry, did not achieve any significant increase in the discovery of innovative drugs during the first decade after the Italian Supreme Court mandated the issue of pharmaceutical product patents.” Cf. with CAMPANELLA, *La politica dei farmaci in Italia con particolare riferimento ai problemi della ricerca scientifica*, in QUERINI, *La concentrazione industriale. Problemi teorici e considerazioni empiriche con particolare riferimento all'industria farmaceutica*, 1979; FERRAGUTO, LUCIONI and ONIDA, *L'industria farmaceutica italiana. L'innovazione tecnologica*, 1983.

²³⁸ ITALIAN CONSTITUTIONAL COURT, judgement n. 20 of 20 March 1978, in case *Dr. Madaus & Co. ed altri contro Ufficio Centrale Brevetti*. The Court also maintained that art. 14 of the Royal Decree was contrary to the principle of equality set forth by art. 3 of the Italian Constitution, because “pone in condizione di svantaggio le imprese che organizzano la ricerca stessa rispetto a quelle che si avvalgono, puramente e semplicemente, della possibilità di imitare le invenzioni altrui, realizzate in Italia e all'estero”. See comments on the judgement from UBERTAZZI and GROPPALI, in *Rass. Dir. Farm.*, 1978, p. 301-317.

The Italian Constitutional Court acknowledged that in this context patents play an essential function, as they keep alive companies' incentive to invest in innovation, to the benefit of society. For this reason, the Court considered that the best way to serve the collective interest in the field of pharmaceuticals was to allow the exercise of individual exclusive rights²³⁹.

At the same time, the Court admitted that the need to discover new medicines and therapies that improve quality and length of life in society is necessarily coupled with the duty for public bodies to make them available and affordable to their citizens.

In order to comply with the universality principle, the Court stated that the generalised access to medicines would have been ensured to citizens through public intervention on prices, especially through the tools of price controls and compulsory license²⁴⁰. The last two means in particular were, according to the Court, essential to grant the appropriate quantity of drugs to satisfy domestic demand and impede an excessive increase in price²⁴¹.

In sum, from the decision of the Court it can be inferred that public health should be protected and guaranteed through the necessary combination of two different policies: on the one hand, patents should be enforced to foster pharmaceutical innovation; on the other hand, regulation of prices should cap prices to a certain extent, in order to grant a generalised access to the new medicines.

1.3 'Law in book' v. 'law in action'

From the analysis conducted in the previous sections, one can safely affirm that the IPRs and competition are complementary tools, which *latu sensu* pursue the common goal of economic efficiency²⁴². And indeed, IPRs provide an equilibrium to the intersection between 'property' and 'liberty'.

²³⁹ MASSIMINO, *Brevetto di base e Certificato Protettivo Complementare per le specialità medicinali: la conferma di un bilanciamento*, in *Dir. Pub. Com. Eur.*, 2000, no. 1, p. 306.

²⁴⁰ FRANCESCHELLI, *Ciarlatani, speciali*, cit., p. 496-498.

²⁴¹ See comments on the judgement from UBERTAZZI and GROPPALI, cit., p. 301-317. RISTUCCIA, *Il farmaco tra autorizzazioni amministrative e privative industriali*, in *Riv. Dir. Civ.*, no. 1, 1993, p. 91. For later comments on the issue, see PARDOLESI and GRANIERI, *Alcune considerazioni sui rapporti tra proprietà intellettuale e concorrenza nel settore farmaceutico*, in *Dir. ind.*, 2002, p. 379.

²⁴² Confirmation of this view comes from the EU Commission Guidelines on the Application of Article 81 EC to Technology Transfer Agreements ("TTBE Guidelines"), no. 7, where it is affirmed, "both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources". Similarly see US jurisprudence: in *Atari Games v. Nintendo*, 897 F.2d 1572 (Fed. Cir. 1990), the Court opined that "When [a] patented product is so successful that it creates its own economic market or consumes a large section of an existing

How this equilibrium takes place depends on how IPRs are exercised.

For instance, the potential anti-competitive effects of patents are evident: depending on the characteristics of the market, they can facilitate the consolidation of a dominant position or even a monopoly.

The described solution of coordination offered by IPRs, thus, remains in the domain of the 'law in book'. The concrete interplay between IPRs and competition law, i.e. what is 'law in action', puts the interpreter in a situation of constant balancing of conflicting interests.

Parallel trade of pharmaceuticals represents a meaningful example of fleeting boundaries in the intersection between free competition and IPRs, as well as of the tension existing between the need to grant wide access to medicines for patients and the need to reward pharmaceutical companies for their creativity efforts.

Such a form of arbitrage, being a form of cross border trade, represents one of the most noteworthy examples of the opportunities available to economic agents in an integrated economic area. On the contrary, IPRs, which are characterised by territoriality, have an obvious propensity to interfere with the principle of free movement of goods driving the integration of the internal market.

In addition, parallel trade constitutes a form of *intra-brand* competition capable of offering a cheaper choice to consumers, i.e. bringing allocative efficiency. But at the same time, by exerting pressure on the price of original products, it can reduce the IPR

market, the aims and objectives of patent and antitrust laws may seem, at first glance, wholly at odds. However, the two bodies of law are actually complementary, as both are aimed at encouraging innovation, industry and competition". In the literature there is not a consensus about what is the ultimate goal of competition law. In US he thinking of the Chicago School was very much influential in instilling the idea such goal is efficiency intended as consumer welfare. See MURIS, *Competition and Intellectual Property Policy: The Way Ahead* (announcing the jointly-sponsored FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-based Economy), who affirms that *"The tensions between the doctrines tend to obscure the fact that, properly understood, IP law and antitrust law both seek to promote innovation and enhance consumer welfare"*. BRODLEY, *The Economic Goals of Antitrust: Efficiency, Consumer Welfare, and Technological Progress*, cit., p. 1023, affirms that competition law, besides being animated by social and political motivations, pursues the three objective of allocative, productive and dynamic efficiency; MOTTA, *Competition Policy, Theory and Practice*, 2004, p. 30, believes that competition policy is *"the set of policies and laws which ensure that competition in the marketplace is not restricted in a way as to reduce economic welfare"*. Partially *contra* to this opinion see BRUNNEL, *Appropriability in Antitrust: how much is enough?*, in 69 *Antitrust Law Journal*, 2001, p. 42, where he affirms that *"This is not to say that dynamic efficiency considerations are unimportant or should be ignored [...] But the limitations of dynamic efficiency analysis should be recognized, and the analysis should not obscure the "non-economic" values that are inherent in antitrust policymaking"*. It is known that this thinking has been embraced only partially in the EU, where competition law was shaped by the ordoliberal School of thought, which based its view on the economic freedom of market actors. Also, EU competition law bears market integration overtones that render it unique.

owner's profits. From this point of view, the possibility to grant wider access to consumers through affordable prices for products may clash with the need to grant inventors the appropriability of their investments, in order to provide them an incentive to discover newer and better products.

The acknowledgement of the existence of a certain degree of tension between IPRs and competition triggered a threefold action from European Institutions aimed at striking the balance between the two bodies of law:

- a) the Commission started from the early '60s to provide privates with guidelines to the appropriate use of IPRs through communications and regulations and the application of Articles 101 and 102 TFEU²⁴³;
- b) the Council and the Parliament carried on, on the basis of the proposals of the Commission, an important program of harmonisation national laws on IPRs²⁴⁴;
- c) the EU Court have been constantly engaged in a long and progressive activity of interpretation, in order to establish what is the permitted use of IPRs under the rules of the Treaty.

The scope of this Chapter is to analyse the third action mentioned.

²⁴³ See the Notice on patent licensing agreement, OJ n. 139, 24 December 1962, p. 2922, where the EU Commission applied the criterion of the "inherent restrictions" and exempted them from the application of Art. 101(1) TFEU. Such criterion has been revised and the Notice repealed with the EU Commission Regulation (EC) No. 2349/84 of 23 July 1984, with which the Commission started embracing the idea that there are exclusivity clauses linked to the patent rights that may fall within the scope of such provision. The position of the Commission on the issue has been refined with the Regulation No 240/96 of 31 January 1996 and with the Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 85(3) of the Treaty to certain categories of technology transfer agreements. At the same time, the Commission released the Guidelines for the application of Art. 81 EC to technology transfer agreements. See also *infra* Section 4 of this Chapter.

²⁴⁴ With regards to patents, see the European Convention on patents signed in Munich in 1973 and in force from 1978, which established a centralised system of notification that allowed the patentee to register its patent contemporarily in all adhering States. See the Convention on the Community Patent signed in Luxembourg 1975, which establishes the possibility to obtain a patent valid in all Member States. The Convention, however, never entered into force. With regards to trademarks, see the Council Directive n. 89/104/EC of the 21 December 1988, containing different aspects of the trademark disciplines, e.g. the exhaustion (see fn 276 below); the Council Regulation no. 40/49 of the 20 December 1993 on the Community trademark. With regards to copyrights, see the Council Directive no. 93/98/EC of the 29 October 1993 harmonising the duration of copyright and other connected rights.

2. The relationship between intellectual property rights and competition law under the EU Treaty

Under EU law, the balance between competition policy goals and IPRs has been shaped by the architecture of the EU Treaty, as interpreted by the EU Courts²⁴⁵. The consolidation of these principles into an organic and systematic set of rules *de facto* provides a second layer of regulation of IPRs²⁴⁶. The Court, in fact, always maintained that the exercise of intellectual property right must in principle be compatible with the rules of free movement of goods (Artt. 34-36 TFEU), as well as with those regarding competition law (Artt. 101-102 TFEU).

As seen in the previous Chapter²⁴⁷, in the field of free of movement of goods, the Treaty itself provides for an explicit balance mechanism.

The prohibition of quantitative restrictions to trade, and of any equivalent measures to such restrictions, is accompanied by the provisions set forth by Article 36 TFEU, which states that ‘the protection of industrial and commercial property’²⁴⁸ can justify impediments to import or export among Member States, as long as it does not constitute a ‘means of arbitrary discrimination or a disguised restriction on trade’.

Despite the existence of this framework, the rules on the free movement of goods ‘articulate a conflict between two competing interests’²⁴⁹, namely the goal of free trade in the establishment of the common market and the need to safeguard the national interest in respect of industrial property rights. Whereas the former is concerned with the fusion of national markets into one single market, the latter is inherently territorial²⁵⁰. This

²⁴⁵ See the opinion of AG Jacobs in case C-10/89 HAG GF (see better *infra*), affirming at para. 10 that the Treaty does not lay down any exhaustive code of rules, but ‘[i]t merely provides a skeleton. The task of putting flesh on the bones falls to the Community legislature and to the Court of Justice’.

²⁴⁶ See ANDERMAN, *The interface between intellectual property rights and competition policy*, 1998, p. 3. *Contra* see REINDL, *Intellectual Property and Intra-Community Trade*, in *Fordham Corp. Law Inst.*, 1996, p. 453; GOVAERE, *The Use and Abuse of Intellectual Property Rights in EC Law*, 1996, who maintain that IPRs and EU competition law should be viewed as of equal weight under EU law.

²⁴⁷ See *infra* Section 4 of Chapter I.

²⁴⁸ Such provision contained in Art. 36 TFEU should be read in conjunction with Art. 345 TFEU, which reads as follows: “This Treaty shall in no way prejudice the rules in Member States governing the system of property ownership.” Art. 345 TFEU is designed to protect the national systems of property ownership. It prevents Community law from interfering with the status or ownership of industrial and commercial property rights.

²⁴⁹ See the opinion of AG Jacobs in HAG GF, at para. 9.

²⁵⁰ See COPINGER and SKONE, *Copyright*, 1980, p. 1016, saying: “The fact that an industrial property right is the creature of the national laws of the State granting the right necessarily places limits on the territory within which such right is effective. This has been referred to as the ‘territoriality principle’ of industrial property rights, ... but it is really no more than a necessary reflection of the territorial limit to the sovereignty of the State concerned.”

triggered an intense work of reconciliation of these two conflicting forces co-existing under the Treaty from the ECJ.

With regards to competition law rules, the Treaty contains no comparable balance. Therefore, the interplay between competition law and intellectual property rights has been entirely built on the interpretative work of the EU Courts, on a case-by-case basis.

Such balancing has been made in light of the principle set forth by the former Article 3(g) EC (repealed by the Lisbon Treaty), which required the institution of a system to ensure that competition in the internal market is not distorted, where Articles 81 and 82 EC (now Articles 101 and 102 TFEU) were (and still are even under the new Treaty) the means available to achieve such goal²⁵¹, as well as by largely borrowing from the principles developed by the Court in the field of free movement of goods.

2.1 In search of a compromise (I): existence v. exercise of an IPR

The foundations of the current form of reconciliation between competition law and IPRs trace back to the landmark case *Consten and Grundig*²⁵², where a German manufacturer used its trademark, registered also in France by its exclusive distributor, to stop exports by an unauthorised distributor from Germany into France. The Commission condemned the practice as contrary to Article 101(1) TFEU, because it was giving absolute protection from imports to the authorised distributor, and therefore it impeded goods protected by the trademark to freely circulate in the EEA.

The defendant argued that the importation of the good protected by trademark constituted a counterfeit, since only the authorised distributor was entitled to use it. The defendants responded that such interpretation of the Treaty was contrary to Articles 34 and 345 TFEU, because it impeded the IPR owner to benefit of a right whose existence was granted by national law. However, the Commission responded that the use of the trademark done by defendants was going beyond its function for which it was originally

²⁵¹ Art. 101 TFEU voids “all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market”. Art. 102 TFEU prohibits “any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States.”

²⁵² ECJ, 13 July 1966, in joint cases C-56/64 e C-58/64 *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*.

granted, i.e. guaranteeing the origin of the good, because it was aimed at protecting the French market from competition²⁵³.

The tension between national industrial policies and EU policies aimed at constructing a single market through competition and free trade was then evident.

The way the ECJ stroke the balance is well known: the Court observed that there exists a fundamental distinction between the *existence* and the *exercise* of an IPR²⁵⁴. EU law does not interfere with the *existence* granted at a national level of an IPR but only limits its *exercise* when this runs contrary to the Treaty's provisions. Articles 34 and 345 EC, in the view of the Court, cannot limit the scope of competition rules and thus do not impede that the exercise of rights granted at national level is scrutinised under the principles of EU competition law.

It follows that the exercise of the exclusive right can fall under the prohibition set out by the Treaty, for instance, when, by preventing imports from other Member States, it is a means to partition the common market.

In the specific case, the defendant was the owner of a valid right nationally granted, but the exercise of such right was linked to an agreement that could have

²⁵³ See the EU Commission decision of 23 September 1964 IV-A/00004-03344 *Grundig-Consten*, p. 2547 and 2548.

²⁵⁴ See KORAÏ, *Dividing the Common Market through National Industrial Property Rights*, in *MLR*, 1972, no. 32, p. 634, at 636, affirming that the distinction between the existence and the exercise of an intellectual property right is a tenuous one, since the way in which a property right is exercised is the practical expression of its existence; CORNISH, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 1989, p. 21, where he states that "[...] these definitions have the appearance of being formulated only in the wake of a policy decision to give preference to EEC policies beyond a certain point. All this may seem an exercise in legal obscurantism, but the basic intent is not hard to grasp: intellectual property rights are properly exercised when used against goods that come from independent competitors in trade; but they are not to be used against the movement from one Member State to another of goods initially connected with the right owner." Similarly JOLIET, *Patented Articles and the Free Movement of Goods within the EEC*, in *Current Legal Problems*, 1975, no. 28, p. 15, at 23-24; and AG Fennelly in his opinion in the Joined Cases C-267 and 268/95, *Merck & Co. Inc., Merck Sharp & Dohme Ltd and Merck Sharp & Dohme International Services BV v Primicrovum Ltd, Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd and Beecham Group plc v Europharm of Worthing Ltd*. Merck (ruling of the ECJ, 5 December 1996), at para. 97: "The distinction between the 'existence' and the 'exercise' of rights can, at times, be quite unreal; it has not been referred to in recent case-law [...] and may now, at least in so far as the interpretation of Articles 30 to 36 of the Treaty is concerned, be discarded." FLORIDIA and LAMANDINI, *Privative Industriali e artt. 30-36 e 86 del Trattato: la Corte di Giustizia può risolvere la vexata quaestio dei pezzi di ricambio*, in *Contratto e Impresa/Europa*, 1998, p. 144 et seq., suggest that the distinction between 'existence' and 'exercise' of an IPR was functional to the national character of IPR law. The Court was therefore (temporarily) entrusting Member States of the definition of the requirements necessary to grant the existence of IPRs, confident of an upcoming (but never realised) harmonisation. However, the authors believe that the distinction may have lost meaning, given the progressive trend of determining the existence of IPRs at Community level (see, for instance, the Supplementary Certificate Protection established by Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products).

violated Article 101(1) TFEU²⁵⁵. In particular, the defendant's behaviour frustrated the rules of competition law and prevented intrastate trade through the use of its trademark right. Permitting that would have reduced the Treaty to empty words²⁵⁶.

In practice the Court singled out three categories in the interface between EU law and IPRs:

1. *Existence*, whose conditions remain competence of Member States (as there is no competition interest in how Member States grant IPRs)²⁵⁷;
2. *Permitted exercise*, and,
3. *Prohibited exercise*, which are both determined by EU competition law and free movement of goods.

With this categorization, the negative interference between competition law and IPRs did not take place, at least in relation to the existence and to the permitted exercise.

Whilst this conceptualisation represented a nice practical solution to the presented trade off, still it does not consider that any exercise of an IPR can potentially go against competition rules, given that by definition the bundle of rights embedded into it restricts competition²⁵⁸.

The Court in *Parke Davis* grasped this problem and affirmed that "*a patent taken by itself and independently of any agreement of which it may be subject... exhibits none of the elements of contract or concerted practice required by art. 85(1). Nevertheless it is possible that the provisions of this article may apply if the use of one or more patents, in concert between undertakings, should lead to the creation of a situation which may come within the concepts of agreements between undertakings, decision of associations of undertakings or concerted practices within the meaning of article 85(1).*"²⁵⁹

Still, the Court reaffirmed the above-mentioned distinction between existence and exercise of an IPR, by saying that a patent is merely the expression of a legal status

²⁵⁵ See *Consten and Grundig*, pp. 522-523.

²⁵⁶ The Court found that neither Art. 36 TFEU or Art. 345 TFEU could operate to exclude 'any influence whatever of Community law on the exercise of national intellectual property rights'.

²⁵⁷ See ECJ, 6 April 1995, Joined Cases C-214/91 P and C-242/91 P *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v. Commission of the European Communities* (also known as '*Magill*'), where the Court affirmed that 'in the absence of Community standardisation or harmonisation of laws, determination the conditions and procedures for granting protection of an intellectual property right is a matter for international rules'.

²⁵⁸ See PAPPALARDO, *Il Diritto Comunitario della Concorrenza. Profili Sostanziali*, 2007, p. 745.

²⁵⁹ See ECJ, 29 February 1968, in case C-24/67, *Parke Davis and Co. v. Probel*, where the Court decided that a Dutch patent could be used to prevent the import to Holland of drugs put on the market in Italy, where no patent protection was possible. In particular, see para. 72.

granted by Member States, whose '*normal exercise*' shall not interfere with the rules set forth in the Treaty²⁶⁰.

But what is the '*normal exercise*' of an IPR?

The ECJ inferred such concept from the interpretation of Article 36 TFEU.

In *Sirena*²⁶¹, the ECJ affirmed that, in line with the first paragraph of this provision, agreements that strictly pertain to the IPRs, i.e. they contain clauses that are necessary for their existence, are excluded from the application of the principle of free circulation of goods (as well as of competition rules²⁶²). Such immunity, however, does not apply when the clauses constitute a means for discrimination or dissimulated restraints to trade among Member States, as the second part of Article 36 TFEU states. Similarly, agreements that contain restrictions to trade or to competition, which are not necessary for the existence of IPRs are immediately caught by this provision²⁶³.

In other words, Article 36 TFEU admits derogations from the rules of the internal market only to the extent that such exceptions are justified for the purpose of safeguarding the rights that constitute the core of the IPR. From this, it follows that the normal exercise of an IPR encompasses those exclusivity rights necessary to realise the *essential function* for which the right has been conferred, or, as it will be defined later, its *specific subject matter* (see *infra*).

For instance, the use of an IPR that imposes *additional restrictive effects* on competition to those already inherent to the IPR, which are realised by the owner through the exploitation of his market power (like leveraging its dominant position from a market to another one) may constitute a prohibited exercise of an IPR and for this reason may be subject to antitrust scrutiny.

²⁶⁰ See *Parke Davis* and cf. with ECJ, 14 July 1981, in case C-187/80, *Merck & Co. Inc. v Stephar BV and Petrus Stephanus Exler*: the elements of the case were essentially the same, except for the fact that it was the Dutch patentee who had put the drugs onto the market in Italy. It was held that it was not permissible to use a patent to prevent importation from Italy in this circumstance.

²⁶¹ See ECJ, 18 February 1971, in case C-40/70, *Sirena S.r.l. v Eda S.r.l. and others*. An Italian trademark owner brought action against the German owner of the same trademark, because the former was exporting into Italy. The Court envisaged the existence of an agreement between the two, in order to apply Art. 101(1) TFEU and condemn the attempt to stop export from the Italian trademark owner.

²⁶² The Court explicitly said that although Art. 36 TFEU belongs to the dispositions related to restrictions to trade among Member States, it is based on a principle that is applicable to competition law rules as well, in the sense that even if IPRs attributed by the legislation of a Member States are not included in Articles 101 and 102 TFEU, they can always fall within the scope of such provisions. See *Sirena*, p. 69.

²⁶³ See *Sirena*, p. 69.

2.2 *In search of a compromise (II): the 'specific subject matter'*

In the first phase of the jurisprudential stream dealing with the tension between national industrial policies and EU goals, the ECJ saw in the competition law rules a means to remove obstacles to the integration of the internal market.

Such approach has been subject to criticism. In *Consten and Grundig*, the Court saw an agreement between Consten and Grundig in the joint registration of the trademark *Gint* in France. However, the defendants claimed that the lamented negative effect on competition derived not from an agreement, but from the existence of an IPR that conferred an exclusive right pursuant national law²⁶⁴.

In *Sirena*, the judge envisaged the existence of an agreement where its elements were not clearly proved. In fact, the parties acquired the same trademark in a different period, and no economic or financial connection existed between them. The Court, nevertheless, affirmed that the existence of the agreement resided in the contract signed by the importer to purchase the trademark. This, together with the negative effect on intrastate trade, was considered sufficient for the application of the provision.

For this reason, it has been argued that the Court had been pursuing the policy objective of common market integration, through a non-orthodox application of competition rules²⁶⁵. At the same time, the non-application of competition rules to those cases would have created a gap that impeded to condemn practices that *de facto* ran contrary to the objectives of the Treaty.

This loophole in the system has been filled in by the Court through the recourse to the rules on free movement of goods.

Already in *Parke Davis*, the Court also touched upon the real issue behind the whole problem, when affirmed that '*the national character of the protection of industrial property and the variations between the different legislative systems on this subject are capable of creating obstacles both to the free movement of the patented products and to competition within the Common Market*'²⁶⁶.

²⁶⁴ See *Consten and Grundig*, p. 522. See PAPPALARDO, *Il Diritto Comunitario della Concorrenza*, cit., p. 736.

²⁶⁵ Among many see PAPPALARDO, *Il Diritto Comunitario della Concorrenza*, cit., p. 746. See *Sirena*, p. 82.

²⁶⁶ See *Parke Davis*, pars. 71.

In *Deutsche Grammophon*²⁶⁷, a German undertaking manufacturing owner of a copyright on sound recordings used its exclusive right of distribution to prohibit the import from France into Germany of sound recordings which had itself supplied to its French subsidiary.

The Court, drawing especially from *Sirena*, recalled that while the *existence* of an IPR is protected under both Articles 36 and 345 TFEU, the *exercise* of an IPR may violate the rules contained in the Treaty. The reasoning goes, when such exercise runs against the free movement of goods, it should be verified whether there are grounds for justifications under Article 36 TFEU. The latter, being an exception to the paradigm of free movement, should apply as long as this derogation is indispensable to protect the rights that constitute the *specific subject matter* of the IPR. Therefore, any exercise of IPRs that contrasts the rule of free circulation of goods is justified only when it is functional to the realisation of the IPR's *specific subject matter*. Any other use of IPRs that exceed their *specific subject matter* is considered unjustified under the rules on free movement and prohibited²⁶⁸.

The next issue is to understand what is a '*subject matter*'²⁶⁹.

The specific subject matter of a trademark has been defined by the ECJ as '*the guarantee that the owner of the trademark has the exclusive right to use that trademark, for the purpose of putting products protected by the trademark into circulation for the first time, and is therefore intended to protect him against competitors wishing to take advantage of the status and reputation of the trademark by selling products illegally bearing the trademark*'.

Further the Court said that the essential function of a trademark is to: '*... guarantee the identity of the origin of the trademarked product to the consumer or ultimate user, by enabling him without any possibility of confusion to distinguish that product from products which have another origin. This guarantee of origin means that the consumer or ultimate use can be certain that a trademarked product which is sold to him has not been subject at a previous stage of marketing to interference by a third person, without the authorisation of the proprietor of*

²⁶⁷ See ECJ, 8 June 1971, C-78/70 *Deutsche Grammophon GmbH v. Metro-SB-Großmärkte GmbH & Co. KG*.

²⁶⁸ On the basis of this qualification, in his opinion on the case *Magill*, the AG Gulman inferred that the concept of '*existence*' is not confined to the conditions that have to be fulfilled to qualify for the grant of an IPR, but it encompasses both the notion of '*normal exercise*', '*permitted exercise*' and '*specific subject matter*'. However, see ANDERMAN, *EC Competition Law and Intellectual Property Rights*, 1998, p. 12, noting that the application of the two concepts often generated confusion.

²⁶⁹ CORNISH, *Intellectual Property: Patents, Copyright, Trade Marks*, cit., p. 43.

the trademark, such as to affect the original condition of the product. The right attributed to the proprietor of preventing any use of the trademark which is likely to impair the guarantee of origin so understood is therefore part of the specific subject-matter of the trademark right'²⁷⁰.

With regards to patents, the Court affirmed that the specific subject matter is the 'guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licenses to third parties, as well as the right to oppose infringements'²⁷¹.

The subject matter of copyrights has been defined much later by the ECJ, which in *Volvo* stated "the right of the proprietor of a protected design to prevent third parties from manufacturing and selling or importing, without its consent, products incorporating the design constitutes the very subject-matter of his exclusive right"²⁷².

The Court clarified in several instances that the use of the IPR from third parties wishing to export goods protected by such IPR did not deprive it of its *specific subject matter*, as it was defined by the ECJ, and therefore it did not infringe the exclusivity right of the proprietor. On the contrary, the use of the IPR from the owner in order to prevent parallel trade was considered beyond the protection of the *specific subject matter* of the IPR and, because it contributed to the isolation of national markets, contrary to the rules on free movement of goods.

According to the revisited approach taken by the ECJ, the owner of an IPR conferred by national law, who impeded other firms to commercialise the good protected by that exclusive right in a given Member State, was *contravening the rules on free movement of goods*, and not competition law rules. But, the negative effect on competition and on free movement of goods was not to be attributed to individual firms

²⁷⁰ See ECJ, 23 May 1978, in case C-102/77, *Hoffmann-La Roche et Co. AG v. Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse MBH*, para. 7. Cf. GENDREAU, *An Intellectual Property Renaissance in European Community Law*, in IRISH, STEWART and TAWFIK, *International Trade and Intellectual Property*, 1994, p. 51.

²⁷¹ See ECJ, 31 October 1974, in case C-15/74, *Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc.*, p. 1162, n. 9. See also the definition provided by AG Trabucchi in his opinion on the case at para. 4: "The real essence of the protection conferred on the patent owner is the exclusive right to manufacture and market the patented product, given to compensate him as the inventor of a process and bring him a financial reward for his efforts and the commercial risks he runs, and it is recognized on a purely temporary basis...". See SNELL, *Free Movement of Pharmaceutical Products: An Overdose of Cheap Drugs?*, in EBLR, 2003, no. 29(2), p. 513.

²⁷² See ECJ, 5 October 1988, in case C-238/87 *AB Volvo v Erik Veng (UK) Ltd*, para. 8.

that were exercising their exclusive right by virtue of the law of Member States, but to Member States themselves²⁷³.

Such approach has been confirmed by the ECJ in *Hag I*²⁷⁴, where, similarly to *Sirena*, no agreement between the two owners of the same IPR in two different Member States existed. In that occasion the judges explicitly refused the previous approach by the ECJ and affirmed that in absence of an agreement to be scrutinized under Article 101(1) TFEU, the case was to be examined in the light of the rules on free movement of goods. At this regard, the judge maintained that the exclusivity right enjoyed by an IPR owner does not entitle him to stop distribution from non-authorized firms in a given Member State of goods having the same origin, i.e. produced by the IPR owner under the same trademark in another Member State²⁷⁵.

From this judgement onwards, the EU jurisprudence on the subject started to split in two strands: one stream focused on competition law rules to be applied to undertakings whenever it was clear that impediment to parallel trade derived from restrictive agreements or from the abuse of dominant position; the other one was based on the application of the rule of free movement of goods to Member States, when obstacles to parallel trade came from the inappropriate use of the exclusivity right.

3. The principle of 'regional exhaustion'

From the above, it appears that the ECJ was not able, until *Deutsche Grammophon*, to properly solve the *impasse* that arose in *Consten and Grundig*.

As emphasized in the previous section, national law may give the IPR owner the right to impede the re-importation of a good protected by his, or her IPR, into a country where the latter is recognised. But, it may also occur the opposite case and the IPR owner may not be allowed to prevent re-imports, when the country applies the exhaustion of the mentioned right, i.e. the loss of the right to further control goods' movement after first sale (see better *infra*)²⁷⁶.

²⁷³ See *Deutsche Grammophon*, p. 500.

²⁷⁴ ECJ, 3 July 1974, in case C-192/73, *Van Zuylen frères v Hag AG (Hag I)*.

²⁷⁵ See *Hag I*, p. 742. However, notice that the test based on the common origin will be reversed some years later in the case C-10/89 *CNL-SUCAL NV v. HAG GF AG (Hag II)*, and abandoned in favour of the principle of consent (see *infra*).

²⁷⁶ At the time of the entry into force of the Treaty between the original Member States, virtually all of the national patent laws limited the patentee's monopoly to the first sale (the US *first sale doctrine* applied in

The former case, preventing free circulation of goods, collides with the goal of the internal market.

The attribution of the market segmentation effects to Member States granting exclusive rights that permitted the impediment of re-imports within the territory of the said Member State, instead of ascribing the obstacle to market integration to firms which were merely exercising such rights, opened the way to the solution to the problem and gave rise to the doctrine of the '*regional exhaustion*' of IPRs²⁷⁷.

In *Deutsche Grammophon*, the ECJ maintained that national rights of exclusivity of an IPR-owner cannot be used to prevent the import and distribution of products, which have been marketed in another Member State by the IPR-owner himself with his consent, or by a person economically or legally dependent on him. A similar impediment would in fact amount to a violation of Article 34 TFEU.

Otherwise stated, once a good is legally produced and placed onto the market within the EU by the owner of the right, the latter cannot use its trademark, copyright or

Adams v Burke 84 US 453 (1873) is commonly considered the first application of the exhaustion principle) of the patented product, either as a result of the statutory definition of patent infringements or as a result of an express exhaustion doctrine. The accession of the common law Member States to the Community somewhat altered the picture: United Kingdom and Irish patent laws are different because purchasers of patent-protected products are allowed to use such products under the fiction that an *implied licence* is granted on their sale by the patentee. This system is also called '*optional exhaustion*' and is mainly applied in most of the common-law countries including Australia, Canada, New Zealand and the United Kingdom. According to this theory, an exhaustion of the exclusive rights is presumed if the owner of the IPRs abstained from imposing in the sale contract restrictions with regard to the use, sale or distribution of the product by the acquirer. In the absence of any restriction embodied in the sale contract, purchasers will be able to freely dispose of the goods covered by an IPR. On the other hand, no exhaustion of exclusive rights takes place if the title-holder imposes strict conditions with regard to the use and distribution of the product in a sale contract or in a restrictive licensing agreement. See DEMARET, *Patents, Territorial Restrictions and EEC Law: A Legal and Economic Analysis*, in IIC *Studies in Industrial Property and Copyright Law*, 1978, no. 2, Ch. 3.

²⁷⁷ According to the '*exhaustion of intellectual property rights*', from the moment of first sale the product can freely circulate along the distribution chain within a given market and in those countries where the manufacturer did not apply for the intellectual property right. Given the territoriality of IPRs, traditionally, exhaustion was limited to national territories and thus referred to as '*national exhaustion*'. Nevertheless, some countries apply the principle of '*international exhaustion*', where after the good is put into the market the IPR protecting such good is considered exhausted everywhere in the world and re-importation in the country of origin is allowed. On the contrary, if the principle of '*national exhaustion*' is applied, the IPR is considered exhausted only within the country of origin. It follows that re-importation from other countries is illegal. The '*regional exhaustion*' option is a choice that stands in the middle of the two, where free circulation of goods after the first sale is allowed only within the European Economic Area. The above principles of exhaustion, which have their origin in continental Europe, are also called '*automatic exhaustion*'. See for discussion FORSYTH and ROTHNIE, *Parallel Imports*, in ANDERMAN, *The Interface between Intellectual Property Rights and Competition Policy*, cit., p. 429; AMMANN, *Intellectual Property Rights and Parallel Imports*, in *Legal Issues of Economic Integration*, 1999, no. 26(1-2), pp. 91-122; YUSUF and MONCAYO VON HASE, *Intellectual Property Rights and International Trade – Exhaustion of Rights Revisited*, in *World Competition*, 1992/93, no. 6(1), p. 115-131.

patent right to hinder the further sale of the product elsewhere in the EU, except in exceptional circumstances where, for example, public health is at risk²⁷⁸.

The exclusivity right (of production and first commercialisation) of the IPR owner is, in other words, exhausted in the moment he/she voluntarily puts the goods protected by IPR in one of the national markets belonging to the EU. A different solution, in fact, would entail the fragmentation of the internal market and frustrate one of the main goals of the EU Treaty.

After the first sale, thus, the owner of the IPR is entitled to enforce only those rights that are essential to it and that are damaged by third parties' activity.

The exhaustion of the IPR is based on the *principle of the consent*²⁷⁹. Goods should be placed on the market with the IPR owner's consent for the rights connected to the IPR to be exhausted.

The jurisprudence considers such consent as given when the good accessed the market through the IPR owner (of his own free will, not by expropriation or under a compulsory licence, as the Court had the chance to clarify later (see *infra*)), or through an authorised licensee²⁸⁰. Also, any connection – legal, economic, financial or technical – between enterprises is considered sufficient to infer the existence of 'consent'. So, for instance, if the marketing of a product is by one subsidiary of a group, or by a manufacturing licensee, or the licensor, none of the latter can object to parallel importation.

Only if the IPR has been assigned so as to belong to different owners in separate countries will there be no exhaustion²⁸¹. But even then, when this arrangement that forms part of an agreement, is a mere pretext to partition the internal market, competition law rules come into play again and it may well be that the latter falls within the scope of Article 101 TFEU.

²⁷⁸ As it will be defined later by the ECJ, 31 October 1974, in case C-16/74, *Centrafarm BV et Adriaan de Peijper v Winthrop BV* and in *Centrafarm v Sterling*.

²⁷⁹ See para. 12 of the judgment in *Deutsche Grammophon*, where the Court referred to the principle of consent before even formulating the exhaustion principle: "If a right related to copyright is relied upon to prevent the marketing in a Member State of products distributed by the holder of the right or with his consent on the territory of another Member State on the sole ground that such distribution did not take place on the national territory, such a prohibition, which would legitimize the isolation of national markets, would be repugnant to the essential purpose of the Treaty, which is to unite national markets into a single market."

²⁸⁰ See ECJ, 14 September 1982, in case C-144/81, *Keurkoop BV v Nancy Kean Gifts BV*, p. 2873, n. 5.

²⁸¹ See ECJ, 22 June 1994, in case C-9/93, *IHT v. Ideal Standard*, in relation to trademarks.

3.1 *The exhaustion of trademarks*

The identification of circumstances that allow derogation from the principle of free movement of goods, i.e. of situations where ‘consent’ has not been expressed, has been the object of many cases concerning pharmaceuticals before the ECJ²⁸².

With regards to trademarks, there is a flourishing case law dealing with the issue of whether there are legitimate reasons for the IPR owner to oppose the circulation of the goods. These cases are particularly important in the field of pharmaceuticals, because most Member States require pharmacists to dispense drugs in their original packaging and, for some reason or another, package sizes and quantities prescribed quite often vary considerably across Member States.

In *Centrapharm v. Winthrop*²⁸³, a pharmaceutical company tried to prevent the sale in the Netherlands of a medicine it had previously marketed in England, by invoking its Dutch trademark rights, while simultaneously enjoying parallel rights in the United Kingdom.

The Court established that beyond the protection of the specific subject matter of the trademark, its exercise aimed at preventing parallel importation of genuine goods from other Member States, is contrary to the provisions of the EU Treaty on free movement of goods. The ECJ confirmed the key role of consent to the exhaustion of rights. If the goods are placed on the market by the trademark holder itself, or with its consent, the exclusivity rights connected to the IPR are exhausted.

In subsequent cases, the ECJ set forth the conditions under which the trademark owner may prevent or not prevent such action.

In *Hoffmann-La Roche v. Centrafarm*, Hoffmann brought an action for infringement of its German trademark when Centrafarm obtained in the UK drugs, which it then repackaged (to comply with German packing requirements) before selling them there, using Hoffmann’s trademark. Hoffmann argued that repackaging interfered with the essential function of the trademark, i.e. the indication of the origin and guarantee of the quality of the product.

²⁸² CORNISH, *The free Movement of Goods I: Pharmaceuticals, Patents and Parallel Imports*, in GOLBERG and LONBAY, *Pharmaceutical Medicines, Biotechnology and European Law*, 2000, p. 19, affirms that the fact most of cases were on pharmaceuticals is due to the very different regulatory regimes present in each Member States that cause large price differentials, which in turn spur parallel trade.

²⁸³ See *Centrafarm v Winthrop*, p. 1194.

The ECJ rejected this claim. It held that the trademark owner could not impede the repackaging of the product without artificially partitioning the market. However, the repackaging activity should be done in a way that users are not confused and that the original conditions of the product are not negatively affected. In particular the parallel importer has to indicate in the box that the goods have been repackaged, and by whom. Also, he has to notify the trademark owner of its intention to repack²⁸⁴. Absent these conditions, the trademark owner is entitled to oppose repackaging²⁸⁵.

In *Bristol-Myer Squibb*²⁸⁶, the Court dealt again with the issue of repackaging of pharmaceutical products from parallel importers. In this case, the parallel importer went one step further: not only it repackaged the product, but it introduced additional material or replaced it with a product coming from a source other than that of the original manufacturer²⁸⁷. Refining the criteria set by the Court in *Hoffmann-La Roche v. Centrafarm*, the ECJ identified five conditions under which repackaging does not infringe the right of the trademark owner:

²⁸⁴ See ISAAC, *The free Movement of Goods II: Pharmaceuticals, Trademarks, and Parallel Imports*, in GOLBERG and LONBAY, *Pharmaceutical Medicines, Biotechnology and European Law*, cit., p. 34, saying that the effect of *Hoffmann-La Roche* was to grant the parallel importer the right to re-affix the a registered trademark belonging to a third party, provided that the requirements indicated in the text were satisfied. This may give importers the opportunity to take advantage of trademarks and build up their own trademarks and good will. See on this issue GROSS and HARROLD, *Fighting for Pharmaceutical Profits: the Decision of the ECJ in Boehringer Ingelheim v. Swingward*, in *EIPR*, 2002, no. 10, p. 497-503, at 497.

²⁸⁵ Such principles have been subsequently codified in the Directive 89/104/EC (the Trade Mark Directive) and in the Regulation EC n. 40/94 (the Community Trade Mark). See art. 7 Section 2 of the Trade Mark Directive: "1. The trademark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trademark by the proprietor or with his consent. 2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market". See further art. 13 Section 2 of the Regulation: "1. A Community trademark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trademark by the proprietor or with his consent. 2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market".

²⁸⁶ ECJ, 11 July 1996, in joined cases C-427/93, C-429/93 and C-436/93, *Bristol-Myers Squibb v. Paranova A/S (C-427/93) and C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v. Paranova A/S (C-429/93) and Bayer Aktiengesellschaft and Bayer Danmark A/S v. Paranova A/S (C-436/93)* (hereinafter, sometimes referred as 'BMS').

²⁸⁷ In *BMS*, the plaintiff sought clarification as to whether the repackaging of goods and the inclusion of material of a different origin constituted a 'legitimate reason' within the meaning of Art. 7(2) of the Trademark Directive to object the repackaging or whether this provision should have been interpreted in light of previous jurisprudence.

- i) The repackaging is necessary for the parallel trader to enter the market (so called ‘necessity requirement’)²⁸⁸, under which “the change brought about by any new carton or relabelling of a trade-marked medicinal product creates by its very nature real risks for the guarantee of origin which the mark seeks to protect. Such a change may thus be prohibited by the trade mark proprietor unless the new carton or relabelling is necessary in order to enable the marketing of the products imported in parallel and the legitimate interests of the proprietor are also safeguarded.”²⁸⁹
- i) The repackaging does not alter the original conditions of the good;
- ii) The name of the importer, and of the firm which realised the repacking, if different from the importer, and of the producer shall appear in the box;
- iii) The presentation of the new package should not damage the reputation of the trademark and of its owner;
- iv) The importer, before selling the products in the new package, should inform the trademark owner and send him a mock-up.

That last condition enables the proprietor to check that the repackaging is not carried out in such a way as directly or indirectly to affect the original condition of the product and that the presentation after repackaging is not likely to damage the reputation of the trade mark²⁹⁰.

Subsequent case law²⁹¹ clarified that the parallel importer bears the burden of proving compliance with the five conditions. As regards to the fifth condition, it is sufficient, however, that the parallel importer furnishes evidence that leads to the reasonable presumption that that condition has been fulfilled. This applies *a fortiori* also to the condition that the presentation of the repackaged product must not be such as to be liable to damage the reputation of the trademark and of its proprietor. Where the importer provides this initial evidence that the latter condition has been fulfilled, it will

²⁸⁸ This requirement has been inferred from the following passage contained in the BMS ruling at para. 56: “[T]he power of the owner of trademark rights protected in a Member State to oppose the marketing of repackaged products under the trade mark should be limited only insofar as the repackaging undertaken by the importers is necessary in order to market the product in the Member State of importation”.

²⁸⁹ See ECJ, 12 October 1999, in case C-379/97 *Pharmacia & Upjohn v. Paranova*, para. 39.

²⁹⁰ See BMS, para. 78.

²⁹¹ See ECJ, 26 April 2007, in case C-348/04, *Boehringer Ingelheim KG and Others v. Swingward Ltd and Others*, Reference for a preliminary ruling from the Court of Appeal of England and Wales, and the subsequent decision from the Court of Appeal, 21 February 2008, in the case *Boehringer Ingelheim & Ors v Dowellhurst Limited*, 2000, basically following the decision of the ECJ.

then be for the proprietor of the trade mark, who is best placed to assess whether the repackaging is liable to damage his reputation and that of the trade mark, to prove that it has been damaged²⁹².

Also, the condition that the repackaging of the pharmaceutical product, *inter alia* by reboxing it, be necessary for its further marketing in the importing Member State is directed only at the fact of repackaging the product, and not at the manner or style in which it has been repackaged. Thus, the condition of necessity is directed only at the fact of repackaging the product, and not at the presentation of that new packaging²⁹³.

A recent case, a reference from the Austrian Supreme Court to the ECJ²⁹⁴, raised a question as to whether there should be some principle of 'minimum intervention' limiting the right of the parallel importer to repackage. The Court held that it would be inconsistent to accept that there is no need to ascertain whether the presentation of the new packaging of the product in question, chosen by the parallel importer, is necessary for the further marketing of the product and, at the same time, to demand that the importer satisfy the criterion of the minimum possible adverse affect on trade mark rights²⁹⁵.

With regards to parallel imports of identical products with different marks (re-branding), the Court first affirmed in *Centrafarm v. American Home Production* that the trademark owner was entitled to prevent repackaging and subsequent resale of his product under a different name with respect to that used in the source country. However, later on in *Pharmacia & Upjohn*, the Court affirmed that if such change of name were necessary for the parallel importer to access the destination market, then this action would be permissible²⁹⁶.

Another strand of the case law, mainly at national level, relates to the issue of co-branding, i.e. the activity from parallel importers to affix their own trademark together

²⁹² See *Boehringer Ingelheim v. Swingward*, para. 48 and 54.

²⁹³ See *Boehringer Ingelheim v. Swingward*, para. 38 and 39.

²⁹⁴ See ECJ, 22 December 2008, in case C-276/05 *The Wellcome Foundation*.

²⁹⁵ See *Wellcome v. Paranova*, para. 27.

²⁹⁶ See *Pharmacia & Upjohn*, para. 44: "the condition of necessity will not be satisfied if replacement of the trademark is explicable solely by the parallel importer's attempt to secure a commercial advantage". However, see what the AG Jacobs said in his opinion at para. 54: "I do not find it helpful to postulate a necessity of 'purely commercial reasons' which can never fall within the concept of necessity [...] The decisive test is whether in a given case prohibiting the importer from re-branding would constitute an obstacle to effective access by him to the markets of the importing State".

with the manufacturer's. The case was referred from a Norwegian court to the EFTA Court²⁹⁷. The latter held, contrary to the national court, that 'legitimate reasons' may exist to oppose co-branding if this is liable to damage the reputation of the trademark. Therefore, this was an issue left to national Courts. Still, the EFTA court gave some indications: it held that the mere fact that a parallel importer gains additional advantage from a particular type of graphic design is, in itself, immaterial. Damage to the trademark could only be found where the repackaging may give the impression that there is a commercial connection between the importer and the manufacturer, or that the importer is part of the official distribution chain.

Finally, the case law discussed the issue of de-branding. The UK Court of Appeal expressed the view that, *"to say that removing (or not applying) the original supplier's mark to the goods amounts to an infringement is absurd. There is simply no answer to the proposition 'no use, no infringement' "*. A trademark owner, therefore, has no right to insist that his trademark stays on the goods for the aftermarket²⁹⁸.

3.2 *The exhaustion of patents*

The Court defined for the first time the exhaustion of patents in *Centrafarm v. Sterling Drug*. Centrafarm purchased a drug called Negram in the UK and exported it to the Netherlands where prices were higher. Sterling Drug, which held the patents for the drug in both countries, brought an action against Centrafarm to prevent them selling in Holland.

The ECJ held that *"the exercise, by a patentee, of the right which he enjoys under the legislation of a Member State to prohibit the sale, in that State, of a product protected by the patent which has been marketed in another Member State by the patentee or with his consent is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the Common Market"*²⁹⁹

The Court recognized that the IPR might be invoked subject to the presence of a twofold condition: that the product is not patentable in the State of export *and* that it has

²⁹⁷ See EFTA Court, 8 July 2003, in case E-3/02, *Paranova AS v. Merck and Co. Inc. & Others*.

²⁹⁸ See *Boehringer Ingelheim v. Dowellhurst*, para. 34.

²⁹⁹ See *Centrafarm v Sterling*, cit., summary, para. 15. Similarly, for trademarks, see *Centrafarm v. Winthrop*, cit., para. 12. This general principle, based on the distinction between the existence and the exercise of IPRs, has been enshrined in EU legislation on industrial property. See article 7 of Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trademarks, which reiterates the case law of the ECJ.

been produced by a third party without patentee's consent. Lacking this second condition, i.e. where the product was put onto the market in a legal manner, by the patentee himself or with his consent, derogations from the free movement of goods were not justified³⁰⁰.

For instance, in *Parke Davis*, the two conditions were both missing: the pharmaceutical company invoked its Dutch patent for chloramphenicol in the Dutch Courts to prevent imports by Centrafarm and other companies of products manufactured by third parties in Italy, allegedly in breach of its patent, at a time when no patent could be obtained there for pharmaceutical products or their processes. However, at that time the Court had not developed the doctrine of exhaustion of IPRs yet, and could not rule on the basis of the principle of consent.

Until the '80s, the Court never faced the situation where only one of the two conditions was satisfied, i.e. when parallel trade originates from a Member States where the company voluntarily put the product, which is not patentable there.

The issue came up in *Merck v. Stephar*: Merck & Co. Inc. owned parallel patents in most Member States for Moduretic®, a pharmaceutical product used in the treatment of hypertension. It marketed the patented product in Italy at a time when patent protection was expressly excluded for pharmaceutical products and their manufacturing processes. Stephar purchased batches of the product sold in Italy by Merck and imported them into the Netherlands where, due to the prevailing high Dutch prices, it was able to undercut the prices charged by Merck.

Merck argued that the impediments to import of a drug from Italy into the Netherlands where he had a patent did not run contrary to the rule of exhaustion, because there was no patent protection in Italy, and hence its sales in that country did not secure it any monopoly return.

However, the Court, strictly following the principle of consent, maintained that even in that case the patent owner could not oppose the re-importation, since, by putting the good in the market, he was implicitly accepting the consequences of the rule of free circulation of goods within the EU³⁰¹.

³⁰⁰ See *Centrafarm v. Sterling Drug*, para. 11.

³⁰¹ See *Merck v. Stephar*, cit., p. 2082, n. 11.

Subsequently, the Court showed more willingness to qualify the principle of exhaustion of intellectual property rights in cases concerning copyright, when the application of the principle appeared inappropriate to the Court due to the special features of the situation. In particular, the Court showed itself prone to consider divergences in national protection for copyright and the different legal nature of certain forms of copyright protection.

In *Coditel*³⁰², the Court affirmed that the right of a copyright owner to require fees for any showing of the film was part of the specific subject matter of the right. Also, the Court held that exclusive territories are necessary to enable the licensor to regulate the collection of royalties, and this formed the specific subject matter of the copyright, too.

This approach was re-affirmed in subsequent case law³⁰³ where the Court emphasized that denying to the copyright owner the special rights conferred by domestic copyright law would be tantamount to a denial of the existence of the right itself.

Also the evolution of Court's attitude to the issue of common origin represented a qualification of the principle of regional exhaustion. In *Hag I* the Court held that prohibiting the marketing of a product in one Member State of a product covered by the a trademark, for the sole reason that the same mark is protected in the Member State of importation by another proprietor in circumstances where divided ownership is a result of expropriation, is contrary to free circulation of goods. In *Hag II* the ECJ held that the specific circumstances of the case were excluding the existence of consent on the part of the trademark owner. Therefore, each of the owners of the trademark was entitled to prevent the importation and marketing of the parallel mark³⁰⁴.

³⁰² See the application of the doctrine of protection of copyright that is incorporated in a material form, as in products incorporating musical work and performing rights. See ECJ, 6 October 1982, in case C-55 and 57/80 *Coditel SA v. Ciné Vog Films SA*, concerning licences of copyright in the film *Le Boucher*. A Belgian company, Ciné Vog, was given the exclusive licence for seven years for both film and television in Belgium and Luxembourg. The same happened in Germany with a German television company. However, a cable company picked the film showed in the German television and retransmitted in Belgium, thereby infringing the Ciné Vog's exclusive right.

³⁰³ See ECJ, 9 April 1987, in case C-402/85 *Basset v. SACEM*; ECJ, 17 May 1988, in case C-158/86 *Warner Brothers Inc. v. Christiansen*; ECJ, 24 January 1989, in case C-341/87 *EMI Electrola GmbH v. Patricia*.

³⁰⁴ See the opinion of the AG Jacobs in *Hag II*, para. 26. The doctrine was established in *Hag I*, and overruled in *Hag II* and in case C-9/93 *IHT Internationale Heiztechnik GmbH v. Ideal-Standard GmbH*. In *Hag II*, the AG Jacobs made clear that the doctrine of common origin "was not a legitimate creature of Community law".

These developments in the case law triggered the question of whether the principle set forth in *Merck v. Stephar* had to be overruled.

This answer came in *Merck v. Primecrown*³⁰⁵. The case called into question the legitimacy of a consensual exhaustion of rights in a market, like the pharmaceuticals, where regulatory intervention is substantial, and where patent protection had not existed before and a 'Specific Mechanism' was operational³⁰⁶.

Despite the favourable opinion of the AG Fennelly towards a departure from the principle of consensual exhaustion, the Court finally decided that "*if a patentee decides... to put a product on the market in a Member State in which it is not patentable, he must accept the consequences of his choice as regards the possibility of parallel imports*". The Court also stated that the only legitimate exception to the principle set forth in previous case law would be the existence of a genuine, existing legal obligation to market pharmaceutical products in a Member State. Only in that case the patentee could not be deemed to give his consent to the marketing of the product concerned³⁰⁷.

The logic of the principle of the consent was replicated in *Pharmon v. Hoechst*³⁰⁸: a compulsory license was awarded in a Member State because of the failure by the patentee to exploit its patent. The ECJ held that there was no exhaustion in such circumstances, because there was no consent on the part of the patentee. In these circumstances the import of the goods could be prevented³⁰⁹.

Some commentators saw a contradiction in the way the jurisprudence developed the principle of regional exhaustion. The latter does not apply when parallel imports originated from an involuntary source. However, a compulsory licence, which is likely

³⁰⁵ See *Merck v Primecrown*, p. I-6386, n. 36. This approach was extended also to copyrights: in *Musik-Vertrieb v. GEMA*, the Court held that the owner of a phonogram could not recover the difference in royalties between the country where the protected work was first marketed and the country of import, where a higher royalty was paid to copyright.

³⁰⁶ For a definition of the Specific Mechanism see fn 126 in Chapter I.

³⁰⁷ The reasoning of the Court was guided by the fact that the opposite principle would allow IPR holders to partition national markets along borders and for this reason it was heavily criticized. See REINDLE, *Intellectual Property and Intra-Community Trade*, in *Fordham Corporate Law Institute*, 1996, p. 453-466; KON and SCHAEFFER, *Parallel Imports of Pharmaceutical Products: a New Realism, or Back to Basics*, in *ECLR*, 1997, no. 3, p. 138, where it is affirmed that the reasoning in both *Merck v. Stephar* and *Merck v. Primecrown* is seriously flawed because it favours irrational decision that are potentially harming also for consumers to withhold products from the market of Member States where exports start from. See also KORAH, *Merck v Primecrown: The Exhaustion of Patents by Sale in a Member State where a Monopoly Profit could not be earned*, in *ECLR*, 1997, no. 18, p. 265.

³⁰⁸ See, ECJ, July 1985, in case C-19/84, *Pharmon BV v Hoechst AG*.

³⁰⁹ In his opinion to this case, Advocate General Mancini stated that it is the patentee or licensee's consent which '*opens the door of the common market to patented products*' and not the actual realization of a monopoly profit. If this consent does not exist, then import of the goods can be prevented.

to have been voluntarily negotiated between the government and the company, justified an exception to the principle of free movement, even where the patent was present in both countries. On the contrary, the absence of a patent in one of the countries, which did not involve any type of consent, did not provide any justification³¹⁰.

The strongest argument in favour of a derogation from the exhaustion principle is that, since the specific subject-matter of a patent consists of the exclusive right of first marketing the patented product, permitting parallel imports of such products marketed by the patentee in a Member State where no patent protection exists and where, consequently, the patentee is subject to potential competition already at the first marketing stage, would empty that exclusive right of much of its significance. In other words, it may be that the patentee must at least have had the opportunity of obtaining monopoly profits in the exporting Member State before its national rights in the importing Member State can be said to have been exhausted³¹¹.

Thus, the question of what the specific subject matter of a patent includes arises again.

By interpreting the exhaustion principle in light of the definition of the subject matter of patents provided in *Centrafarm v. Sterling Drug*³¹², it may seem that the

³¹⁰ See JOLIET, *Patented Articles and the Free Movement of Goods*, cit., p. 15; DEMARET, *Patents, Territorial Restrictions and EEC Law*, cit., Ch. 3; ROTHNIE, *Parallel Imports*, 1993, ch. 6. See CORNISH, *The free Movement of Goods I*, cit., p. 20, who says that the mere fact that a proprietor of rights elsewhere in the EU was connected with the goods when initially marketed made the all difference between the two cases. This connection made the 'consent'. However, see the opinion of AG Fennelly in the case *Merck v. Primecrown* at para. 111: "The diverging policies of Member States regarding the patentability of pharmaceutical products were the real cause of the non-uniformity in the common market. In such circumstances, to impose a form of 'venire contra factum proprium' [...] on patentees attempting to exercise their national patent rights, on the sole basis that they have already sought to profit from another national market despite being denied patent protection there, effectively imposes on patentees the discipline of the Common Market where it does not in fact exist." The reasoning goes: "Patents are creatures of national, not Community law. The doctrine of exhaustion exists in some, not all Member States. A right conferred by a national patent cannot be exercised and, consequently, cannot be exhausted by an act of marketing in a Member State which recognizes neither that nor any other patent right in the relevant product". Similarly AG Warner in his opinion in *Musik-Vertrieb Membran v. GEMA* affirmed that "[T]here can be no exhaustion of rights where no rights exist". Also see KON and SCHAEFFER, *Parallel Imports of Pharmaceuticals*, cit., p. 137, report that at the oral hearing before the ECJ in *Merck v. Primecrown*, the Commission favoured reviewing the principle of exhaustion of patent rights where patent protection is not available and there is a legal or ethical obligation to supply the market.

³¹¹ This view was supported by JOLIET, *Patented Articles and the Free Movement of Goods*, cit., p. 37, who stated: "to say that the product has been manufactured by the patentee is irrelevant if someone else could have manufactured it as well. The test of whether the manufacturing took place with the consent of the patentee implies in my view, that the patentee could control it, i.e. that he enjoyed a parallel patent in the exporting country. Needless to say that consideration of the patent function also justifies a restriction on imports in such a situation".

³¹² See fn 271 above and accompanying text.

patentee is entitled to earn a monopoly profit at the point at which the products are first put onto the market, but after having done so his right is exhausted.

However, AG Reischl in *Merck v. Stephar* rightly opposed that “the rights recognized as forming part of the specific subject-matter of a patent cannot be regarded as an end in themselves; but they are designed to provide the patentee with ‘the possibility of obtaining a recompense for his creative effort of invention ... [which although being] one of the objectives of a patent right [...] is not ... inherent in that right ... the realization of which depends on numerous market factors such as the presence of substitute products, commercial exploitability and similar conditions’³¹³.

A patent, in fact, surely encompasses a *ius excludendi alios* in the manufacturing and first marketing of the protected product, but not a grant of the level of profitability coming from the selling of that product.

Keeping this distinction in mind, a third view that sees in the subject matter of a patent the *exclusivity at the point of first marketing*, which is not a guarantee of any monopoly profits, appears more appropriate³¹⁴. In other words, EU-law version of the exhaustion doctrine merely permits the patentee to choose the place where he wishes to be first in marketing the relevant products in the EU. Once that choice is made, the goods must, in accordance with the EU exhaustion principle, thereafter be allowed to circulate freely throughout the Common Market.

If one accepts this definition of the subject matter of a patent, the rulings of the Court in the cases *Merck v. Stephar* and *Merck v. Primecrown* lose grounds. The absence of a patent system, in fact, prevented the company from having the exclusivity in the first marketing of the drug there, given that generic companies could legally enter the market and sell the same drug³¹⁵.

It should be noted that the arguments, which suggest a qualification of the exhaustion principle when patent is absent in the Member State of export, do not appear to justify a departure also when regulation on prices is present.

³¹³ See the opinion of the AG Reischl at p. 2090.

³¹⁴ Cf. the opinion of the AG Fennelly at para. 97. See also para. 9 and 10 of the judgement in *Merck v. Primecrown*: the specific purpose of a patent “lies essentially in according the inventor an exclusive right of first placing the product on the market. It is this right which enables the inventor, by allowing him a monopoly in exploiting his product, to obtain the reward for his creative effort without, however, guaranteeing that he will obtain such a reward in all circumstances”.

³¹⁵ Nevertheless, *Merck* had a *de facto* monopoly in the commercialization of the drug in Italy.

In *Centrafarm v. Sterling Drug*, the defendant claimed that allowing parallel imports from a country where there was price regulation would have deprived it from the possibility to have an appropriate return on the investment made, i.e. the subject matter of the patent would have been damaged. The Court, however, expressly stated that the fact that prices were low due to government controls was immaterial³¹⁶.

Such approach is consistent with the definition of patents' subject matter provided above: the absence of patent protection does not allow the manufacturer to be first in the market, due to the exposure to competition from generics; under these circumstances, restrictions to parallel trade should not be seen as going against the principle of regional exhaustion because the subject matter of the patent has not been exhausted. But when the company is granted a patent, it has the exclusivity right that allows it to protect its profits from generic companies, no matter the presence of regulation on prices.

3.3 *The exhaustion of IPRs covering products coming from third countries*

A different policy towards IPRs that are used to prevent entry in the EU of products coming from third countries prevails.

With regards to trademarks, the issue was discussed first when the Trade Mark Directive was enacted. A first proposal in the text of the Directive³¹⁷ contained a wording of Article 7 that provided for international exhaustion³¹⁸. However, during the debate at the European Parliament, an amendment changing the text of Article 7 and inserting the wording '*in the Community*' was adopted³¹⁹.

During the re-drafting procedure, thus, the Commission faced the choice of introducing the principle of international exhaustion or establishing a EU-wide exhaustion principle. In the end the Commission decided to opt for the second

³¹⁶ See *Centrafarm v. Sterling*, para. 2, summary. "It is a matter of no significance that there exist as between the exporting and importing Member States price differences resulting from governmental measures adopted in the exporting State with a view to controlling the price of the product..." The principle was confirmed in *Merck v Primecrown*, para. 47. See also *Bristol-Myers Squibb v. Paranova*, cit., and *Centrafarm v. Winthrop*, cit. Finally see *General Motors v Commission*, where it was affirmed that lacking harmonisation, it is normal that domestic and export sales are subject to different regulations, albeit this does not modify the anticompetitive features of an agreement.

³¹⁷ See the older proposal in OJ C351/1, 1980.

³¹⁸ The older text of Art. 7 read as follows: "The trade mark should not entitle the proprietor thereof to prohibit its use in relation to goods which have been put on the market [i.e. in or outside the Community] under that trade mark by the proprietor or with his consent".

³¹⁹ See the amended proposal in the OJ, C351/4, 1985.

alternative, in consideration of two policy issues: the possibility of a lack of reciprocity from third countries in commercial relations, and the cost of introducing the principle of international exhaustion into national laws at a stage where not all Member States applied such principle.

Still, the literature had been for some time speculating about whether Article 7 introduced a EU-wide exhaustion or a minimum standard such that Member States could implement international exhaustion if they wished³²⁰. This second option was suggested by the EFTA Court in *Mag Instruments v. California Trading Co.*³²¹

However, the Court in the *Silhouette* case settled the debate and indicated that the first option was the more appropriate from a legal point of view³²².

Silhouette brought a trademark action to prevent parallel imports into Austria of spectacles frames that it had sold in Bulgaria. Under Austrian trademark law, *Silhouette* had exhausted its rights, after having placed them on the market voluntarily. Austrian law did not distinguish between sales within the EU and sales between Austria and third countries, i.e. it applied international exhaustion of IPRs.

The ECJ was asked whether Article 7(1) of the Trade Mark Directive precluded national laws from providing for the exhaustion in respect to products that were coming from outside the EU. The Court, following the opinion of the Advocate General (hereinafter, sometimes referred as 'AG') Jacobs³²³, held that the principle of EEA exhaustion could not apply, because the latter, as well as the Trade Mark Directive, have the purpose of promoting the single market³²⁴. An opposite interpretation would have imposed the adoption of international exhaustion on Member States. Such obligation would not be legally valid because the principle of regional exhaustion was developed in the context of intra-EU trade and it was not appropriate in an international scale³²⁵.

³²⁰ See CARBONI, *Cases Past the Post on Trade Mark Exhaustion: an English Perspective*, in *EIPR*, 1997, p. 198.

³²¹ See EFTA, 3 December 1997, in case C-2/97 *Mag Instruments v. California Trading Company Norway*.

³²² See ECJ, 16 July 1998, in case C-355/96 *Silhouette International Schmied GmbH v. Hartlauer Handelsgesellschaft GmbH*.

³²³ The AG based his opinion on the legislative development of the Directive and on the wording of the Council Regulation 40/94/EEC on the Community Trade Mark, which used wording equivalent to Art. 7 of the Trade Mark Directive.

³²⁴ The Court drew this conclusion despite the arguments put forward by the Swedish government that international exhaustion would have brought advantages for consumers thanks to price competition.

³²⁵ Reaction to the ruling were mixed. Brand owners were pleased, whilst parallel importers and consumers associations were outraged. For comments see ABBOTT and FEER VERKADE, *The Silhouette of a Trojan Horse: Reflections on Advocate General Jacobs' in Silhouette v. Hartlauer*, in *JBL*, 1998, p. 413; CARBONI, *Cases about*

In *Sebago*³²⁶, the defendant brought an action to prevent import of shoes from El Salvador. The Plaintiff argued that given that Sebago had put identical shoes on the market within the EU, it has exhausted its rights in relation to all shoes, wherever they were marketed. However, the ECJ confirmed the approach taken in *Silhouette* and re-affirmed that trade mark rights are exhausted only if the products have been put on the market in the EU and that consent must relate to each item or product concerned.

In *Zino Davidhoff*³²⁷, the Court faced the issue of the definition of 'consent', as this had not been addressed before and remained open to speculation. In this case, a parallel importer sold in UK toiletries and cosmetic products that the trademark owner had marketed outside the EU. Davidhoff argued that its rights were not exhausted. When referring the questions to the ECJ, Laddie J's affirmed that the Trade Mark Directive does not impose the regime of international exhaustion, but if the proprietor of the IPR agrees, expressly or implicitly, to allow the entry of goods marketed in a third country into the EU, he cannot afterwards use its IPR to prevent re-imports. Such consent may be inferred from the circumstances prior to, simultaneously or subsequent to the placing of the goods on the market outside the EU³²⁸. *Zino Davidhoff* thus seemed to provide a qualification to the principle expressed in *Silhouette*.

Another derogation to the principle seems to come from the judgement *Javico*³²⁹, where the Court held that an export ban in a distribution agreement with a non-EU distributor restricting sales into the EU might be found to infringe Article 101(1) TFEU, if the effect of this provision is to restrict or distort competition within the EU³³⁰.

With regards to patents, national patent laws determines the legal treatment of re-imports of patented goods when they are initially marketed by the patentee or an

Spectacles and Torches: Now Can we see the Light?, in EIPR, 1998, no. 20, p. 472; HAYS and HANSEN, *Silhouette is not the Proper Case to Decide the Parallel Importation Question*, in EIPR, 1998, no. 20, p. 277; WHITE, *Sunglasses: a Benefit to Health?*, in EIPR, 1999, no. 21, p. 176; KUILWIJK, *Parallel Imports and WTO Law: Some thoughts after Silhouette*, in ECLR, 1999, no. 292; ALEXANDER, *Exhaustion of Trade Mark Rights in the European Economic Area*, in ELR, 1999, no. 24, p. 56; NORMAN, *Parallel Imports from Non-EEA Member States: the Vision of Remains Unclear*, in EIPR, 2000, no. 22, p. 159; JONES, *Does an Opportunity still Exist for the Development of a Doctrine of International Exhaustion at a Community level under Article 28 and 30?*, *ibid.*, p. 171.

³²⁶ See ECJ, 1 July 1999, in case C-173/98 *Sebago Inc v. GB-Unic SA*.

³²⁷ See ECJ, 20 November 2001, in case C-414/99 *Zino Davidhoff SA v. A & G Imports Ltd*.

³²⁸ However, consent cannot be inferred by the fact that the IPR owner does or says nothing about parallel imports from third countries. See para. 48-65 in *Zino Davidhoff*.

³²⁹ See ECJ, 28 April 1998, C-306/96 *Javico v. Yves Saint Laurent*.

³³⁰ This hypothesis was first outlined by the AG in the *Silhouette* case. See ROTHNIE, *Parallel Imports*, *cit.*, p. 315.

associate elsewhere. There is no overarching law operating at a EU level, which imposes a common solution upon all countries. True, Member States signed the EU Patent Convention in 1975, and revised it in 1989. Although the Convention has not been brought into effect, it requires national patent laws to adopt the principle of EU-wide exhaustion³³¹. But no provision clarifies whether patent rights are exhausted when protected products are first marketed outside the EU. Therefore, also parallel imports of patented products coming from outside the EU follow the rules set out in the mentioned case law for trademarks.

From the above it appears doubtless that the EU law embraced the principle of regional exhaustion, which ring-fences the EU and its single market, leaving the Commission the power to negotiate reciprocity agreements with third-party States.

In this context, the question of whether the regional exhaustion principle applies also to countries with which the EU has signed a free trade agreement, arises. These agreements, based on Article 284 TFEU, generally contain a clause that is the mirror image of Article 36 TFEU: in the free trade agreement with Israel, for instance³³², it is stated at Art. 11 that *“l'accord ne fait pas obstacle aux interdictions ou restrictions d'importation, d'exportation ou de transit justifiées par des raisons de [...] protection de la propriété industrielle et commerciale. Toutefois, ces interdictions ou restrictions ne doivent pas constituer un moyen de discrimination arbitraire ni une restriction déguisée dans le commerce entre les parties contractantes”*.

From this it should follow that the principle of regional exhaustion is valid also for trade between Israel and the European Union, and that, consequently, the use of IPRs that restricts imports from Israel is not permitted. However, this interpretation rests on the hypothesis that such agreement is binding for the EU and has direct effect. Whilst it is true that agreements signed by the European Union become part of the sources of EU

³³¹ Art. 28 of the Patent Convention states: *“The rights conferred by a Community patent shall not extend to acts concerning a product covered by that patent which are done within the territories of the Contracting States after that product has been put on the market in one of these States by the proprietor of the patent or with his express consent unless there are grounds which, under Community law, would justify the extension to such acts of the rights conferred by the patent.”*

³³² Israel and the European Community signed a free trade agreement on May 11, 1975.

law within the EU, this does not necessarily entail that they have direct effect, so that individuals can action them before the ECJ³³³.

It was in *Bresciani* that the Court for the first time considered an international agreement had a direct effect, “*simultaneously paid regard to the spirit, the general scheme and the wording of the Agreement and the provision concerned*”³³⁴. This principle has been subsequently re-affirmed in *Kupferberg*³³⁵, where the Court held that the principle of free movement of good between the EU and third countries is valid if there is a free trade agreement that lays it down in clear, precise and unconditioned³³⁶ manner.

This cannot, however, lead to the conclusion that the principle of regional exhaustion is *tout court* extended to countries with which there exists a free trade agreement containing a clause that provides for the free circulation of goods between the signing parties.

In *Polydor*³³⁷, the ECJ held that provisions related to the free movement of goods and to the prohibition of measures having equivalent effect to restrictions to trade contained in an international agreement should be interpreted in a more restrictive way with respect to those contained in the Treaty. The reason for this differential treatment is that only the latter aim at building the internal market.

It follows that “*in the context of the agreement restrictions on trade in goods may be considered to be justified on the ground of the protection of industrial and commercial property in a situation in which their justification would not be possible within the Community*”³³⁸. That means that the exclusive licensee of a copyright in a EU Member State could validly

³³³ See ECJ, 12 December 1972, in case C-21-24/72 *International Fruit*, where the Court held that some clauses of the GATT agreement, invoked against the Community legislation, had direct effect, because they were indeterminate.

³³⁴ See ECJ, 5 February 1976, in case C-87-75, *Conceria Daniele Bresciani v Amministrazione Italiana delle Finanze*, where the ECJ considered the Yaounde Convention providing for non-reciprocal duty free entry into the Community of goods from the ACP countries.

³³⁵ See ECJ, 15 January 1985, in case C-253/83 *Sektkellerei C.A. Kupferberg & Cie KG a.A. v Hauptzollamt Mainz*, where the ECJ considered the Free Trade Area Agreement between the Community and Portugal which eliminated all tariffs and other barriers to trade between the two parties.

³³⁶ A legal provision is considered unconditioned when it can be applied as it is, without any intervention from national legislators.

³³⁷ See ECJ, 9 February 1982, in case C-270/80 *Polydor*.

³³⁸ See *Polydor*, para. 19.

oppose his right to importations of disks from non EU Member State, where the licensor voluntarily sold them³³⁹.

4. The balance of IPRs with the European competition law rules

The strand of the case law dealing with the use of IPRs under competition law rules developed along the definition of ‘permitted exercise’.

The European Courts have, from *Parke Davis*, established that the exclusivity right connected to an IPR and its exercise is not in itself regarded as anticompetitive under Articles 101 and 102 TFEU. Only where the IPR becomes the means to implement and agreement restrictive of competition that the prohibition comes into play.

4.1 The exercise of IPRs under Article 101 TFEU

The antitrust assessment of the use of patents under Article 101 TFEU predominantly concerned IPR licensing agreements.

Before the ruling in *Consten and Grundig*, the Commission considered patent licensing agreements as not restrictive of competition, as long as the content of the license remained within the ‘scope of patent’³⁴⁰. In the *First* and in the *Fourth Report of Competition Policy*³⁴¹, the Commission distinguished between licensing agreements that were related to the subject matter of the IPR and formed part of the right itself and the clauses of these agreements that went beyond it and represented an attempt to extend the market power of the licensor³⁴².

³³⁹ See LAMANDINI, *Le importazioni parallele tra l’Unione Europea e Israele*, in *Il Diritto Industriale*, 1995, no. 4, p. 357-360.

³⁴⁰ The concept of ‘scope of the patent’ was derived from US antitrust law, where patent law developed the patent misuse doctrine, which was later taken by antitrust law to identify clauses, such as price and territorial restrictions on the sale of a patented product, that went beyond the scope of the original exclusivity and that were prohibited *per se*. See, for instance, *Mercoind Corp. v. Mid Continent Investment Co.* 320 US 661 (1943). Similarly, S.20(1) of the German Act Against Restraints on Competition provides that patent licensing agreements are void to the extent that they impose restraints on the licensee that exceed the scope of the patent grant.

³⁴¹ See the *First Report on Competition Policy*, 1972, p. 65-74 and the *Fourth Report on Competition Policy*, 1974, para. 20.

³⁴² This approach emerges from Art. 4(2) of EC Regulation no. 17/62 that provided that notification was not required with respect to bilateral agreements that imposed restrictions on the exercise of IPRs from the assignee. Also, in the *Notice on Patent Licensing* of 1962 the Commission affirmed that limitations as to technical applications or field of use, quantity products to be manufactured, or restrictions in time were out of the scope of Art. 101(1) TFEU.

With *Consten and Grundig*, the awareness of the potentials of IPRs to compartmentalise markets and limit intrastate trade and competition emerged³⁴³.

The legacy of this *grand arrêt* was to establish that an IPR-related agreement that has the object of restricting competition in the internal market goes against the provision set forth by Article 101(1) TFEU, and therefore to delimit the permitted exercise of the IPR itself.

Such limitation, nevertheless, cannot apply in the absence of the elements that constitute an agreement. On the contrary, the use of an IPR in connection with an agreement restrictive of competition within the internal market is not permitted, because it runs contrary to the provisions set forth by the mentioned article. So, for instance, an IPR licence is unlawful if it is ‘*the means of*’ an agreement restrictive of competition³⁴⁴.

Accordingly, exclusive licensing agreements, which as such may be thought of falling within the scope of the *Grundig* rule, are not by themselves anticompetitive. Under this type of agreements, which just limit the number of licensees with the right to manufacture and sell in the protected area, there is always the possibility for licensees to compete among themselves, thanks to the rules of free movement of goods that allow them to engage in direct sales in other territories where other licensees manufacture the protected good³⁴⁵. The territorial sales restrictions, on the contrary, limit this possibility and for this reason may run contrary to Article 101(1) TFEU, provided that the restriction has an appreciable effect³⁴⁶.

The appreciability test and the distinction between exclusive licence to manufacture and territorial sales restriction came in *Nungesser*³⁴⁷. The Court held that

³⁴³ See *Consten and Grundig*, p. 343, where the Court held that the infringement of Art. 101(1) TFEU consisted in the attempt of the licensor and the licensee to isolate the French market for Grundig products and maintain artificially separated national markets.

³⁴⁴ See *Coditel*, para. 14.

³⁴⁵ See JOLIET, *Trademark Licensing under the EEC Law of Competition*, in IIC, 1984, p. 31.

³⁴⁶ ANDERMAN, *EC Competition Law and Intellectual Property Rights*, cit., p. 63, affirms that from the reading of both *Société Technique Minière* and *Consten and Grundig*, it appears that the Courts do not exclude the appreciability test for exclusive licence agreements in vertical commercial relationships. The concern of the Court was directed towards the import ban placed on wholesalers.

³⁴⁷ See ECJ, 8 June 1982, in case C-258/78 *L.C. Nungesser KG and Kurt Eisele v Commission*, para. 53. The case concerned a licence of breeders’ rights to maize seed variety from a French institution, INRA, to a German company. INRA undertook to refrain, and prevent others, from importing maize seeds in Germany. Eisele relied upon its IPR to stop a parallel importer that was importing seeds from France into Germany.

‘open exclusive licence’ agreements do not violate competition rules³⁴⁸, while ‘closed exclusive licence’ agreements do, being the former a contract where the exclusivity relates only to the commercial relationships between the licensor and the licensee, and the latter a contract that limit the possibilities of sales from other licensees in other territories³⁴⁹.

Although this case did not explicitly draw any line between the exercise of IPRs and competition law, it implicitly started sketching a criterion for this distinction: if the territorial restriction is essential to the licensing agreement that is aimed at opening up the market for a new product, then this may represent a permitted exercise of the IPR under competition law.

The Court went further in *Coditel*, where - as already underlined - it held that an agreement conferring an exclusive right to exhibit a film for a certain period in a given Member States with absolute territorial protection is not necessarily caught by Article 101(1) TFEU. In the view of the Court, the fact that a literary or artistic work can be infinitely copied and transmitted, differentiated films from other products covered by copyright that, however, can be circulated only in their physical form. Also, the Court observed that the copyright includes the right for the owner to charge a fee for any showing or performance. Therefore, impeding such right by allowing other companies to transmit the film would have emptied the copyright completely. The concern of the Court then seems to be directed to the impossibility to recoup, under competition from other companies, the investment made for the realisation of the film³⁵⁰.

The judges made clear that this qualification, however, does not apply when the agreement has the object or the effect of restraining the distribution of films or where competition in the market for films is distorted³⁵¹.

³⁴⁸ The Court, however, did not hold that all ‘open licences’ were cleared, but at para. 55-57 it set out four conditions that have to be satisfied in order for the agreement to be compatible with Art. 101(1) TFEU: first, the product had to be new to the licensee’s market; second, the technology had to be developed after years of research and experimentation; third, without the exclusivity licence the licensee would not be willing to take on the risk of developing and marketing that new product; four, the absence of intrabrand competition would result in the improvement of interbrand competition.

³⁴⁹ See *Nungesser*, para. 58.

³⁵⁰ The AG suggested that a fair return for IPRs in the film industry related to the specific object of the IPR and was therefore not caught by Art. 101(1) TFEU. But the Court only mentioned a fair return upon the investment made.

³⁵¹ See *Coditel*, para. 20.

4.2 The exercise of IPRs under Article 102 TFEU

Regarding cases under Article 102 TFEU, the Court held several times that the ownership of an IPR does not entail a dominant position. For instance, in *Deutsche Grammophon*, the Court stated that possession of an IPR does not automatically amount to dominance³⁵². As one prominent scholar has noted, in fact, an IPR is a negative right for other parties to commercially exploit the protected product and not a positive right attributed to the IPR owner³⁵³.

This obviously does not mean that ownership of an IPR and dominance can never coincide. On the contrary, the possession of an IPR *might* give rise to a position of dominance. There are, in fact, situations where the power to exclude the marketing of infringing goods can create a dominant position by impeding competition. Or, there are situations where the ownership of an IPR amounts to a *de facto* monopoly. And for this reason, it may be scrutinized under Article 102 TFEU³⁵⁴.

Whether the two situations coincide, much depends on how the relevant market is constructed. If it is constructed narrowly, i.e. there is a single product market, the existence of an IPR could extinguish competition and put the IPR owner in a position of *de facto* monopoly.

In *Hugin*³⁵⁵, for instance, the ECJ found that the defendant was dominant in the market for spare Hugin parts of cash registers, because the latter were covered by an IPR. This meant that there were no substitutes and maintenance firms were forced to source their supplies from Hugin.

Also, both in *Volvo*³⁵⁶ and in *CICRA*³⁵⁷, the Advocate General underlined that when the relevant market is reduced to a single product, which is covered by an IPR, the absence of substitutes itself entails the finding of dominance³⁵⁸.

³⁵² See *Deutsche Grammophon*, para. 16: “The manufacturer of sound recordings who holds a right related to copyright does not occupy a dominant position within the meaning of Article 86 of the Treaty merely by exercising his exclusive rights to distribute the protected article.”

³⁵³ See ANDERMAN, *EC Competition Law and Intellectual Property rights*, cit., p. 169.

³⁵⁴ See ECJ, 3 October 1985, *Centre belge d'études de marché - Télémarketing (CBEM) v SA Compagnie Luxembourgeoise de Télédiffusion (CLT) and Information publicité Benelux (IPB)*, para. 16, where the Court affirmed that “the fact that the absence of competition or its restriction on the relevant market is brought about or encouraged by provisions laid down by national law in no way precludes the application of Article 86.”

³⁵⁵ See ECJ, 31 May 1979, in case C-22/78, *Hugin Kassaregister AB and Hugin Cash Registers Ltd v Commission of the European Communities*.

³⁵⁶ See ECJ, 5 October 1988, in case C-238/87, *AB Volvo v Erik Veng (UK) Ltd*.

This conclusion has been inferred also when the exclusivity right conferred by IPRs was seen as a barrier to entry.

In *Hoffman La Roche*, the Court found that the defendant enjoyed technological superiority, despite the fact that the patent for the manufacture of vitamins had expired. The extensive know-how of the company was a factor giving it a lead over its competitors was essential to a finding of technological advantage that determined the persistence of the dominant position³⁵⁹.

However, even in those cases where the mere ownership of an IPR gives rise to a *de facto* monopoly, this does not equal to the finding of an unlawful conduct. The breach of Article 102 TFEU, in fact, takes place when such position in the market is abused.

At first reading, the wording of Article 102 TFEU would trigger antitrust concerns whenever IPRs are at stake. In fact, the first two conducts indicated in the provision – (a) unfair pricing, and (b) limitation of production, which are concerned with the ability of a dominant firm to exploit its consumers and customers respectively by extracting monopoly rents – are the essence of an IPR.

However, competition law has long ago acknowledged that the mentioned corporate practices just represent the way the IPR owner seeks the reward for his inventive activity.

Accordingly, the ECJ said that ‘*the mere fact of securing the benefit of an exclusive right granted by law, the effect of which is to enable the manufacture and sale of protected*

³⁵⁷ See ECJ, 5 October 1988 in case C-53/87 *Conorzio italiano della componentistica di ricambio per autoveicoli and Maxicar v Régie nationale des usines Renault*.

³⁵⁸ See FRIDEN, *Recent Developments in EEC Intellectual Property Law: The Distinction between Existence and Exercise Revisited*, in *CML Rev.*, 1989, n. 193, p. 209, says “the crucial point is the definition of the relevant market. If it can be defined with reference to the supply of products or the provision of services, subject to the right in question, then the right can in practice be said to make the holder dominant... such absence of substitutes logically implies dominance”.

³⁵⁹ See *Hoffmann-La Roche*, para. 48. Technological superiority *vis-à-vis* rivals has been often adduced as an element leading to the reinforcement of dominance. See ECJ, 2 March 1994, in case C-53/92 P, *Hilti AG v Commission of the European Communities*; GC, 10 July 1990, in case T-51/89 *Tetra Pak Rausing SA v Commission of the European Communities (Tetra Pak I)*; ECJ, 9 November 1983, in case C-322/81 *NV Nederlandsche Banden Industrie Michelin v Commission of the European Communities (Michelin I)*. In this last case, see at para. 57 the reported arguments of the French government, claiming that this criterion was implicitly levying a penalty for R&D investments and high quality of the products. The Commission has generally replied to this kind of arguments that the finding of dominance was not itself a finding of an abuse, but simply puts the company under the special responsibility of not engaging in prohibited conducts. Still, see WHISH, *Competition Law*, cit., p. 268, saying that, nevertheless, the finding of dominance raises the costs for the company of defending its conduct under Art. 102 TFEU.

products by unauthorised parties to be prevented, cannot be regarded as an abusive method of eliminating competition'³⁶⁰.

In *Hoffmann-La Roche*, it was established that the use of a trademark right, if exercised in accordance with Articles 34–36 TFEU, could not be contrary to Article 102 TFEU just because it comes from an undertaking in a dominant position. Only if the trademark right has been used as an '*instrument for the abuse*' of such a position, i.e. the exercise of the IPR must be linked in some way to a commercial practice which runs contrary to competition rules, then the prohibition set forth by Article 102 TFEU comes into play.

So for instance, in *Volvo* the Court pointed out that for a corporate conduct to be abusive, some '*additional factors*' were required in addition to the elimination of competition from other manufacturers in respect of the protected product³⁶¹.

When the exercise of the exclusive rights connected to the IPR remains in the primary market for the protected product, this does not normally fall within the scope of Article 102 TFEU.

However, this principle suffers an exception: in *Continental Can*³⁶², the Court faced the issue of whether the acquisition of an IPR by a dominant undertaking may be considered abusive. It is generally acknowledged that the development of an innovation and the related inventive and economic effort entitles the IPR owner to exclude potential competitors from the primary market. The question was whether the same principle was valid when the innovation was purchased. In *Tetra Pak I*, the Court and the Commission responded negatively, given the absence of any inventive activity from the dominant purchaser³⁶³. It follows that the special position of an IPR owner under Article 102 TFEU cannot be extended to a licensee, and the latter, if it occupies a dominant position, is not entitled to exclude potential competitors from using the research tools.

This does not mean that the acquisition of an IPR from a dominant company is always unlawful and is to be prohibited. For the purpose of applying Article 102 TFEU,

³⁶⁰ See *CICRA*, para. 15.

³⁶¹ See *Volvo*, para. 8.

³⁶² See ECJ, 21 February 1973, in case C-6/72 *Europemballage Corporation and Continental Can Company*.

³⁶³ See the opinion of AG Kirschner at p. 47 saying: "Where a patent or registered design is obtained by its originator, the undertaking is protecting its own development work from imitation by third parties. [...] In contrast, the acquirer of a patent licence procures for himself the development work carried out by others. That is legitimate, but it distinguishes his legal position from that of the original proprietor of the protective right. It is to the latter that the exclusive entitlement belongs and it is intended to allow him to obtain the reward for his creative effort".

the circumstances surrounding the purchase must be taken into account, i.e. attention should be paid to the competitive structure of the market. If, for instance, the acquisition, prevents or delays significantly the entry of competitors in the market, where little or no competition exists because of the dominant position, the finding of an abuse is likely to hold³⁶⁴.

The extension of the exclusivity right to a second market or to a second product unprotected by the IPR, through a tie-in or a refusal to supply or licence, also, generates concerns under antitrust law³⁶⁵.

Two prerequisites before the finding of abuse is made are necessary: the link between the primary and the secondary market, and the dominant position of the defendant precluding an alternative sources of supply. This generally happens in case the dominant company owns an IPR that protects an essential inputs necessary to access the second market, and refuses to supply such inputs to potential competitors in that market. By foreclosing access to rivals in the second market, the dominant company can leverage its market power from the first into the second market³⁶⁶.

4.2.1 *The refusal to licence IPRs*

When essential inputs or infrastructures necessary to access the second market are covered by an IPR, the use of the latter that leads to refuse to licence the access to such inputs may give rise to an abuse of dominant position³⁶⁷. However, in the early case law it was not clear whether and to what extent the obligation of a dominant undertaking not to refuse to supply a product could be extended to a refusal to licence an IPR.

³⁶⁴ See *Tetra Pak I*, para. 23.

³⁶⁵ Note that the refusal to supply may fall under the scope of letter b), if the dominant company refuses to supply a product that does not exist in the second market and that is required by consumers; instead, it falls within the scope of letter c) if the dominant company has a subsidiary in the secondary market, and the refusal to supply has a discriminatory effect.

³⁶⁶ See ECJ, March 1974, in case C-7/73, *Istituto Chemioterapico Italiano S.p.A. and Commercial Solvents Corporation v Commission of the European Communities*, where the world monopolist in the production and commercialisation of the raw material nitropropane refused to supply a customer, producer of ethambutol, for which this raw material was necessary input. The refusal allowed the dominant company to monopolise the downstream market for the production and distribution of ethambutol, since the only competitor was forced out of the market. For this reason, the conduct was considered abusive by the ECJ. See also *Télémarketing*, para. 25-27; and GC, 10 July 1990, in case T-64/89, *BPB and British Gypsum v. Commission*, para. 69.

³⁶⁷ The issue of refusal to licence is strictly related to the scope of this work but it does not constitute a core subject in the field of parallel trade. For this reason, jurisprudential developments will be only briefly described.

The first attempt to solve this question came in cases about the refusal to supply car body panels covered by copyright.

As already said, both in *CICRA* and in *Volvo*, the ECJ suggested a qualified test of permitted exercise of an IPR. Volvo had used its design right to stop Veng from importing cheaper copies of Volvo front wings. The ECJ held that “*the right of a proprietor of a protected design to prevent third parties from manufacturing and selling or importing, without its consent, products incorporating the design constitutes the very subject matter of its exclusive rights. It follows that an obligation imposed upon the proprietor of a protected design to grant to third parties ... a licence for the supply of a product incorporating the design would lead to the proprietor being deprived of the substance of its exclusive right.*”³⁶⁸ And in this way, it concluded that refusing to grant such licence could not itself constitute an abuse of a dominant position.

However, leveraging on the distinction between ‘existence’ and ‘exercise’ of an IPR, the Court also added that the “*arbitrary refusal to supply spare parts to independent repairers, the fixing of prices for spare parts at an unfair level or a decision no longer to produce spare parts for a particular model even though many cars of that model are still in circulation*” may be prohibited by Article 102 TFEU, if it is capable to affect trade between the Member States³⁶⁹.

The balance operated by the Court in this case unfortunately left many issues unsolved. The precise circumstances in which refusal to licence an IPR is abusive remained unclear, because the ECJ discharged the analysis by relying on the subject matter of copyrights and assuming the conduct within the scope of the latter. Also, the Court did not further deepen the question of the permitted exercise.

Clarification arrived when the European Commission started applying the ‘*essential facility doctrine*’³⁷⁰ to the cases of refusal to licence. In its view, the preservation

³⁶⁸ See *Volvo*, para. 8.

³⁶⁹ See *Volvo*, para. 9.

³⁷⁰ The essential facilities doctrine (sometimes also referred to as the essential facility doctrine) is a legal doctrine that describes a particular type of claim of monopolization made under competition laws. In general, it refers to a type of anti-competitive behavior in which a firm with market power uses a ‘bottleneck’ in a market to deny competitors entry into the market. It is closely related to a claim for refusal to deal. The doctrine has its origins in United States law, but it has been adopted (often with some modification) into the legal systems of the United Kingdom, Australia, South Africa, and the European Union. The first case to use the idea was the Supreme Court’s judgment in *United States v. Terminal Railroad Association*, 224 U.S. 383 (1912). A group of railroads controlling all railway bridges and switching yards into and out of St. Louis prevented competing railway companies from offering transportation to and through

of effective competition required dominant companies which owned 'essential facilities' to offer access to competitors as well as customers on a non-discriminatory basis.

In this regard, three fundamental cases trace the route taken by the European Courts: *Magill*, *Oscar Bronner*, and *IMS*.

In *Magill*³⁷¹, three TV broadcasting companies in Ireland, RTE, BBC, and ITP, refused to licence the information contained in their programme listings for publication in a new weekly comprehensive TV guide. Such content was covered by copyright and for this reason the defendants argued that they were entitled to reserve the right to publish weekly TV listings in their own single channel weekly guides.

The Commission held that the conduct of the TV companies was abusive, because they were using their dominant position to prevent the entry of a new product in the market. The Commission saw in the TV listings covered by copyright an essential facility used by the defendants to reinforce their position in the market.

The General Court (hereinafter sometimes referred as the 'GC'), confirming the concerns of the Commission, declared that refusal to licence cannot itself constitute an abuse, even if put in place by a dominant undertaking, but such practice may under certain exceptional circumstances be considered abusive³⁷². The Court regarded the refusal to licence opposed by the defendants as going beyond the essential function of the copyrights protecting the magazines and being used as an instrument to monopolize the market, because it prevented the introduction of a new product for which there was demand and retained the derivative market for weekly guides for the defendants³⁷³.

On appeal, the AG Gulman questioned this approach in his opinion. He affirmed that the use of the IPR from the defendant was within the subject matter and that Article 102 TFEU could restrict the use of an IPR that falls within its specific subject matter only in special circumstances. However, the appearance of a new product did not prove to be

that destination. The court held it to be an illegal restraint of trade. A unilateral refusal to deal with 'essential facilities' means potential liability as a monopoly violation of Section 2 of the Sherman Act. See VENIT and KALLAUGHER, *Essential Facilities – a Comparative Law approach*, in *Fordham Corp. Law Inst.*, 1994, p. 315.

³⁷¹ See ECJ, 6 April 1995, in joined cases C-241/91 P and C-242/91 P, *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities*.

³⁷² ANDERMAN, *EC Competition Law and Intellectual Property Rights*, cit., p. 205, sees in this approach the EC Commission's concern that the ruling in *Volvo* could have provided the immunity to IPRs from Art. 102 TFEU, thereby creating the conditions to use them as instruments of abuse.

³⁷³ The Court at para. 74 affirmed that where the copyright is exercised in a manner manifestly contrary to the objectives of Art. 102 TFEU, it is no longer exercised in a manner that corresponds to its essential function.

a 'special circumstance' to him. On the contrary, the obligation to licence permitted the entry of directly competing products that could have endangered the possibility of earning the necessary profits to reward the inventive activity, as well as his incentive to engage in such activity in the first place. But, if the new product was not competing with the one covered by IPR, then a refusal to licence would be abusive³⁷⁴.

The ECJ was not persuaded by the opinion of the AG, and upheld the decision of the GC and the Commission. In doing so, it re-affirmed that it is wrong to assume that the exercise of an IPR that is legal under national law cannot be scrutinized under EU law. Also it held that requirements for granting the IPR are dealt with at national level, in absence of harmonisation; that the exclusive reproduction is part of the essential function of a copyright and, therefore, that a refusal to licence is not necessarily abusive, even when it comes from a company in dominant position. But it finally added that in exceptional circumstances this refusal may run contrary Article 102 TFEU.

For this reason, in light of Article 3 of Regulation EC no. 17/1962, the Court entrusted the Commission with the task of imposing a compulsory licence on the defendant against the payment of reasonable fees from the plaintiff³⁷⁵.

The Court also refined the concept of '*exceptional circumstances*', where the refusal to licence constituted an abuse of dominant position: firstly, there should not be substitute for the product covered by IPR (i.e. the company enjoys a *de facto* monopoly)³⁷⁶; secondly, there should not be an objective justification to the refusal; finally, the refusal allows the IPR holder to reserve for itself the secondary market³⁷⁷.

³⁷⁴ AG Gulman attempted to define a minimum level of protection of IPRs against competition law, by affirming that the essential function of the IPR, i.e. its subject matter, should have been treated equivalently to its existence. Moreover, he affirmed that even if the product is newer and better, the interest of consumers should not always trump the function of IPR and the right of IPR owners to get a reward for their effort. However, the Court interpreted this suggestion as indicating that the essential function of IPRs is subject to the competition rules. See, Magill, para. 48.

³⁷⁵ See BENABOU, *Droits d'auteur, droits voisins et droit communautaire*, 1997, p. 209, predicting '*des effets particulièrement désastreux*', in fact '*poussée au paroxysme, cette théorie viderait les droits de propriété intellectuelle de leur attrait principal: le droit exclusif. Le droit ... s'apparenterait, au mieux, à un simple droit à rémunération*'.

³⁷⁶ This requirement, i.e. the essentiality of the facility, according to ANDERMAN, *EC Competition Law and Intellectual Property Rights*, cit., p. 212 *et seq.*, remains unclear, because it is not straightforward to distinguish when a product is an essential facility or just a part of another product. Take, for instance, the application for diagnostic software for maintenance purposed included in a hardware: they may be considered integral parts of the same products, or the latter can belong to a separate secondary market for maintenance.

³⁷⁷ See Magill, para. 54.

It should be noted that the Court explicitly said to follow *Volvo* and the criteria set forth there³⁷⁸. Yet, the two rulings appeared to be at odd, because in *Magill* the notion of ‘exercise’ of an IPR was extended to comprise also what previously had been considered to be merely its ‘existence’³⁷⁹.

An important judgement where the *Magill* doctrine was applied was *Oscar Bronner*³⁸⁰.

In *Oscar Bronner*, an Austrian court referred to the ECJ the question whether the refusal by a newspaper group holding a substantial share of the market in daily newspapers to allow the publisher of a competing newspaper accessing its home-delivery network, or to do so only if it purchased from the group certain additional services, constituted an abuse of dominant position contrary to Article 102 TFEU.

The claimant argued that under the doctrine of ‘essential facilities’, the defendant was obliged to allow access to the home-delivery service by competing products and at market prices.

Following the opinion of the AG Jacobs, the Court ruled in favour of the IPR owner. The ECJ established, in fact, that the eventual compulsory licence to access an essential facility should be based on a strict indispensability test. According to the ECJ, the refusal to licence is abusive when the essential facility is indispensable for the claimant to access the downstream market and that without it, it would be out of that market. Furthermore, the claimant should demonstrate that it cannot technically replicate the essential facility or that this is not economically feasible³⁸¹. Absent this condition, the compulsory license cannot be imposed on the IPR owner.

So, according to the Court, in order for an IPR to be an ‘essential facility’, it is necessary that the product covered by such IPR (i) does not have substitutes, i.e. it

³⁷⁸ However, see FLORIDIA and LAMANDINI, *Privative Industriali*, cit., p. 146, affirming that, on the contrary, the rulings reached diametrically opposed conclusions. Similarly see GOVAERE, *The Use and Abuse of Intellectual Property Rights in EC law*, 1996, Section 8.45.

³⁷⁹ See ANDERMAN, *EC Competition Law and Intellectual Property Rights*, cit., p. 14 and 15, claiming that the qualifications of the right of normal exercise of an IPR indicated in *Volvo* where misunderstood and given excessive weight, leading to the outcome in *Magill*. Similarly, FRIDEN, *Recent Developments in EEC Intellectual Property Law*, cit., p. 210, saying that “one should not read too much into them... the Court probably felt obliged to, after having given an example of what was not abusive conduct, to give a few examples of what would be considered as abusive”. Contra FLORIDIA and LAMANDINI, *Privative Industriali*, cit., p. 145 et seq.

³⁸⁰ See ECJ, 26 November 1998, VI Ch, in case C-7/97, *Oscar Bronner GmbH & Co. KG v Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co. KG, Mediaprint Zeitungsvertriebsgesellschaft mbH & Co. KG and Mediaprint Anzeigengesellschaft mbH & Co. KG*.

³⁸¹ See *Oscar Bronner*, para. 41.

confers a monopoly to the owner; (ii) is an indispensable input to another product in a secondary market³⁸². As it appears, the element of the new product was not mentioned³⁸³. This inconsistency in the case law created quite some confusion about the concept of 'exceptional circumstance' in the literature³⁸⁴.

Clarification came with the *IMS* case³⁸⁵. The case concerned a refusal by IMS to grant a licence to its competitor NDC to use part of a copyrighted database, using a brick structure, containing all the information related to the volume of sales of pharmaceutical products in the German market.

The Commission ordered IMS to grant a licence to NDC for the use of the brick structure against the payment of royalties, even if the plaintiff claimed its right to access it without the intention of providing a new product in the market.

The ECJ confirmed that a refusal to grant a licence could amount to an abuse of a dominant position. The ruling further clarified the 'exceptional circumstances', which justify compulsory licensing of intellectual property rights under EU competition law rules: the refusal must prevent the emergence of a new product for which there is potential consumer demand, must be unjustified and must exclude any competition in the secondary market³⁸⁶. The Court also made clear that these circumstances are cumulative³⁸⁷.

For the same reasons, the Court clarified that Article 102 TFEU is applied to refusal to licence IPRs, subject to the tripartite test, only when the conduct relates to a secondary market separated from the primary where the company is dominant.

³⁸² Under US law, the basic elements of a legal claim under this doctrine under United States antitrust law, which a plaintiff is required to show to establish liability, are: 1) control of the essential facility by a monopolist; 2) a competitor's inability to practically or reasonably duplicate the essential facility; 3) the denial of the use of the facility to a competitor; and 4) the feasibility of providing the facility to competitors. The U.S. Supreme Court's ruling in *Verizon v. Trinko* (2004) added a fifth element: absence of regulatory oversight from an agency with power to compel access.

³⁸³ The Court affirmed that the refusal to supply must be likely to eliminate all competition in a downstream market, that it must lack any objective justification, and that the requested input must be indispensable for doing business in the downstream market, because there is no actual or potential substitute to the product.

³⁸⁴ See PRETE, *From Magill to IMS*, in *EBLR*, 2004, p. 1076; GOVAERE, *The use and abuse of intellectual property rights in EC Law*, 1998, p. 149, who considers the definition of the concept of 'exceptional circumstances' as the crucial issue left open by the jurisprudence.

³⁸⁵ See ECJ, 29 April 2004, V Ch., in Case C-418/01, *IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG*.

³⁸⁶ See *IMS*, para. 34-38.

³⁸⁷ Some authors believe that *IMS* has further extended the *Magill* rule. See KORAH, *The Interface between Intellectual Property and Antitrust: the European Experience*, in *AJL*, 2001, p. 825; *contra* see FINE, *NDC/IMS: in Response to Professor Korah*, in *ALJ*, 2002, p. 250.

However, it is sufficient that this second market is just hypothetical and not currently existing. What matters is that two different production stages are identified and that they are interconnected³⁸⁸.

This interpretation also helped find some consistency between *Volvo* and the other cases.

First of all, as it appears from this summary of the ruling, the Court re-introduced the criterion of the new product. According to the Court this requirement was necessary to balance the economic freedom of the copyright holder with the interest of free competition. This, according to AG Tizzano, explains why the Court ruled differently in *Volvo*: in that case, the plaintiffs were merely replicating the car body panels, without providing a new product³⁸⁹. Allowing such 'copying' from rivals would greatly undermine inventors' incentives to innovate. The development of a new product, instead, places competitors in a different market, without that the inventor is exposed to direct rivalry from them. In this case, incentive to innovate are protected enough and further restrictions to competition are not justified.

Secondly, whilst *Volvo* pertained to the exclusive use of the IPR in the market where the IPR holder was dominant, the three cases applying the 'essential facility doctrine' were about the use of IPRs to leverage the dominant position in a second market³⁹⁰.

From this brief overview, it appears that, although IPRs are granted a higher standard of protection than other forms of property under European competition law, they do not enjoy an *a priori* blank cheque. The case law clearly indicates that the enforcement of EU competition law should safeguard innovation incentives, but this cannot justify a suppression of competition that is unnecessary for this purpose.

³⁸⁸ See the opinion of the AG Tizzano at para. 40-45.

³⁸⁹ See the opinion of the AG Tizzano at para. 65.

³⁹⁰ This triggered a very intense debate in the literature. For criticisms see STAMATOUDI, *The hidden agenda in Magill*, in *JWIP*, 1998, p. 161; VAN DER WAL, *Article 86 EC: the limits of compulsory licensing*, in *ECLR*, 1994, p. 232; SUBIOTTO, *The right to deal with whom one pleases under EEC competition law: a small contribution to a necessary debate*, in *ECLR*, 1992, p. 239; REINDL, *The Magic of Magill: TV Program Guides as a Limit of Copyright Law?*, in *IIC*, 1993, p. 60; *Contra*, and favourably to the ruling see VINJE, *The final word on Magill*, in *EIPR*, 1995, p. 297.

Altogether, it thus appears that innovation as such cannot be a policy objective under EU competition law³⁹¹.

5. The early case law on parallel trade

The principles that the European Courts and the Commission have been developing in the effort of reconciling IPRs with competition law have provided the legal guidance that helped the Courts and the Commission in shaping the policy towards parallel trade.

5.1 *Export bans and other indirect obstacles to exports*

The relevant case law under Article 101 TFEU mainly deals with agreements containing export bans and similar clauses, like dual pricing, that confer absolute protection to authorised distributors from parallel imports.

Dual pricing clauses consists of a two-tier price model where two different prices are applied to the same good depending on its final destination. If the drug is distributed in the domestic market, a lower price is set; *vice versa*, a higher price is applied if the drug crosses the border. In this way, the price differential between the low-priced country and the high-priced country automatically disappears, together with the economic incentive to trade for the parallel distributors.

In this sense, it could be thought of dual pricing as a form of geographical price discrimination. However, dual pricing automatically eliminates or drastically reduces the price differential between the low-priced country and the high-priced country, thereby discouraging intermediaries to enter the importing markets. It follows that, being an indirect disincentive to trade across the borders, dual pricing actually has the same effects as an explicit prohibition to export³⁹².

³⁹¹ This approach appears to be remarkably different from what applied in US, where there is a reverting trend in the assessment of IPRs in the context of monopolization provisions. For instance, see *Verizon Communications Inc v Law Offices of Curtis V Trinko, LLP*, 540 US (2004), where the US Supreme Court criticised antitrust infringements consisting in a mere refusal to deal. See para. 11 of the *Trinko* decision, where the Court stated: “Compelling such firms to share the source of their advantage is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities.” For a comparison of the EU and US systems on this point see Section 4 in Chapter IV.

³⁹² See the Commission decision *Gosme-Martell*, cit., where the Commission found that the elimination of the usual discount system applied to customers by the manufacturer *de facto* rendered export more expensive and equated it to an export ban; similarly, see in particular the Commission decision *Pittsburgh Corning*

By applying a higher price for goods intended for export, the manufacturer *de facto* raises its competitors' costs³⁹³. In fact, the price at which wholesalers purchase products from the manufacturer constitutes their marginal cost (always provided that repackaging and shipping costs are small). The higher price applied to exports increases this marginal cost up to a point where export is economically less interesting or impossible.

As a result, intermediaries lose their price advantage necessary to penetrate the foreign market, and the manufacturer ensures that no competitor having lower costs enters the importing markets, thereby contending its market share.

The enforcement of this pricing policy is also easier than an export ban: the indirect influence of the economic conditions of transactions automatically renders intrastate trade economically uninteresting and thus it does not require the establishment of monitoring devices³⁹⁴.

On the one hand, dual pricing restricts the economic opportunities available to other agents as a result of the establishment of the internal market, whereas, on the other hand, it allows the manufacturer to seal off the market of origin for exports and to protect the destination markets.

In the European context, these effects clearly represent a concern, as they lead to the restoration of trade barriers along national borders, thereby holding up the economic interpenetration that the Treaty intends to bring about. In other words, they frustrate the policy goal of internal market integration, which constitutes one of the 'constitutional'

Europe, cit., the increase of Belgian wholesale prices of 40% aimed at impeding re-importation into Germany was considered to be anticompetitive by the Commission, which explicitly drew up an analogy between *export bans* and *dual pricing systems*, having the former the same effects as the latter on parallel trade. There is also a clear parallelism – not mentioned by the GC – between the *Glaxo* case and the previous *Sandoz* case. In that occasion, the ECJ established that sending invoices to wholesalers with the wording 'export prohibited' constitutes a vertical agreement capable of hindering competition under Art. 101 TFEU. See ECJ, C-277/87 *Sandoz v. Commission*, cit., para. 13, and also ECJ, 15 July 1970, in case C-41/69, *ACF Chemiefarma NV v Commission of the European Communities*, para. 12.

³⁹³ From this point of view, dual pricing can represent a preferable alternative to price war, as it has the advantage of avoiding profit reduction and sacrifice of financial resources. See SALOP and SCHEFFMAN, *Raising Rivals' Cost*, in *American Economic Review*, 1983, no. 73(2), p. 267-271.

³⁹⁴ Similarly, in *Distillers*, cit., the Commission considered the non-applicability of price allowances on spirits for export and the application to the same customers of different prices for spirits for export and for spirits for United Kingdom consumption a more efficient way to discourage export than direct export bans. See point 2 of the cited decision.

objectives of the European Union³⁹⁵.

For this reasons, all agreements entailing absolute market protection from imports are considered as running against Article 101(1) TFEU in their object.

The counterargument traditionally adduced to justify the existence in an agreement of a clause of absolute protection rests on the need to protect the authorised distributors from competition and to spur the entry of a new product in a market, i.e. to foster *interbrand* competition³⁹⁶. However, both the Commission and the European Courts have repeatedly refused this argument, by opposing that allowing parallel imports to erode price differentials was not capable of endangering the market position of authorised distributors. They both believed, in fact, that such competition would just induce more competitive prices from the originator, which would prevent importations in the first place and at the same time help the authorised distributors to gain the market.

5.1.1 *The Commission practice*

Such approach has been constantly re-affirmed and almost never suffered exceptions in the Commission practice. According to the Commission, all types of territorial restriction that impedes parallel trade, also in the forms of passive sales³⁹⁷, are hardcore restrictions that fall outside the Commission's block exemption regulation on vertical restraints and do not meet the requirements of Article 101(3) TFEU³⁹⁸.

³⁹⁵ In *Consten and Grundig*, p. 518, the Court recalled that the Treaty aims at suppressing barriers to trade among Member States and that, in various provision contained therein, it harshly prohibits their restoration.

³⁹⁶ See, among many, BORK, *The Rule of Reason and the Per Se Concept: Price Fixing and Market Division*, in *Yale L. J.* 775, 1965, no. 74(Part I), p. 775; COMANOR, *Vertical Territorial and Customer Restrictions: White Motor and its Aftermath*, *Harv. L. Rev.*, 1968, no. 81, p. 1419. For further references see *infra* Section 1.1.1 in Chapter V.

³⁹⁷ Passive sales are sales in response to unsolicited requests from individual customers including delivery of goods or services to such customers. Sales generated by general advertising or promotion in media or on the Internet that reaches customers in other distributors' exclusive territories or customer groups, are normally considered passive. On the contrary, active sales are sales made by actively approaching individual customers inside another distributor's exclusive territory or exclusive customer group by for instance direct mail or visits, or by actively approaching a specific customer group or customers in a specific territory allocated exclusively to another distributor through advertisement in media or other promotions specifically targeted at that customer group or customers in that territory, or by establishing a warehouse or distribution outlet in another distributor's exclusive territory. Clauses limiting a distributor's right to sell actively into another distributor's territory are usually part of exclusive distribution networks and can benefit from the block exemption for vertical agreements. See Commission Regulation 2790/99 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices (OJ L 336, 22.12.1999), Commission Notice - Guidelines on Vertical Restraints (OJ C 291, 13.10.2000).

³⁹⁸ See for instance the Commission decision no. 2003/675/EC of 30 October 2002, COMP/35.587 PO Video Games, COMP/35.706 PO Nintendo Distribution and COMP/36.321 Omega – Nintendo at para. 338: "it is well established in the case-law of the Court of Justice [...] that enhancing the exclusivity granted by virtue of distribution agreements, to a state of absolute territorial protection, by completely prohibiting distributors from making

For instance, *Distillers*³⁹⁹ and *Gosme Martell*⁴⁰⁰ are cases where companies implemented various forms of dual pricing: price allowances, rebates and discounts were granted exclusively for products resold and consumed in the domestic market. Parallel traders, not only were not given the discounts granted to other distributors, but they were also explicitly prohibited to export products bought in the domestic market from being exported to another EU Member State.

The European Commission affirmed that these pricing strategies amounted to an indirect export prohibition, which was likely to affect trade between Member States. This was considered capable of causing an artificial partition of the market along national borders and likely to hinder the establishment of the single market among Member States.

Accordingly, those price allowances constituted an infringement by object of Article 101(1) TFEU.

On the same grounds, in *Moët et Chandon*⁴⁰¹, the European Commission condemned a clause establishing a price list for champagne valid only for consumption in United Kingdom but not for consumption outside that territory, as a restriction by object.

Also this price strategy was considered tantamount to a ban on exports. The Commission considered that both the object and effect of this clause was to restrict competition within the common market. The clause was designed to prevent, and did prevent, the firm's customers in the United Kingdom and persons subsequently buying champagne from them, from reselling champagne in other European countries and hence from competing with resellers in those countries.

any sales outside the territories assigned to them or from selling to customers who intend to export, is not indispensable to realise the potential benefits of an exclusive distribution system. Instead, in regard to the goods in question territories are hermetically sealed off, making interpenetrating of national markets impossible, thereby, bringing to nought economic integration".

³⁹⁹ See the decision of the Commission 78/163/EEC in case IV/28.282 — *The Distillers Company Limited — Conditions of sales and price*.

⁴⁰⁰ See the decision of the Commission 91/335/EEC in case IV/32.186 — *Gosme-Martell — DMP*; similarly see the decision 72/403/EEC in cases IV/26.894, 26.876 and 26.892 — *Pittsburgh Corning Europe — Formica Belgium — Hertel*, where a fine was imposed on a firm that required its distributors to charge different prices according to the destination of the goods, thereby trying to protect the German market from lower priced parallel imports.

⁴⁰¹ See the decision of the EU Commission 82/203/EEC in case IV/30.188 — *Moët et Chandon (London) Ltd*, where the Commission qualified a clause which established a price list for champagne valid only for consumption in United Kingdom but not for consumption outside that territory, as a restriction by object.

It is interesting to note that in that case the Commission underlined that the alleged shortage and the measures taken to deal with it could not justify the deprivation of UK buyers of the possibility of reselling in other countries of their choice products released on to the UK market by the defendant⁴⁰².

5.1.2 The case law

The Commission practice has generally received the support of European Courts, which considered restrictions to parallel trade as a 'mortal sin' going against the goal of market integration⁴⁰³.

Nevertheless, the original approach taken in *Consten and Grundig* has been subsequently qualified by the European Courts, which, already from *Société Technique Minière*⁴⁰⁴, interpreted Article 101 TFEU in a less strict way⁴⁰⁵ and developed the *de minimis* doctrine⁴⁰⁶. Still, plenty of cases on parallel trade, where conditions to apply the *de minimis* Notice were lacking, have been decided on the grounds built by the mentioned *grand arrêt*.

In *BMW*⁴⁰⁷, the ECJ established that when the importer of a given product invited dealers established in the same Member State to subscribe to an agreement whereby they undertake not to re-export the said product, and that agreement is in fact concluded, there is an infringement of Article 101(1) TFEU.

⁴⁰² The issue of shortages recurs in the case law on parallel trade, in particular in the new cases in the field of pharmaceutical. See better *infra* Section 6 of this Chapter.

⁴⁰³ This principle has been firmly upheld by the Community Courts in all cases, and especially by the GC, 9 July 1994, in case T-43/927, *Dunlop Slazenger International Ltd v Commission of the European Communities*; by the ECJ, 21 September 2006, in case C-167/04 P, *JCB Service v Commission of the European Communities*; GC, 30 April 2009, in case T-13/03 *Nintendo Co., Ltd and Nintendo of Europe GmbH v Commission of the European Communities*.

⁴⁰⁴ See ECJ, 30 June 1966, in case C-56/65 *Société Technique Minière (L.T.M.) v Maschinenbau Ulm GmbH (M.B.U.)*.

⁴⁰⁵ The better understanding of economic theory about the functioning of vertical agreements contributed to convey the consideration of pro-competitive effects of exclusive license agreements (among other agreements) into the antitrust assessment. This raised the question of whether there exists a rule of reason in Art. 101(1) TFEU. For a deeper discussion of this issue see Chapter IV and V.

⁴⁰⁶ The *de minimis* doctrine was elaborated by the ECJ in the case C-5/69 *Volk v. Vervaecke* and then 'codified' in the *de minimis* Commission Notice exempting from the application of Art. 101 TFEU those agreements where joint market share of parties does not exceed the threshold of 15%. See better *infra* Section 3.2.1 Chapter V.

⁴⁰⁷ See ECJ, 12 July 1979, in case C-32/78, *BMW Belgium SA and others v Commission of the European Communities*.

In *General Motors*⁴⁰⁸, the defendant was pursuing a policy of systematically obstructing exports of new vehicles from the Netherlands to other Member States. The corporate strategy comprised, *inter alia*, a restrictive bonus policy excluding export sales to final consumers from retail bonus campaigns, and an indiscriminate direct export ban.

The ECJ recalled that previous case law already established that an agreement concerning distribution has a restrictive object for the purposes of Article 101 TFEU if it clearly manifests the will to treat export sales less favourably than national sales and thus leads to the partitioning of the internal market in question. Such an objective could be achieved not only by direct restrictions on exports but also through indirect measures, such as the implementation by a manufacturer in its dealership contracts of a measure excluding export sales from the system of bonuses granted to dealers. Such restrictions are, in fact, capable of influencing the economic conditions of such transactions.

In *Volkswagen*⁴⁰⁹, the ECJ maintained that the implementation by a manufacturer of a policy of imposing supply quotas on dealers with the aim of restricting re-exports is not a unilateral act but rather an agreement within the meaning of Article 101(1) TFEU, inasmuch as the manufacturer, for the purpose of imposing that policy, uses clauses in the dealership contract, such as the restriction of supplies to dealers and, in so doing, influences the business conduct of the latter.

The Court also affirmed that those concerted practices constituted an infringement of Article 101(1) TFEU, since they represent the implementation of a market-partitioning policy⁴¹⁰.

The *Sandoz*⁴¹¹ case represents, in the present context, an important ruling where the ECJ dealt with an export ban applied by pharmaceutical manufacturers to

⁴⁰⁸ ECJ, 13 November 1975, in case C-26/75, *General Motors Continental NV v Commission of the European Communities*.

⁴⁰⁹ ECJ, 8 September 2003, in case C-338/00, *Volkswagen AG v Commission of the European Communities*. See also the decision of the Commission 98/273/CE, 28 January 1998, in case IV/35.733 D VW- Audi/Volkswagen, para. 210, where it is stated that “the obstruction of parallel exports of vehicles by final consumers and of cross deliveries within the dealer network hampers the objective of the creation of the common market, a principle of the Treaty, and is already for that reason to be classified as a particularly serious infringement”.

⁴¹⁰ The Court also explained that those measures were not covered by Regulation No. 123/85 and Regulation No 1475/95, since no provision of those regulations exempts an agreement which aims to prevent parallel exports by final consumers, by intermediaries acting on their behalf or by other dealers in the dealer network. It also stated that an individual exemption could not be granted in the present case, since the applicants did not notify any aspect of their agreement with the dealers, and that in any event the barriers to re-exportation were at variance with the objective of consumer protection set out in Article 101(3) TFEU.

wholesalers. In this case, the manufacturer systematically dispatched to his dealers invoices bearing the words “*export prohibited*”.

Both the Commission and the Court considered this behaviour a signal of the fact that the manufacturer was seeking the cooperation of wholesalers in order to reduce parallel trade of products from Italy to other European countries. This, according to the ECJ, again constituted an agreement prohibited by Article 101(1) TFEU, and not a unilateral conduct, because it formed part of a set of continuous business relations governed by a general agreement drawn up in advance. Such agreement was based on the consent of the supplier to the establishment of business relations with each customer prior to any delivery and the tacit acceptance by such customers of the conduct adopted by the supplier in their regard, which was attested by renewed orders placed without protest on the same conditions.

On this basis, the defendant policy was condemned as contrary to Article 101 TFEU, because of the effect of market compartmentalization.

Interestingly, subsequent case law, which will be the object of analysis of the present work, dealing substantially with the same issues, albeit in different contractual forms, followed a different approach, both with regards to the issue of the elements constituting an agreement⁴¹² and of the object of a pricing policy that by definition has market partitioning purposes⁴¹³.

5.2 *Unilateral conducts restricting parallel trade*

The case law under Article 102 TFEU is much less abounding. However, the cases ruled by the ECJ represented milestones for the development of subsequent jurisprudence.

5.2.1 *The case law under Article 102(d) TFEU*

One strand of the case law related to situations where manufacturers refused to supply some distributors, who were engaging in exporting activities, and for this reason

⁴¹¹ See ECJ, VI ch., 11 January 1990, in case C-277/87, *Sandoz prodotti farmaceutici SpA v Commission of the European Communities*.

⁴¹² See ECJ, full court, 6 January 2004, in joined cases C-2/01 e C-3/01 *BAI v Bayer and Commission of the European Communities*. See better *infra* next Section.

⁴¹³ See GC, IV Ch., ext. composition, 27 September 2006, in case T-168/01 *GlaxoSmithKline Services Unlimited v Commission of the European Communities*. See better *infra* Section 6.

were considered an abuse of dominant position and prohibited under Article 102(d) TFEU⁴¹⁴.

The refusal to deal with competitors, in fact, might pose antitrust concerns, when a company refuses to provide a customer with a good or a service in the upstream market where it holds a position of dominance. The good or service in question is an input necessary for entering the downstream market, where the dominant company wishes to enter and where the customer, previously operating there, can be a competitor. By foreclosing access to rivals in the downstream market, the dominant company can charge prices unrestrained by competition and expand its market power.

EU Courts and the Commission commonly reject the notion that a dominant company has *always* the obligation to deal with rivals⁴¹⁵. Generally, companies enjoy the freedom to choose their trading partners. However, this rule is subject to an exception and a duty to supply could be imposed where the refusal would ‘*eliminate all competition*’ in the downstream market, *i.e.* when the exclusionary effect caused by the conduct results in the creation of a monopoly downstream⁴¹⁶.

The concerns of the Commission and the European Courts about the refusal to deal opposed by dominant companies to competitors arises because this conduct might give rise to leveraging, *i.e.* the attempt to extend market power from an ‘upstream’ into a ‘downstream’ product market⁴¹⁷.

⁴¹⁴ See GC, 10 July 1990, in case T-64/89, *BPB and British Gypsum v. Commission*, para. 69.

⁴¹⁵ See, for instance, the Commission decision 7/500/EEC of 29 July 1987, IV/32.279 - *BBI/Boosey & Hawkes: Interim measures*, where it was affirmed that a dominant company is not expected to subsidize competitors and it would be even entitled to review its commercial ties with a customer that turned to be competitor with a view of terminating “any special relationship”. See also in US, where Courts explicitly rejected the idea that a company always has a duty to deal with rivals. See *United States v. Colgate & Co.*, 250 U.S. 300, 333 (1919) (a business is generally free to deal with whomever it chooses so long as that conduct is “*in the absence of any purpose to create or maintain a monopoly*”); *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601-03 (1985); *American Key Corp. v. Cole National Corp.*, 762 F.2d 1569, 1578 (11th Cir. 1985) (the “*antitrust laws do not compel a company to do business with anyone*”).

⁴¹⁶ Cf. the opinion of AG Jacobs on *Syfait I* at para. 66.

⁴¹⁷ See ECJ, 6 March 1974, in joined cases C-6-7/73, *Istituto Chemioterapico Italiano S.p.A. and Commercial Solvents Corporation v Commission of the European Communities*, where the world monopolist in the production and commercialisation of the raw material nitropropane refused to supply a customer, producer of ethambutol, for which this raw material was a necessary input. The refusal allowed the dominant company to monopolise the downstream market for the production and distribution of ethambutol, since the only competitor was forced out of the market. For this reason, the conduct was considered abusive by the ECJ. Similarly, in *Telemarketing*, the ECJ stated that an abuse is committed when a dominant undertaking, without any objective necessity, reserves for itself a secondary activity in another market, which was carried out by another undertaking. See ECJ, V Ch., 3 October 1985, in case C-311/84, *Centre belge d'études de marché*

Differently from the cited landmark case, in a parallel trade case, the effect of the exclusionary behaviour on competition at the downstream level may have two dimensions: in the export market and in the import markets.

With regards to the export market, the refusal to supply a number of wholesalers is likely to put them at competitive disadvantage *vis-à-vis* others distributors, who continue to receive goods and therefore become the only suppliers capable of satisfying pharmacists' purchase orders. Such differential treatment potentially has the effect of both rendering the supply distribution chain partially foreclosed inside the export market and restricting, if not eliminating, competition among wholesalers.

In addition, the supply restraints are also capable of generating distortions outside the export market. Having been denied deliveries, wholesalers who would engage in export activities lose, in whole or in part, the possibility to supply the import markets. Therefore, the conduct potentially results in a restriction of trade flows between the exporting country and the importing countries.

This type of exclusionary conduct not only has a negative effect on the availability of products in importing countries, but also significantly restricts price competition in that market.

First of all, with a lower stock at their disposal, exporters are forced to charge higher prices than would otherwise have been the case, absent the restrictions on supply⁴¹⁸. As a result, their efficiency in the market is likely to be impaired: by having supply quantities restricted, they lose their competitiveness *vis-à-vis* the authorised distributors.

Furthermore, when foreclosure is total, the manufacturer is able to (indirectly) reserve for itself the distribution in the export market. It follows that, when the manufacturer has a dominant position in relation to a specific product in the export market, it might be able to extend it also to the importing countries, absent the presence of any effective substitute. Free from any price competition, the dominant company

- *Télémarketing (CBEM) v SA Compagnie luxembourgeoise de télédiffusion (CLT) and Information publicité Benelux (IPB)*, para. 25-27.

⁴¹⁸ The concept of 'elimination of all competition' does not necessary imply complete foreclosure of competitors. It might suffice to prevent them to maintain their economies of scale, thereby hampering their efficiency. See ELHAUGE, *Defining Better Monopolisation Standards*, in *Stanford Law Review*, 2003, no. 56, p. 321; SALOP and SCHEFFMAN, *Rising Rivals' Costs*, *American Economic Review*, 1983, no. 73, p. 267.

faces no constraint on its market power and it is able to charge higher prices than it would in presence of parallel trade.

Therefore, consumers in importing countries suffer a direct harm, because they become unable to purchase a cheaper variant of a given product, and an indirect harm, since they are left with no choice but to buy it from authorised distributors at a higher price⁴¹⁹.

For this reason, in *BPB*, the company was found to have infringed Article 102 TFEU by granting rebates to plasterboards merchants in a given Member State in response to a threat from a group of merchants to sell plasterboards imported from another Member State at lower prices. The GC held that the rebates were not directed at meeting competition but at strengthening BPB's dominance and abusing it, because the conduct was likely to affect the structure of the market where, as a consequence of the presence of BPB, competition was already weakened⁴²⁰.

This analysis has been replicated in *General Motors*, where the ECJ has held that a practice by which an undertaking in a dominant position aims at restricting parallel trade in the products that it puts on the market constitutes abuse of that dominant position, particularly when such a practice has the effect of curbing parallel imports by neutralising the more favourable level of prices which may apply in other sales areas in the EU⁴²¹.

In *United Brands*, the Court affirmed that the fact that an undertaking is in a dominant position cannot disentitle it from protecting its own commercial interests if they are attacked, and that such an undertaking must be conceded the right to take reasonable steps to safeguard the said interests⁴²². However, this does not entitle it to stop supplying a long-standing customer who abides by regular commercial practice, because its effect on the market are disproportionate with the goal that such measures are deemed to attain. The ECJ, thus, was prepared to tolerate sanctions towards parallel

⁴¹⁹ See ECJ, 21 February 1973, in case C-6/72, *Europemballage Corporation and Continental Can Company Inc. v Commission of the European Communities*, where it was affirmed that the concept of abuse encompasses both direct and indirect harm to consumers. Indirect harm occurs as a result of restrictions on effective competition, such that 'only undertakings remain in the market whose behaviour depends on the dominant one'. Similarly in US law 'a monopolist's act must have an "anticompetitive effect." That is, it must harm the competitive process and thereby harm consumers.' (*U.S. v. Microsoft Co.*, 253 F.3d 34, 346 U.S. App. D.C. 330, p. 23).

⁴²⁰ See *BPB*, para. 69.

⁴²¹ See *General Motors*, para. 12.

⁴²² See *United Brands*, para. 189.

traders when appropriate and suitable to the threat suffered. So for instance, the Court was willing to justify a drastic reaction from the dominant undertaking only if the orders placed by that customers were in no way out of the ordinary⁴²³.

5.2.2 The case law under Article 102(c) TFEU

The other strand of the case law focuses on discriminatory practices prohibited by Article 102(c) TFEU. The landmark case is constituted by above mentioned *United Brands*, where a producer of bananas charged widely different prices to its distributors in different Member States according to the destination of the bananas, although they were sold in the same two ports (Rotterdam and Bremerhaven). Also, it imposed on wholesalers a clause in its general sale conditions whereby it was prohibited to resell bananas when still green. Finally, it systematically refused to supply one of its customers.

The European Commission considered *United Brands'* conducts an abuse of dominant position within the meaning of Article 102 (b) and (c) TFEU.

First, the application of different prices to distributors was considered abusive, because it discriminated among them (*read*: it applied different conditions to similar transactions), with the effect of eliminating a competing trading party from the relevant market (Article 102 TFEU, letter c))⁴²⁴, i.e. it caused as a second-line injury⁴²⁵.

Second, the clause prohibiting the resell of bananas while green had the effect of reducing a lot the period where trade was possible, because bananas are perishable products. Therefore, this clause was found to have similar effects to a prohibition of exports.

The European Commission, thus, believed that, all together, these clauses rendered trade among Member State practically impossible, thereby partitioning

⁴²³ The Court indicated that a proportionality principle was a constituent element of the necessity test. See ECJ, 14 February 1978, in case C-27/76, *United Brands Company and United Brands Continentaal BV v Commission of the European Communities*, para. 139.

⁴²⁴ See *United Brands*, para. 225. The principle has also characterised the approach of Community Courts to discriminatory rebates, starting from *Hoffmann-La Roche*. Courts have traditionally considered discounts not abusive if they are based on quantities purchased. See, for instance, ECJ, 30 September 2003, in case T-203/01, *Manufacture française des pneumatiques Michelin v. Commission of the European Communities (Michelin II)*.

⁴²⁵ Second-line injuries cause distortions of downstream competition, due to the discrimination operated by the dominant company towards its customers, i.e. by imposing on them differential conditions, although transactions are commercially similar. Primary-line injury prejudices competitors of the dominant company and therefore has exclusionary effects.

national markets. Such an effect was further increased by the mentioned supply restriction policy adopted by United Brands.

These practices were considered by the Commission as functional to enabling the manufacturer to control the entire marketing of its product. This indirectly strengthened and consolidated the manufacturer's dominant position.

The ECJ upheld the analysis of the Commission almost entirely⁴²⁶ and affirmed that the 'green bananas' clause was abusive. It affirmed that the policy of differing prices created a rigid partitioning of national markets at the level of prices and enabled the defendant to apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage, was an abuse of dominant position.

The reasoning of the Court raised in the literature several questions about the legitimacy of price differences when the product is sold in different product markets or in different geographic areas⁴²⁷.

From the analysis of the case law, it appears that neither the Commission nor the European Courts are pursuing a policy aimed at equalizing prices across markets. On the contrary, even a dominant company can charge different prices in different product markets when different conditions, like price elasticity, transport cost, taxes, etc., allow it. In fact, the Court several times affirmed that a dominant company is entitled to charge what the market can bear provided that this complies with the rules of the internal market⁴²⁸. In fact, price discrimination alone fosters intra-EU trade and for this reason it cannot be considered in itself unlawful under EU competition law.

Indeed, *United Brands'* conduct did not upset this principle, given that distributors were operating in different markets. Thus, the discriminatory commercial

⁴²⁶ The Court only disagreed with the Commission about the allegation of excessive prices, because it found the findings of the comparative test used by Commission to be incorrect. The Court, in fact, held that comparison of prices can be used but should be based on adequate evidence that lower prices actually cover costs. See *United Brands*, para. 302.

⁴²⁷ See SPRINGER, Borden and *United Brands revisited*, in *ECLR*, 1997, p. 42 and 44.

⁴²⁸ See *United Brands*, para. 228. See also *Deutsche Grammophon*, summary, para. 7, where the ECJ held that "the difference between the controlled price and the price of the product re-imported from another Member State does not necessarily suffice to disclose an abuse [within the meaning of Article 82]"; *Hoffmann-la Roche*, para. 28, where the Court affirmed that if a product can be used for different purposes in accordance with different needs, then relevant market are separate and different prices are justified. On this basis, FRIDEN, *Recent Developments in EEC Intellectual Property Law*, cit., p. 211, affirms that price discrimination should be out of the scope of Art. 102(c) TFEU.

conditions were not capable of putting some of the distributors in a competitive disadvantage with respect to others.

However, the Court saw in that practice an abuse, because it believed it had a discriminatory effect and it was capable of reintroducing barriers to trade.

Still, the market partitioning effect did not come from the price discrimination itself but from the 'green banana' clause⁴²⁹.

But the Court affirmed that it was the involvement of the dominant firm in the local market downstream, where it does not actually bear any risk of competition and consumer choice, that provided indicia for the finding of abuse. In simple words, according to the ECJ, *United Brands* was extending the dominant position enjoyed upstream to the market downstream⁴³⁰.

The literature commenting the early case law on pricing abuses criticised this approach for not taking into account the teaching of the economic theory about the possible welfare-enhancing effect of price discrimination⁴³¹. Still, the landmark principles that have shaped the case law have been constantly re-affirmed by European Courts.

6. New cases on parallel trade of pharmaceuticals: a *revirement*?

After having pursued for almost forty years a policy aimed at protecting and encouraging parallel trade⁴³², through the firm prohibition of corporate conducts that restrict exports, European Courts have recently questioned the legal principles

⁴²⁹ ANDERMAN, *EC Competition Law and Intellectual Property Rights*, cit., p. 239, correctly notes that the clause impeding parallel trade was actually the one relating to green bananas. Therefore the Court could have struck only that clause leaving the discriminating pricing policy intact. Similarly, WAELEBROEK, *Price Discrimination and Rebate Policies under EU Competition Law*, in *Fordham Corp. Law Inst.*, 1995, p. 154; SIRAGUSA, *The Application of Article 86 to the Pricing Policies of Dominant Companies: Discriminatory and Unfair Prices*, in *CMLR*, 1979, no. 16, p. 179.

⁴³⁰ See *United Brands*, para. 229.

⁴³¹ It is largely claimed that, although it would have been possible to give an economic interpretation of Art. 102, lett c), TFEU, in order to seek for a competitive explanation of the rebates, the provision has been applied rather formalistically. See ZANON, *Price Discrimination under Article 86 of the EEC Treaty: a Comment on the UBC Case*, in *International and Comparative Law Quarterly*, 1982, no. 31, p. 36; WAELEBROEK, *Price Discrimination and Rebate Policies under EU Competition Law*, in *Fordham Corp. Law Inst.*, 1995, p. 147, at 148. For further economic references and a deeper discussion about the welfare effects of price discrimination see *infra* Section 2.1 and 2.2 in Chapter III.

⁴³² See ECJ, V ch., 16 January 1992 in case C-373/90 *Criminal Proceeding against X*, where the Court explained the rationale of this policy by affirming that "parallel imports enjoy a certain protection in Community law because they encourage trade and help reinforce competition".

underpinning such a policy with specific regard to their application to the pharmaceutical sector.

6.1 *New cases under Article 102 TFEU: the Syfait saga*

This *revirement*, which stems from the economic-oriented approach advocated within the ongoing process of so-called ‘modernization of EU competition law’⁴³³, started with the mentioned judgment delivered in the *Adalat* case.

In that occasion, both the GC, before, and the ECJ, after, have indirectly ruled in favour of quantity restrictions imposed by Bayer on Spanish and French pharmaceutical distributors. In fact, both European Courts qualified these restrictions as unilateral conduct rather than an export ban falling within the scope of Article 101 TFEU and, in so doing, they reversed the Commission’s decision on this specific issue and dissented from previous jurisprudence⁴³⁴.

But most importantly, according to some commentators, the GC suggested in seemed to suggest that the application of Article 101 TFEU should not bear strong market integration overtones⁴³⁵.

Such shift of the attitude towards parallel trade can be also mapped out of the opinion of the Advocate General in a reference request made by the *Epitropi*

⁴³³ Many commentators consider the application of Article 102 TFEU from the Commission and the Courts to be too formalistic, following the heritage of the ordoliberal theory, and little in line with economic theory. See GYSELEN, *Rebates: Competition on the merits or exclusionary practices?*, in EHLERMANN and ATANASIU, *The European Competition Law Annual 2003: What is an Abuse of a Dominant Position?*, 2003, p. 287; FOX, *Abuse of Dominance and monopolization: how to protect competition without protecting competitors*, in EHLERMANN and ATANASIU, *The European Competition Law Annual 2003: What is an Abuse of a Dominant Position?*, 2003, p. 69; FOX, *We protect competition, you protect competitors*, in *World Competition*, 2003, p. 149; AHLBORN and PADILLA, *From Fairness to Welfare: Implications for the Assessment of Unilateral Conduct under EC Competition Law*, presented at EUI for the Twelfth Annual EU Competition Law and Policy Workshop. *A Reformed Approach to Article 82 EC*, 2007; and finally see also the GCLC *Research Papers on Article 82 EC*, 2005.

⁴³⁴ The concept of ‘agreement’ has been extensively interpreted by the ECJ, which inferred its existence indirectly through the analysis of parties’ behaviour, even in absence of written formalities. For instance, the existence of an agreement has been often based on factual circumstances, like the commercial relationship existing between the parties. Accordingly, the ECJ considered the invoices, sent by the manufacturer to wholesalers, bearing the wording ‘export prohibited’, as *indicia* of the existence of an implicit agreement aimed at impeding parallel trade, to be integrated in the existing commercial relationship. See *Sandoz*, para. 13; ECJ, 15 July 1970, in case C-41/69 *ACF Chemiefarma NV v Commission of the European Communities*, para. 12.

⁴³⁵ I refer here to para. 179 of the *Adalat* ruling in the first instance, where the Tribunal affirmed “it is not open to the Commission to attempt to achieve a result, such as the harmonisation of prices in the medicinal products market, by enlarging or straining the scope of Section 1 (Rules applying to undertakings) of Chapter 1 of Title VI of the Treaty”. VENIT and REY, *Parallel Trade and Pharmaceuticals: a Policy in search of itself*, in *ELR*, 2004, no. 29, p. 154, where the in fn 6 they write that the GC was, with these *dicta*, rejecting an aggressive enforcement policy favouring market integration at all costs.

Antagonismou (i.e. the Greek Competition Commission)⁴³⁶, the '*Syfait I*' case, on refusal to supply.

The AG Jacobs argued, in open contrast with mentioned prior case law under Article 102 TFEU, that a pharmaceutical company does not necessarily abuse its dominant position if it refuses to supply wholesalers in order to protect its commercial interests (*read*: its incentive to innovate) from parallel trade. More specifically, the AG sought for a justification to the abusive conduct based on the efficiency gains deriving by the latter. He claimed, following the defendant's allegations, that the impediment to parallel trade would have allowed the company to recoup money that could be devoted to R&D, thereby providing the possibility to pursue new projects that could lead to the discovery of new and better drugs.

Echoes of this new approach can also be observed at national level. For instance, the French *Conseil de la Concurrence* in its decision n. 05-D-72 of the 20th December 2005 held that pharmaceutical laboratories do not abuse their dominant position when they restrict or refuse deliveries of medicinal products to exporters⁴³⁷.

Nevertheless, the issue of whether supply management strategies specifically designed to hamper parallel trade on pharmaceuticals are legitimate or not is still far from clear from a legal standpoint. Indeed, while significantly departing from the traditional case law, the outcome of the aforementioned cases does not help to identify clear guidance for handling future cases.

Indeed, in the *Adalat* ruling the ECJ focused its reasoning on the issue of the 'concurrence of wills' when discussing the possible existence of an agreement restrictive of competition⁴³⁸. Unfortunately, it did not consider the legal status of supply quotas under EU competition law.

The ECJ dismissed *Syfait I* on procedural grounds since the Greek Competition Authority was not deemed to be a 'Tribunal' within the wording of Article 267 TFEU.

⁴³⁶ See ECJ, 31 May 2005, in case C-53/03, *Reference for a preliminary ruling from the Epitropi Antagonismou in Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and Others*.

⁴³⁷ The *Conseil* with its subsequent decision n. 07-D-22 of 5 July 2007 also accepted the quota system proposed by several pharmaceutical companies to rationalize distribution in the French market.

⁴³⁸ The issue of the existence of an agreement in the *Adalat* case has been subject to animated debate. For comments on this, *inter alia*, see PARDOLESI, *Ritorno dall'isola che non c'è: ovvero l'intesa malintesa e l'integrazione del mercato come obiettivo dell'antitrust comunitario*, in *Mercato concorrenza regole*, 2001, no. 3, p. 561-575.

Therefore, the merits of the case were only addressed in the opinion of the Advocate General.

Three years after the dismissal, a new case, *Sot. Lélou Kai Sia* (hereinafter '*Syfait II*'), stood before the ECJ, based on questions identical to those previously submitted⁴³⁹.

On April 1, 2008 the Advocate General Ruiz-Jarabo Colomer (hereinafter '*AG Colomer*') submitted his opinion. The Advocate General also refused the reading of Article 102 TFEU as a *per se* prohibition of abusive conducts and accepted the application of a *rule of reason* in the antitrust analysis, in consideration of possible *efficiency gains* deriving from them⁴⁴⁰.

However, the Grand Chamber of the ECJ, differently from what AG Colomer argued⁴⁴¹, wiped away the R&D debate entirely and reclassified the R&D issue as an impact of parallel trade on profits⁴⁴². Therefore, rather than an efficiency argument, it looked to be an objective justification looking at protection of commercial interests.

For this reason, the Court left open the possibility that the pharmaceutical manufacturer might be able to justify a refusal to supply where the orders are '*out of the ordinary*', having regard to size of the order and its impact in the market of the exporting country and the previous course of dealing between the pharmaceutical manufacturer and the wholesaler concerned⁴⁴³.

Albeit the outcome of the *Syfait II* case may give some guidance to the solution for future cases dealing with the same issue, there are several problems in the implementation of this criterion too.

The rule of thumb provided by the ECJ does not really solve the appropriability issue alleged by the defendants and does not take a dynamic efficiency perspective. In fact, the reasoning of the Court, rather than an efficiency argument, seems a classical

⁴³⁹ See joined cases C-468 to 478/06, *Sotiris Lélou kai Sia E.E and others v. GlaxoSmithKline AVEE Farmakeftikon Proïonton*.

⁴⁴⁰ See para. 72 of AG Ruiz-Jarabo Colomer's opinion.

⁴⁴¹ The AG Colomer did not believe that the economic arguments put forward by the defendant could provide a valid and proportionate objective justification to the refusal to supply. In particular, he did not consider the existence of the efficiency gains sufficiently proved. See para. 116-118 of his opinion. The ECJ, instead, did not enter at all into efficiency considerations. See para. 70 of the decision. See my article *Parallel Trade and Pharmaceutical R&D: The Pitfalls of the Rule of Reason*, in *European Competition Law Review*, 2008, no. 29(11), p. 649-665 for a comment on the AG Colomer's opinion.

⁴⁴² See para. 29 of the *Syfait II* ruling.

⁴⁴³ See para. 67-70 of the *Syfait II* ruling.

objective justification that looks at the protection of the commercial interests of one of the parties.

6.2 *New cases under Article 101 TFEU: the Glaxo case*

With regards to Article 101 TFEU, the turning point is represented by the ruling from General Court in the *Glaxo* case on *dual* pricing.

The GC affirmed that the application of Article 101(1) TFEU could not depend solely on the fact that the agreement affects trade between Member States and partitions the common market. On the contrary, it also requires checking whether it prevents, restricts or distorts effective competition in the relevant market, to the detriment of the final consumer. In other words, to be considered contrary to Article 101(1) TFEU, the agreement should both impede intrastate trade *and* hinder effective competition in the market⁴⁴⁴.

So, for instance, although an agreement intended to limit parallel trade must in principle be considered to have as its object the restriction of competition, this would apply in so far as the agreement may be presumed to leave final consumers without real benefits.

However, the Court affirmed that it is impossible to presume the existence of such benefits in the pharmaceutical market, given that drug price regulation impedes the occurrence of the competitive pressure traditionally associated to parallel trade⁴⁴⁵.

For this reason, the GC, going against the case law previously analysed⁴⁴⁶, affirmed that such agreement was not contrary to Article 101(1) TFEU in its object but only in its *effect*, insofar it had been demonstrated that it concretely impeded consumers to enjoy savings brought about by parallel trade.

Secondly, the Court said that, in evaluating the conditions for a possible exemption under Article 101(3) TFEU, the European Commission did not properly carry out the necessary economic analysis, required by the specific nature of the pharmaceutical sector. Therefore, the GC annulled its decision in that part and required a new evaluation from the side of the Commission.

⁴⁴⁴ See para. 118-119 of the *Glaxo* ruling.

⁴⁴⁵ See para. 119-147 of the *Glaxo* ruling.

⁴⁴⁶ Cf. Section 2.1 and Section 5.1 of this Chapter, and in particular the *Sandoz* case, given that GC in the *Glaxo* case did not explicitly confront itself with that decision.

The ruling has been appealed by both parties. Following the opinion of the AG Trstenjak, delivered on June 30, 2009, the ECJ ruled as following.

The Court found that the GC committed an error of law, when it required the proof of the concrete disadvantages for final consumers for an agreement to be anticompetitive by object⁴⁴⁷. The ECJ, thus, returned to the principles established by previous case law, whereby an agreement deemed to restrict parallel trade is anticompetitive in its object.

As regards GSK's request for an exemption under Article 101(3) TFEU, the Court agreed with the GC. In fact, it held that the examination of an agreement, for the purposes of determining whether it contributes to the improvement of the production or distribution of goods or to the promotion of technical or economic progress, and whether that agreement generates appreciable objective advantages, must be undertaken in the light of the factual arguments and evidence provided by the undertaking. The nature and specific features of the sector concerned have to be taken into account in the analysis.

Lastly, the Court held that the GC correctly held that the Commission had not taken account of all the relevant evidence produced by GSK regarding the loss in efficiency associated with parallel trade or the gain in efficiency procured by the dual pricing clause, and that such decision was, for this reason, vitiated by a failure to carry out a proper examination.

From the above description of the jurisprudential developments on parallel trade of pharmaceuticals, it appears that two are the main debated issues that led the judges to question the traditional legal approach to restrictions of parallel trade: its effect on static efficiency and on dynamic efficiency, i.e. the competitive impact on prices of original products and on companies' incentive to invest in innovation.

These two topics are going to be at the centre of the following analysis.

⁴⁴⁷ As indicated by the ECJ at para. 65, despite that error of law, the GC judgment remains correct in its operative part: the GC, in fact, confirmed the part of the Commission's decision where it found that the dual pricing clause infringed Art. 101(1) TFEU. Accordingly, the Court dismisses GSK's appeal in so far as it seeks to establish that the general sales conditions were compatible with the prohibition of agreements in restriction of competition.

7. Conclusions

This Chapter has reviewed forty years of European jurisprudence and Commission practice that is at the basis of the development of parallel trade.

Based on the concept of '*specific subject matter*' and on the principle of '*regional exhaustion of IPRs*', traditionally European institutions have protected and encouraged it, through the firm prohibition of corporate conducts that restrict exports, in the belief that it fosters competition and brings about harmonisation in the market. In the pharmaceutical market, in particular, parallel trade has been conventionally considered one of the best ways to achieve market integration, given that direct harmonising measures proved to be ineffective and failed.

For this reason, export bans and other indirect mechanisms that discourage exports have been constantly considered as anticompetitive agreements falling within the scope of Article 101(1) TFEU

Similarly, the refusal to supply wholesalers coming from the manufacturer in dominant position with the aim of impeding exports has been strictly prohibited as an abuse of such position. The same legal treatment, although in a more controversial way, has been generally attributed to discriminatory practices.

The recent more intensive use of the economics in antitrust analysis have led European Courts to question the legal principles underpinning parallel trade and to adapt them to the specificity of the pharmaceutical sector.

However, the history of the analysed cases that marked this U-turn does not provide the possibility of envisaging the concrete boundaries of this policy change: the ECJ very recently solved the doubts cast by the *Glaxo* ruling about whether an agreement restricting parallel trade is anticompetitive by object or by effect; but it left open the R&D issue, because it did not explicitly ruled on the impact that parallel trade has on innovation.

The fact that European Courts opened the way to economic reasoning in a more explicit fashion pays tribute to the right need of modernising European competition law. Yet, the need to reconcile these developments with well-established principles built with forty years of case law arises.

CHAPTER III

Competition and regulation in the pharmaceutical market: the case of parallel trade

Introduction

The negative attitude of the Commission and the European Courts towards restrictions of parallel trade was particularly marked in the field of pharmaceuticals, because it was seen as very damaging for consumers. This type of cross border trade, in fact, is the only form of price competition for drugs during patent validity. Putting obstacles to it was thus seen as depriving patients of the sole source of cheaper drugs.

Nevertheless, such effect did not look apparent either to the GC in the *Glaxo* case or to AG Jacobs in the *Syfait* case, who doubted about the existence of an effective pressure from parallel trade on prices of original products, due to the regulatory intervention on drug prices.

I already reported that the GC in the *Glaxo* case on dual pricing held that Article 101(1) TFEU applies to agreements aimed at restricting parallel trade, not only when they influence intra-EU trade but also when the existence of an appreciable restriction to competition is concretely proven⁴⁴⁸.

The existence of these two conditions, and especially of the second one, should be carefully analysed in light of the specific features of the market in which the agreement takes place⁴⁴⁹. It is, in fact, established case law that in the examination of

⁴⁴⁸ See para. 118-119 of the *Glaxo* ruling.

⁴⁴⁹ See also para. 109 of the *Glaxo* ruling where the Court says that “the degree of competition necessary to ensure the attainment of the objectives of the Treaty [...] may vary to an extent dictated by the nature of the product concerned and the structure of the relevant market. [...] its parameters may assume unequal importance, as price competition does not constitute the only effective form of competition or that to which absolute priority must in all circumstances be given ...”.

business practices under competition law rules, attention should be given to the economic and legal context⁴⁵⁰.

In the case of pharmaceuticals, such specificity was identified with the fact that prices are regulated differently across Europe. In the view of the Court it appeared, firstly, that '*prices are finally set by Member States*'; secondly, that '*prices fall outside the play of supply and demand*'; thirdly, that they are '*established at structurally different levels throughout the Community*'⁴⁵¹.

These characteristics induced the Court to affirm, even after a prior general acknowledgment of the positive effect of parallel trade on prices⁴⁵², that it is impossible to presume the existence of such benefits in the pharmaceutical market, given that drug price regulation impedes the occurrence of the competitive pressure traditionally associated to parallel trade⁴⁵³. The GC, in fact, suggested that economic agents operating at an intermediate stage of the supply chain may keep the price differential for themselves. In that case that advantage will not be passed on to the final consumers.

For this reason, the GC, going against previous case law⁴⁵⁴, affirmed that such agreement was not contrary to Article 101(1) TFEU in its object but only in its *effect*, insofar it had been demonstrated that it concretely impeded consumers to enjoy savings brought about by parallel trade.

In the same wake, in the *Syfait I* case the AG Jacobs, clearly departing from prior jurisprudence under Article 102 TFEU⁴⁵⁵, argued that a pharmaceutical company does

⁴⁵⁰ See *Société Technique Minière*, p. 249, 250; *Consten and Grundig*, p. 343; and ECJ, 12 December 1995, in case C-399/93 *Oude Luttikhuis and Others*, para. 20.

⁴⁵¹ See para. 125-134 of the *Glaxo* ruling.

⁴⁵² See para. 107 of the *Glaxo* ruling, where the Court acknowledged that parallel trade is the only form of competition capable of exercising effective pressure on prices during the period of validity of a patent.

⁴⁵³ See para. 119-147 of the *Glaxo* ruling and especially para. 134 where the Court affirmed that '*That circumstance means that it cannot be presumed that parallel trade has an impact on the prices charged to the final consumers of medicines reimbursed by the national sickness insurance scheme and thus confers on them an appreciable advantage analogous to that which it would confer if those prices were determined by the play of supply and demand*'. See also para. 147 where the Court said '... As the prices of the medicines concerned are to a large extent shielded from the free play of supply and demand owing to the applicable regulations and are set or controlled by the public authorities, it cannot be taken for granted at the outset that parallel trade tends to reduce those prices and thus to increase the welfare of final consumers...'. Cf. the opinion of the AG Roemer in *Consten and Grundig*, cit., p. 299, on the role of parallel trade on prices: "... Parallel imports, which the EC Commission has considered necessary, do not determine a reduction of final prices, but have as effect the provision of substandard services for consumers...".

⁴⁵⁴ Among the cases discussed in Section 2.1 and 5.1 of Chapter II, see *Consten and Grundig*, p. 340-342; *Miller v Commission*, para. 7; *General Motors I*, para. 101-102; *General Motors II*, para. 66-68 (citing IAZ, para. 23), and the opinion of AG Tizzano in that case, para. 63, 69, 71-72, 75; *Sandoz*, para. 3 of the summary.

⁴⁵⁵ See *United Brands* and the analysis of the case and related case law *infra* Section 5.2 in Chapter II.

not abuse its dominant position if the refusal to supply opposed to wholesalers is functional to protect its commercial interests from parallel trade.

In particular, the AG supported the idea that a departure from the traditional anticompetitive assessment of the refusal to supply from the dominant company was justified by the specificity of the pharmaceutical sector.

And, again, the specific nature of the legal and economic context in which the pharmaceutical industry operates has been identified by the AG with the fact that drug prices are subject to governmental regulation. Such interference, responding to public health protection and public expenditures containment goals, would prevent normal conditions of competition from prevailing in the price formation. From this point of view, thus, the pharmaceutical market would be different from other industries.

Furthermore, regulatory intervention on drug prices, coupled with the public service obligation⁴⁵⁶, which obliges pharmaceutical companies to maintain adequate supplies in each Member State, would lock in pharmaceutical companies. In fact, being compelled to supply the export markets, where parallel trade originates, companies cannot defend their profits in the importing markets from the competition triggered by cross-border price differentials caused by Member States' different legislation.

The presence of the strict mentioned regulatory environment, precluding companies the adoption of strategies that would defend their commercial interests from competitors' attack, has been thus claimed to justify the anticompetitive behaviour.

The same features that would justify a dominant company's attempt to prevent parallel trade, according to the AG, would also prevent the latter from bringing benefits to consumers. On the contrary, parallel trade would benefit only traders who pocket most of the price differential, if not entirely⁴⁵⁷.

Dual pricing schemes, as any other form of export ban, have been generally scrutinised under Article 101 TFEU, because they embody anticompetitive agreements.

⁴⁵⁶ See the Art. 81 of the so-called 'Human Use directive', Dir. 2001/83/EC, as amended by the Dir. 2004/27/EC of 31 March 2004, which states: "The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered. The arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition".

⁴⁵⁷ See para. 96-99 of the AG Jacobs' opinion on the *Syfait II* case.

Instead, supply quotas have been traditionally regarded as unilateral conducts that may fall within the scope of Article 102 TFEU, if put in place by dominant companies. Thus, the ban on the oppositions to parallel trade from private parties, albeit inspired by the same policy goal – market integration –, is enforced at two different levels, depending on the business practice in issue⁴⁵⁸.

Notwithstanding this, in the present work the *Glaxo* case and the *Syfait* case are going to be analysed together for the following reasons.

First of all, in a competition law framework that looks at the effects of corporate practices in the market, and leaves aside formalism – as maintained by the supporters of the modernisation of European competition law – a dual pricing clause and a supply quota appear equivalent to a certain extent. In fact, from the perspective of a wholesaler, the former is a type of vertical price-squeeze that may have the same effects of a supply quota. In fact, higher prices for exports discourage arbitrage and induce wholesalers to operate in the domestic markets only. Similarly, in a regulatory context where pharmaceutical wholesalers are subject to the public service obligation and are compelled to serve the domestic market first, the supply of a quantity of goods that satisfies solely the domestic demand also leaves wholesalers with that market only⁴⁵⁹.

Secondly, the novel approach towards restrictions to parallel trade is based on the same claim in both cases: the specificity of the pharmaceutical sector, i.e. the presence of drug price regulation, which would require a change in the traditional anticompetitive assessment.

Under Article 101 TFEU, governmental intervention on prices was seen by the GC as an element of the legal and economic context that influences the assessment of alleged restrictive agreements. In this context, the question arises whether such element is capable of changing the traditional findings about parallel trade and if, for instance, vertical restrictions aimed at impeding intra-EU trade on pharmaceuticals should not be considered anticompetitive in their object any longer.

Under Article 102 TFEU, the presence of a strict regulatory environment that precludes companies the possibility to defend their commercial interests from

⁴⁵⁸ However, note that some corporate practices, like dual pricing, can possibly fall within the scope of both provisions, if dominance in the relevant market is proven.

⁴⁵⁹ Note, however, that from the perspective of a pure exporter that does not have a distribution network in the domestic market but operates only abroad, a dual pricing clause equals to a total refusal to supply.

competitors' attack, was claimed by the AG Jacobs to be equal to those exceptional economic conditions that are generally considered by the jurisprudence as an objective justification to abusive corporate conducts.

It follows that an economic issue – the impact of price regulation on competition – is at the basis of a possible change in the antitrust analysis of corporate practices aimed at hindering parallel trade, and therefore of an eventual reversal of the entire policy at this regard at a EU level in the field of pharmaceuticals.

This Chapter deals with this economic question: whether the pharmaceutical sector can be considered 'special' under competition law.

Such question has been divided in three sub-questions:

- a. whether regulation of prices is such that competition cannot take place;
- b. whether parallel trade on pharmaceuticals brings benefits to consumers and national health care systems,
- c. and how large are these savings.

The answer to sub-question a) influences the outcome of sub-question b). It is clear, in fact, that if the price formation is not entirely shielded from competitive mechanisms, it is reasonable to presume that parallel trade entails savings. If, on the contrary, price pressure is overruled by price controls, parallel trade cannot be presumed to bring the mentioned savings.

It is therefore necessary to investigate to what extent regulatory intervention on pharmaceutical prices changes companies' pricing policies and what is the impact on consumer welfare.

To this purpose I will analyse the characteristics of national pharmaceutical regulation in Europe and its economic rationale. This overview is complemented with the analysis of the theoretical and empirical literature that studied the effect of parallel trade on prices of pharmaceuticals.

The covered literature to date contains comprehensive and updated overviews of the European pharmaceutical systems (Öbig, 2008; Kanavos, 2003). There are also studies (West and Mahon, 2003; Kanavos, 2005; Pedersen, 2006) that examine if and to what extent parallel trade on pharmaceuticals brings benefits to consumers. However, the antitrust implications of these issues have not been enough explored so far.

Answering the research question purported above has very important consequences from an antitrust standpoint: if parallel trade on pharmaceuticals can be presumed to bring savings notwithstanding regulation, there is ground to uphold the traditional legal treatment towards restrictions to parallel trade, also in the pharmaceutical sector.

If, on the contrary, the regulatory environment is such that parallel trade cannot be presumed to bring savings, there may be scope to support a change of the current legal treatment.

Against this backdrop, this Chapter is divided as follows.

Section 1 provides an overview of pharmaceutical regulations of the most representative European Member States, and especially of those where imports mainly take place (Sweden, Denmark, UK, Germany), to check to what extent regulation is capable of excluding price competition.

Section 2 examines the economic literature dealing with the impact of parallel trade on pricing strategies applied by pharmaceutical companies, in order to verify the effect on prices charged in importing and exporting countries. This analysis aims at understanding whether parallel trade is capable of putting pressure on prices of original products, thereby bringing savings.

Section 3 deals with the magnitude of such savings, as measured by recent studies, in order to analyse if there is and how effective is the pass-on mechanism and what is the role of pharmaceutical regulation in determining such effectiveness.

Section 4 looks into the question of whether parallel trade on pharmaceuticals has had the price equalising function that has been legitimating its support at a EU level. The issue, besides being empirical, has an important legal facet: the fact that competence on health remains national may cast doubt on the legitimacy of the policy of harmonisation pursued by the Commission, which may seem a way to bypass the direct consent of Member States.

Section 5 draws the antitrust implications of the foregoing economic analysis. In particular, it focuses on the *Glaxo* case and on the issue of whether an agreement restrictive of parallel trade runs against Article 101(1) TFEU in its object or in its effect.

Section 6 concludes.

1. Regulation on prices: is the pharmaceutical sector ‘specific’?

The first time that the issue of the ‘specificity’ of the pharmaceutical sector under European law came up was in *Merck v. Primecrown*⁴⁶⁰. In particular, as already mentioned in the previous Chapter, the Court was asked whether the absence of patent protection and a system of drug price regulation were sufficient conditions to justify the non-application of the principle of regional exhaustion of IPRs.

Recall that in that occasion the AG Fennelly argued in favour of a qualification of the principle of exhaustion of IPRs essentially grounded on the absence of patent protection⁴⁶¹.

The impossibility to obtain an exclusive right diminished the bargaining power of companies in price negotiations with the authorities. In fact, the presence of copyists that could provide the same product at a lower price impeded companies to obtain prices sufficiently above marginal costs and to recoup R&D investments there. And whilst this policy in itself could not be questioned, given that not all Member States can be obliged to contribute to the recovery of research expenditures, it was claimed that those health care systems enjoying low prices should not have been used by third parties to undermine the ability to recover R&D costs on other markets through parallel trade⁴⁶².

On the contrary, the presence of price regulation in itself was not considered a valid reason to depart from the principle of regional exhaustion. The AG, in fact, based on the view that a patent’s subject matter cannot include the right to a monopolistic profit, affirmed explicitly that *“the fact that the application of such price controls may, along with various other factors, affect the potential profits of pharmaceutical patentees is not relevant for the interpretation of the balance between the free movement of pharmaceutical products and the protection of national patent rights.”*⁴⁶³

⁴⁶⁰ See Section 3.2 in Chapter II for a deeper discussion of the case law.

⁴⁶¹ AG Fennelly at para. 111 of his opinion argued that a right could not be exhausted if it has not been exercised. Exhaustion, in fact, should only occur when the owner of an intellectual property right has used his right once, and correspondingly has had the chance of obtaining a reward for his creative effort. In that case, the right had not been used at all, and the creative effort had not been rewarded, due to the unavailability of patent protection in the country of export.

⁴⁶² See para. 106 of the opinion of the AG Fennelly. It is known that, nevertheless, the Court did not follow the advice of the AG and maintained that the only legitimate exception to the principle would be justified by the absence of any consent to the marketing of the product concerned from the patentee.

⁴⁶³ See the opinion of the AG Fennelly in *Merck v. Primecrown* at para. 163.

Also, the existence of a legal and ethical obligation to supply and the presence of a system of governmental price controls were not regarded by the AG as providing grounds for the qualification of the principle of exhaustion.

Accordingly, the Court followed the AG opinion on this point (only) and confirmed previous case law, where it had already been established that price differentials and heterogeneity of price regulation in the pharmaceutical market do not have any relevance in the evaluation of the anticompetitiveness of restrictions to exports⁴⁶⁴.

Yet, in the context of competition law the issue of the 'specificity' of the pharmaceutical sector seems to be open still⁴⁶⁵.

For instance, one may wonder if placing a restrictive agreement in its economic and legal context includes the consideration of the presence of regulatory intervention⁴⁶⁶. In light of this, the question of whether a departure from the traditional anticompetitive assessment of restrictions to competition is justified by the presence of regulation on prices arises. In case of a positive answer, there would be a discrepancy with the mentioned case law on free movement of goods⁴⁶⁷. It is therefore necessary to ascertain whether there are economic and legal grounds to support this choice.

1.1 An overview of national pharmaceutical policies

From an economic point of view, it is a truism that drug prices formation does not follow classical market mechanisms, given that public health protection and public expenditures containment goals play an important role in their determination.

However, not in each and every Member State prices for medicines are directly fixed by governments. On the contrary, a multiplicity of regulation of prices for drugs

⁴⁶⁴ See *Merck v Primecrown*, para. 47, and *Centrafarm v. Sterling*, summary, para. 2: "It is a matter of no significance that there exist as between the exporting and importing Member States price differences resulting from governmental measures adopted in the exporting State with a view to controlling the price of the product..."

⁴⁶⁵ In *General Motors*, para. 75, it was affirmed that lacking harmonisation, it is normal that domestic and export sales are subject to different regulations, albeit this does not modify the anticompetitive features of an agreement. However, the car industry is not a regulated one, although prices vary to a large extent from country to country because of different VAT charged by Member States.

⁴⁶⁶ At para. 110, the Court said that "[T]he characterisation of a restriction of competition within the meaning of Article 81(1) EC must take account of the actual framework and, therefore, of the legal and economic context in which the agreement to which that restriction is imputed is deployed. Such an obligation is imposed for the purpose of ascertaining both the object and the effect of the agreement."

⁴⁶⁷ This is what is suggested by REY and VENIT, *Parallel Trade and pharmaceuticals*, cit., p. 171 *et seq.*, where it is affirmed that in this respect the application of competition law and free movement of goods rules differ: while the goal of market integration, and the consequent prohibition of impediment to cross border trade, can be correctly attributed to the latter, the same does not apply for the former.

exists in Europe. Whilst in 11 Member States prices are directly fixed by authorities, subject to the information provided by companies⁴⁶⁸, in 8 Member States companies are allowed to set the final price to consumers, subject to the price of competing medicines. Furthermore, in 14 out of 25 EU Member States pharmaceutical companies are either completely free to set their final prices or negotiate them with the authorities.

Let us have a look at the pharmaceutical pricing regulation in some representative European countries, in order to have a better clue of the degree of governmental intervention in this field⁴⁶⁹.

1.1.1 *The pharmaceutical regulations in the importing countries*

In Denmark, all pharmaceuticals at manufacturer and wholesale levels are freely priced. The wholesale margin is not regulated by law, but it is negotiated individually between wholesalers and pharmaceutical companies. The Danish Medicines Agency (hereinafter, the 'DKMA') calculates the pharmacy retail price via a linear mark-up scheme and makes a list that is distributed to all pharmacies. Prices can be modified by companies every two weeks when a new official price list is drawn up by the DKMA.

The Agency negotiates total pharmacy profits every two years and the pharmacy mark-up scheme is adjusted accordingly.

Finally, the DKMA calculates the reimbursement price based on internal reference pricing. The part of the price that exceeds the reimbursement level is on patients. This should contribute to render them price sensitive to a certain extent.

⁴⁶⁸ Similarly see para. 59 of the *Syfait II* ruling, where the Court said that "... in the majority of Member States, medicines, in particular those available only on prescription, are subject to regulation aimed at setting, at the request of the manufacturers concerned and on the basis of information provided by them, selling prices for those medicines and/or the scales of reimbursement of the cost of prescription medicines by the relevant social health insurance systems...".

⁴⁶⁹ I will here consider eight Member States, four importing countries (Germany, UK, Denmark and Sweden) and four exporting countries (France, Italy, Spain and Greece). I chose the first four as representative of importing countries, because they present the highest parallel import market penetration, as it appears from Table 8 in Chapter I. After a general overview, I will restrict my analysis to these countries, in order to understand if and how price competition takes place there.

The following analysis is based on KANAVOS, *Overview of pharmaceutical pricing and reimbursement regulation in Europe*, in *Japanese Pharmacology and Therapeutics*, 2003, no. 31(10), p. 819-836, and on the information collected in the website of ÖBIG, Österreichisches Bundesinstitut für Gesundheitswesen, a division of the Gesundheit Österreich GmbH (Health Austria) responsible for the development of basic principle, methodology and instruments regarding the planning, the governance and the evaluation of Austria's health care system. Among the projects run by ÖBIG, there is the PPRI (Pharmaceutical Price and Reimbursement Information). This project included the writing of specific reports on health and pharmaceutical systems of European countries, with a special focus on pricing, reimbursement and rational use of pharmaceuticals. The PPRI Pharma Profiles were written by country experts, often involved in pricing and reimbursement decisions, and were reviewed by an experienced editorial team.

This pricing system has existed for many years, along with *ad hoc* interventions or agreements between the authorities and one or more of the industry associations, providing temporal price freezes, price cuts and price ceilings.

In Germany, besides temporal price freezes occurring from time to time, ex-factory prices are basically determined by manufacturers without negotiations involving governmental agencies, direct price or profit controls and public procurement. The Pharmaceutical Price Ordinance (PRO) stipulates fixed mark-ups on manufacturers' selling prices and thereby guarantees identical prices for prescription drugs in all German pharmacies. In this way, manufacturers can determine the ex-wholesaler and the ex-pharmacy price of the drug by setting the ex-factory price.

However, price setting by companies takes into consideration regulations in other parts of the market, e.g. reimbursement regulation through reference pricing establishing an upper limit for sickness fund reimbursements.

Cash discounts can be negotiated between manufacturers, wholesalers and pharmacies. In addition, pharmaceutical providers have been obliged to give rebate to sickness funds⁴⁷⁰.

In general full reimbursement is granted for all reimbursable drugs. Currently, co-payments are set to 10% of the drugs' price⁴⁷¹.

In UK, the prices of branded prescription medicines and the profits that manufacturers are allowed to make on their sales to the National Health Service (hereinafter, the 'NHS') are regulated by the PPRS. It is a voluntary agreement made every five years between the Department of Health and the branded pharmaceutical industry - represented by the Association of the British Pharmaceutical Industry (ABPI)⁴⁷².

The PPRS provides that there is freedom of pricing at launch for new active substance. That means that prices for single products are not directly regulated. The

⁴⁷⁰ While some rebates are mandatory for certain types of drug (e.g. the pharmacy rebate of € 2.30 per package), others depend on the existence of contractual agreements (e.g. rebates to an individual sickness fund) or special drug characteristics.

⁴⁷¹ Due to a minimum of € 5.00 and a maximum of € 10.00, insured are only price sensitive in a price range below € 5.00 and between € 50.00 and € 100.00.

⁴⁷² The PPRS covers all licensed, branded, prescription medicines sold to the NHS. A new five-year PPRS commenced on 1 January 2005 in succession to the 1999 scheme. The 2005 scheme included a 7% price reduction.

PPRS only establishes a profit cap⁴⁷³, calculated as the return on capital (hereinafter the 'ROC') target plus a margin (almost 30% of ROC)⁴⁷⁴. When a manufacturer's profits exceed the target ROC, one or more of the following measures may be taken: price reduction, restriction or suspension of price increases requested by the manufacturer, repayment of excessive profits⁴⁷⁵.

The PPRS sets the NHS list price at which pharmacists are reimbursed. This is a maximum price, as pharmacists are able to purchase at a discount.

All items that can be prescribed on the NHS are fully reimbursable. In particular, in England fixed co-payment arrangements apply. A standard prescription fee - GBP6.65 from 1 April 2006 – is payable in respect of each item supplied.

In Sweden, the Medical Products Agency (*Läkemedelsverket*, hereinafter 'MPA') is the national authority responsible for regulation and surveillance of the development, manufacturing and sale of pharmaceuticals and other medicinal products. Pricing and reimbursement decisions are made by the Pharmaceutical Benefits Board (*Läkemedelsförmånsnämnden*, hereinafter the 'LFN') simultaneously. Reimbursement and pricing processes are combined and an application from a pharmaceutical company results in a joint reimbursement and price decision by the LFN.

⁴⁷³ Companies' profits are capped by the PPRS if their total home sales of NHS medicines in the United Kingdom exceed a certain threshold. The PPRS caps profits by setting 'target' returns on capital employed on all sales. These target returns on capital are based on the historical average value of invested capital. The assessment of profitability is performed on the basis of three main elements: the value of its sales of branded prescription medicines to the NHS; the company's costs that would be appropriate for the NHS to bear (manufacturing costs, research and development up to 28% of NHS sales, and marketing expenditure up to 6% of NHS sales); the capital employed by the company in delivering NHS sales.

⁴⁷⁴ There are two levels of ROC. The NHS uses a general ROC of 21% in determining a company's liability to repay excess profits. A lower ROC of 17% will be used to decide price increase application. Companies are allowed to deduct a percentage of their sales revenue from 'gross' profits as a reward for their R&D investments.

⁴⁷⁵ The success of the PPRS in securing low prices of medicines for the NHS is undetermined. Some authors have argued that the PPRS has done little to control the prices of medicines for the NHS, as the pharmaceutical budget has increased approximately 10 per cent per year from 1967 to 1997. United Kingdom prices are among the highest in the EU. This is despite the savings of £89.8 million resulting from 1993 price reductions. See BORRELL, *Pharmaceutical price regulation: a study on the impact of the rate-of-return regulation in the UK*, in *Pharmacoeconomics*, 1999, no. 15(3), p. 291-303, and most importantly see the OFT report on PPRS released in February 2007, available at where it is clearly affirmed that the NHS is paying too much for drugs. This is probably the result of important drawbacks of the PPRS: it provides little incentive for efficiency, as increased costs can be recovered through allowable price increases, and too much incentive for overinvestment in capital equipment or artificially inflating its asset base. Finally, as target profits are negotiated and the process may not be transparent, there is the potential for 'regulatory capture'. See DEPARTMENT OF HEALTH UK, *Pharmaceutical Price Regulation Scheme: Sixth Report to Parliament*, 2002, December, available from <http://www.doh.gov.uk/pprs.htm>.

One important aspect of the Swedish reimbursement system is that the LFN does not negotiate prices. It looks upon the price as an integral part of the cost-effectiveness analysis. If the price is too high, the product will not be considered cost-effective. And the LFN will reject the application in question. The company will have to decide if they should apply again and suggest a lower price.

Sweden made some major changes to its reimbursement system in 2002. Earlier almost all prescription medicines were automatically approved for reimbursement. Today applications are thoroughly scrutinized and cost-effectiveness is a crucial decision-making criteria. Reimbursed medicines are priced accordingly and no further negotiations of the price take place. However, it is common that county councils are given discounts on medicines used in hospitals.

Price freezes or price cuts are not applied. Prices and pricing procedures are reviewed and evaluated on a regular basis⁴⁷⁶. However, companies can appeal against the LFN's decisions in a public administrative court.

The pharmaceutical policy of the Dutch government is based on the principle of safe and affordable pharmaceutical care for all citizens. This policy is implemented by the Dutch Ministry of Health, Welfare and Sport and by regulating the price and the reimbursement of medicines.

All prescription-only medicines' purchased through pharmacies are subject to the Medicinal Product Prices Act (hereinafter, 'MPPA'). This law specifies that the price for prescription-only medicines may not exceed a maximum level. The maximum level for the prescription-only medicines are determined twice a year by calculating the average price of comparable medicinal products (same active substance, same strength, same pharmaceutical dosage form) in four reference countries: Germany, France, Belgium and the United Kingdom.

The pharmacist may override the pricing level as determined by the MPPA (submit a price other than the level specified in the law) to the purchaser (patient or his insurance company), but subject to these restrictions:

- a discount is made of 6.82% or maximum F15.00 for one prescription (so called claw

⁴⁷⁶ However, by order of the government the LFN is currently conducting a review of the entire list of pharmaceuticals that were eligible for reimbursement when the new Pharmaceutical Benefits Scheme came into force in October 2002.

- back, to compensate for discounts and bonuses earned by pharmacists);
- for generics the lowest price listed of the same generic can be declared;
- for parallel imports the lowest listed price per country should be taken;
- if the price of the delivered medicinal product is lower than the (reference) price of an (usual branded) equal medicinal product the pharmacist can charge one third of the price difference.

The Medications Reimbursement System (hereinafter, 'MRS') determines the level of reimbursement for pharmaceuticals in the sickness funds' health care package, whether they are prescription-only pharmaceuticals or pharmaceuticals for self-medication use (OTC). Within the Medications Reimbursement System, which was introduced by the Pharmaceutical Pricing Act in 2006, the level of reimbursement is based on the average price of pharmaceuticals that have a comparable effect, are mutually replaceable and can therefore be regarded as a group (according to the mechanism of the reference price system). If the price of a given product is higher than the group average, the additional costs must be paid by the patients. In practice, there are usually enough alternatives available to allow for the selection of a fully reimbursable drug.

1.1.2 The pharmaceutical regulations in the exporting countries

In France, prices for reimbursed pharmaceuticals are negotiated between the Economic Committee for Health Care Products (*Commission d'Evaluation des Médicaments*, hereinafter 'CEPS') and pharmaceutical companies. As a rule, they agree on a price in line with the technical level of relative improvement provided by the product in comparison with other products available in the same therapeutic area.

The negotiations are carried out in compliance with a procedure described in a general agreement between the industry and the CEPS (so called '*accord cadre*'), the duration of which is four years. A new agreement was signed at the beginning of 2007.

According to the *accord cadre*, prices are determined through external reference pricing. That is, the price of pharmaceuticals with good/high of improvement of clinical benefit should not be lower than the cheaper price observed in comparable European countries, i.e. Germany, Spain, Italy and the United Kingdom, over a period of five years starting from their inclusion in the positive list of reimbursable products (the

information on these prices is provided directly by the company).

Non-reimbursable pharmaceuticals in the outpatient sector have benefited from free pricing at all levels since 1986, according to an edict that cancels the general price control in France. The same goes also for pharmaceuticals purchased by hospitals.

In Greece, the responsibility for pricing of pharmaceuticals lies with the Ministry of Development. The government in 2005 passed a new law (Law no. 3048/2005) stipulating a new price setting.

External price referencing is applied to all new pharmaceutical products including OTCs. External pricing is not applied to generic products. External pricing is used to determine the ex-factory price of pharmaceuticals. The price of new drugs will be determined based on the average manufacturer price level calculated by considering the average of the three lowest prices among EU-25 countries system.

The price of medicinal products for which there is proof that the patent expires, is reduced by 20%.

The government passed a new law in 2006 that defines the reimbursement of medicines in Greece (Law no. 3457/2006). According to this new reimbursement law, the expenditure for all medicines holding a marketing authorisation is covered by all sick funds. Moreover, sick funds cover the expenditure for medicines for the uninsured and the poor. Law no. 3457/2006 established that drugs have to be divided in clusters on the basis of therapeutic value, cost-effectiveness, cost of daily treatment, safety and budget impact: each cluster has a level of co-payment, which goes from 0% to 25%.

There are no price negotiations in Greece taking place, or free pricing.

In Italy prices of pharmaceuticals reimbursed by the NHS are regulated at the central level and are the same across the whole country.

In January 2004, the old system based on the Average European Price (AEP) was withdrawn and a new price setting system was introduced based on a negotiation procedure applicable to all reimbursable pharmaceuticals.

So, now two different methods for setting prices of pharmaceuticals are used: price negotiation for reimbursable pharmaceuticals, and free pricing, with some limitations, for non-reimbursable products, including OTCs.

The negotiation procedure with manufacturers is managed by the Italian Medicines Agency (*Agenzia Italiana Farmaco*, hereinafter 'AIFA') Pricing and Reimbursement Unit (PRU), assisted by the Committee for Pricing and Reimbursement (*Comitato Prezzi e Rimborso*, hereinafter 'CPR'). Pricing and reimbursement decisions are strictly interlinked, because the responsibility rests with the same body and because both decisions are made within the same procedure.

AIFA Technical Scientific Committee (*Commissione Tecnico-Scientifica*, hereinafter 'CTS') expresses an opinion on reimbursement classification. The process of negotiation takes place only after this evaluation.

The negotiation procedure is conducted following criteria: product therapeutic value; pharmacovigilance data; price in other Member States; price of similar products within the same pharmacotherapeutic group; domestic market forecasts on the number of potential patients; and therapeutic innovation.

Pricing decisions are made at the ex-factory level, then wholesale and pharmacy prices are calculated by formula.

In case of absence of an agreement about the price as a result of the negotiation, the reimbursement decision made by the CTS is amended and the pharmaceutical is classified as non-reimbursable⁴⁷⁷.

In Spain, pricing of pharmaceuticals is negotiated between the health authority and the manufacturer following a cost plus criterion, where not only variable costs and R&D costs are taken into account, but also the fact that an additional benefit of the 15-20% of the final price should be granted to the manufacturer. Also, parties often agree on price-volume agreements for expensive products⁴⁷⁸.

Reimbursement decisions are taken from the Joint Committee for the evaluation of New Medicines – composed by experts from the governmental regions of Andalusia, Catalunya and Pais Vasco⁴⁷⁹ – based on external reference pricing for estimating a maximum reimbursement.

⁴⁷⁷ See JOMMI, *Il governo del settore farmaceutico: un quadro complessivo*, in BRUSONI, *L'impresa farmacia: cultura e strumenti gestionali per il nuovo mercato*, 2001, p. 225-295. See also PARDOLESI, CASSESE and CAROVITA DI TURITTO, *La disciplina dei prezzi dei farmaci*, in *Il foro amministrativo*, 2003, p. 3117.

⁴⁷⁸ See ROVIRA, and DARBA, *Pharmaceutical pricing and reimbursement in Spain*, in *European Journal of Health Economics*, 2001, no. 2(1), p. 39-43.

⁴⁷⁹ The Spanish health care system has been decentralised in 2002 and Regions have become active in initiating demand-side measures to reduce health care expenditures.

1.1.3 National policies on parallel trade

Affirming that drug price controls impede that savings deriving from parallel trade are passed on to consumers implies that price negotiation leads to fixed price at each level of the distribution chain. However, from what was outlined above, it appears that in all Members States where price controls mechanisms are applied, prices are only upper caps, which do not impede to have lower prices in the market through competition at the retail level.

Policies implemented in several Member States aimed at inducing relevant agents, like wholesalers and pharmacists, to seek for cheaper supplies seem to confirm the willingness of the regulator to create favourable conditions for competition. This, on the one hand, should improve access to medicines and, on the other, relieve public finances.

Table 5: Policies used to Promote Use of Parallel Imported Medicines in Selected European countries

Policies that promote Use of PI drugs at pharmacy level	Denmark	Germany	Netherlands	Norway	Sweden	UK
Mandatory information on availability of PI	X	X			X	
Mandatory dispensing of PI drugs if price differential is least equal to a fixed range	X	X			X	
Mandatory quota on PI dispensing rate		X				
Financial incentives to dispense PI drugs			X	X		X
Financial incentives to dispense lower-priced drugs, including PI				X	X	
Lower consumer out-of-pocket expenses (price or co-payment) for PI products	X		X		X	

Source: Kanavos, Gross and Taylor, *Parallel Trading in Medicines: Europe's experiences and its implications for commercial drug importation in the US*, AARP Public Policy Institute, June 2005, as updated by me through with information from members of the EAEPC in 2007.

In Denmark, reference pricing and parallel import prices play a direct role in setting reimbursement prices. In UK, schemes that claw back (part) of the price

reduction obtained by pharmacists from wholesalers and parallel traders seek to translate such rebates in savings for the NHS.

Direct pass-through arrangements are also implemented. In Denmark, Netherlands and Sweden the pharmacist is required to inform the patient of the availability of parallel imported drugs and the patient is charged a lower price if he purchases them. The same applies in Germany but patients do not face lower prices for parallel traded drugs.

Further, in the Netherlands, Germany and Sweden financial incentives are provided to pharmacies to purchase parallel traded drugs. Also Norwegian pharmacists face financial incentives to purchase parallel imported drugs but pharmacists do not have to inform patients of the availability of such drugs nor do patients face a lower price for purchasing parallel traded products.

In Germany and in Denmark pharmacists are required to sell the parallel imported product if its price is lower of a certain percentage with respect to the original one⁴⁸⁰.

1.1.4 The negotiation of prices for pharmaceuticals

One of the claims underlining defendants' allegations in defence of practices restrictive of parallel trade on pharmaceuticals is that the regulatory intervention on prices for drugs is the primary source of the distortion to competition in this sector⁴⁸¹.

However, it should be recalled also that distortions to competition come in the first place from the market failures that characterise this sector and that require regulatory intervention⁴⁸². Regulation, in fact, seeks to achieve prices that strike a balance between the need for the cost effective availability of medicines and the pharmaceutical companies' right to earn a fair rate of return⁴⁸³.

The negative externalities that relevant stakeholders (government, physician,

⁴⁸⁰ In Germany, as of January 2004, the pharmacist is required to dispense the parallel imported product only if its price is more than 15% cheaper than the original (for values less than €100) or if the price exceeds €15 (for values greater than €100). In Denmark substitution with parallel imported products is mandatory for 5 DKK (0.7 €) price difference for prices less than 100 DKK (13 €), for 5% price difference for prices between 100 and 400 DKK (13 to 54 €) and for 20 DKK (2.7€) for prices above 400 DKK (54 €).

⁴⁸¹ See REY and VENIT, *Parallel Trade and pharmaceuticals*, cit., p. 167; GREEN, *Is price regulation necessary? A Summary of the arguments*, *Pharmacoeconomics*, 1998, n. 14, p. 137; DANZON and CHAO, *Does regulation drive out competition in the pharmaceutical market?*, in *Journal of Law & Economics*, no. 43, 2000, p. 311-357.

⁴⁸² Cf. Section 1.1 and 1.2 of Chapter I.

⁴⁸³ See CAPRI and LEVAGGI, *Reconciling social and industrial goals: a bargaining model to pricing pharmaceuticals*, Liuc working paper Economia e Impresa 42, 2005. On this issue see better Section 4.1 of this Chapter.

pharmacist, patient) impose on each other in the decision making process⁴⁸⁴, the limits to substitutability among products and the market power enjoyed by companies through patents convey rigidity in the supply chain. That is why a regime of pure free pricing may not be adequate to discipline prices. *Vice versa*, a system of direct or indirect control of pharmaceutical prices, through parallel trade and other policy tools, serves the purpose of setting a more appropriate price.

The goal of the bargaining process between the regulator and the company is to achieve a twofold outcome: on the one hand, it renders the drug accessible to that part of the population that would have not afforded it on a private market, and on the other hand, it allows the pharmaceutical industry to earn a profit larger than that it would have obtained in the private market. Therefore, the authority, through a successful negotiation, can obtain the enlargement of the target market for the company and the generation of considerable savings for those who had bought the drug anyway⁴⁸⁵.

In those countries where prices are negotiated, they are thus a function of the willingness to supply of the seller and the willingness to pay of the buyer, even in the presence of regulation. It follows that, like in a Nash bargaining process, the agreed level of price depends on where the negotiation power resides the most: this in turn depends on the social value attributed to the product, on the number and characteristics of the alternatives already on the market, and on the presence of the availability of reference pricing information, of cross-country price comparisons, as well as of parallel imports⁴⁸⁶.

On the one hand, it is true that health care agencies having the task to bargain for the price of drugs enjoy the buyer power typical of monopsonists. On the other hand, the authoritative power of health care agencies in setting pharmaceutical prices is mitigated by the provisions of the so-called 'Transparency Directive' (Dir. 89/105/EC). Articles 2.1 and 2.2 of this Directive provides that (i) pharmaceutical companies participate in the price setting procedures, (ii) authorities are obliged to justify objectively the rejection of a company's price, and (iii) companies have the right to market the product at their proposed price if they do not receive notification of the

⁴⁸⁴ Cf. Section 1.2 in Chapter I.

⁴⁸⁵ See CAPRI and LEVAGGI, *Reconciling social and industrial goals*, cit., p. 3.

⁴⁸⁶ Similarly the ECJ in *Syfait II* affirmed that "the control exercised by Member States over the selling prices or the reimbursement of medicinal products does not entirely remove the prices of those products from the law of supply and demand."

authorities' rejection of the price within ninety days from filing⁴⁸⁷. Furthermore, the Directive mandates, for instance, that any price freezes be reviewed annually to determine whether macroeconomic conditions justify their continuance.

Also, pharmaceutical companies have a certain amount of influence over the market⁴⁸⁸, thanks to the exclusivity rights granted by patents in the production and the first commercialisation of the patented drug. This advantage is further strengthened by the dossier protection⁴⁸⁹. The large investments in R&D and marketing efforts endow them with a competitive advantage over any potential entrant and thus constitute an effective barrier to entry. For this reason, it might happen that there exists no available substitute for a given medicinal specialty. This gives them bargaining power *vis-à-vis* governments, especially when the product is life-saving.

What may additionally weaken governments' position in the negotiation procedure is the responsibility they bear for their citizens' health. If price negotiations fail because the authority does not accept the proposed price, or if it decides to delist it from the reimbursed product list, and the company decides to not introduce the drug into the market, governments may be held accountable for the lack of newer or more effective drugs in the market.

This may explain why authorities may refrain from using their authoritative power and may need to use indirect leverages in order to obtain price concessions from companies during negotiations.

⁴⁸⁷ See AG Ruiz-Jarabo Colomer's opinion in the *Syfait II* case at para. 89.

⁴⁸⁸ See para. 60-62 of the *Syfait II* ruling, where the Court said that "...the control exercised by Member States over the selling prices or the reimbursement of medicinal products does not entirely remove the prices of those products from the law of supply and demand. [...] Furthermore, even though the public authorities in other Member States set the selling prices of medicines as well, that does not in itself mean that the manufacturers of the medicines concerned have no influence upon the level at which the selling prices are set or the proportion of those prices which is reimbursed. [...] in some Member States, the public authorities do not intervene in the process of setting prices or limit themselves to setting the scale of reimbursement of the cost of prescription medicines by the national health insurance systems, thereby leaving to the pharmaceuticals companies the task of deciding their selling prices."

⁴⁸⁹ The provision establishing data protection for medicinal products for human use restrict the access to the clinical dossier of reference of medicinal specialties from parties other than the patent owner. Article 14(11) of the European Parliament and Council Regulation (EC) No 726/2004 states: "Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorized in accordance with the provisions of this Regulation shall benefit from an eight-year period of data protection and a ten-year period of marketing protection, in which connection the latter period shall be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies". The new periods of protection only apply to reference medicinal products for which an application for authorisation has been submitted after 20 November 2005 (Article 89 of Regulation (EC) No 726/2004).

These leverages are different in nature: some have been created by law, like reference pricing, which allows health authorities to ask for prices equal to those charged in countries considered similar in terms of wealth per capita, consumption patterns, citizens' life style, etc.; some others, like parallel trade, were not created by Member States *ad hoc*, but spring from the economic opportunities provided by the EU. Member States' governments may decide to use them to introduce some competition in the supply chain to reduce their pharmaceutical expenditures⁴⁹⁰.

1.2 The role of parallel trade in price negotiations

Parallel trade may display such function at two different stages: before the launch, during price negotiations, and after the launch, in reimbursement and substitution policies⁴⁹¹.

In presence of parallel trade, price negotiation in the high-price country can take a new dynamic. By the means of the reimbursement system, the regulator (or the insurance fund) has the power to govern all sales within the country: it could, for instance, deny reimbursement (or insurance coverage) of the current price and ask for a lower one, under the threat of the alternative source of supply present in the market. The manufacturer may then adjust its price properly so that parallel trade cannot take place. As a result, both the regulator and the manufacturer are better off: the government can reduce pharmaceutical expenditures and the company can recoup part of its lost profits thanks to the elimination of competition⁴⁹².

This analysis suggests that parallel trade can display an important potential in competitive terms.

The threat of parallel trade, in fact, gives bargaining power to authorities and

⁴⁹⁰ See better *infra* Section 4.1 of this Chapter.

⁴⁹¹ KANAVOS, *The Single Market for Pharmaceuticals in the European Union in Light of European Court of Justice Rulings*, in *Pharmacoeconomics*, 2000, no. 18(6), p. 523, at 528, where the affirms that parallel trade could be a key factor in the process of renegotiation of reimbursement levels in line with price levels prevailing in neighbouring countries. As an example see the several aspects of the Danish legislation described in this Chapter.

⁴⁹² See NASH, *The Bargaining Problem*, *Econometrica*, 1950, no. 18, p. 155-162; RUBINSTEIN, *Perfect Equilibrium in a Bargaining Model*, *Econometrica*, no. 50, 1982, p. 57-109; MUTHOO, *Bargaining Theory with Applications*, 1999. See para. 5.100 of the OFT report on PPRS: "However, it seems clear that there will always be an element of loss to the system – the costs incurred and profits earned by parallel traders. Therefore, pricing systems (such as those based on rebates) that take account of parallel trade effects may offer a win / win outcome for industry and government – by encouraging industry to accept a higher price cut than would otherwise be the case and ensuring the benefits are shared exclusively between industry and the public purchaser".

insurance funds *vis-à-vis* the companies in price negotiations for domestic products. Symmetrically, pharmaceutical companies are more favourably disposed to price reductions⁴⁹³.

When parallel trade takes place in equilibrium, thus, the allocative function of the bargaining procedure can be enhanced. A larger opening up of the market can be negotiated in exchange for a price reduction, to the benefit of public finances on the one hand and of firms' profit on the other. In this way, savings entailed by parallel trade are passed on to consumers and appropriation from third parties is avoided.

If, for whatever reason, negotiations terminate in favour of the company and its proposed price, the government can always expose it to competition from parallel trade through three concurring measures: the granting of a market authorisation to a parallel importer on a certain product, the negotiation with the latter of a enough lower price (if applicable⁴⁹⁴), and the introduction of provisions that impose on pharmacists the substitution through parallel imported products when possible.

This may help reducing pharmaceutical expenditures in two ways: patients buy (and the government reimburses) cheaper products and the companies, subject to competition, may decrease the price of their products, if market conditions allows for it.

The above analysis supports the idea that, despite the presence of regulation on prices for pharmaceuticals, there exists in countries where imports take place an appropriate legal framework that allows *in principle* the possibility to have competition through lower prices during the validity of a pharmaceutical patent.

⁴⁹³ This general effect has been noted by The Swedish Competition Authority in its review of parallel trade: "Apart from the direct impact on prices noted above, there are instances of potential parallel imports having an indirect impact on prices. Faced with the prospect of competition from an incipient parallel import trade, some original suppliers of drugs have on occasion voluntarily chosen to cut prices by over 10%, which had the effect of eliminating the conditions necessary for parallel imports." See Swedish Competition Authority, *Parallel Imports- Effects of the Silhouette Ruling*, 1999, p. 39. Also see the OFT report on the PPRS, February 2007, at p. 69, para. 4.64: "The effects of modulations targeted on parallel imports are complex [...] but on balance are likely to be beneficial to the NHS. Perhaps most importantly, the advantages to companies of being able to modulate are likely to make them willing to accept in negotiations a larger overall price reduction than in the absence of modulation", and then at p. 81, para. 5.48: "The potential distortion to competition could in principle be addressed by removing companies' freedom to modulate prices but this would substantially reduce their flexibility, in particular to respond to parallel imports. Under the current framework, this would in turn make companies less willing to accept price cuts and hence may result in higher prices".

⁴⁹⁴ In those countries where, as previously indicated, there is free pricing, regulators do not negotiate prices with parallel importers but leave them free to compete with manufacturers.

It follows that the pharmaceutical sector cannot be considered 'specific' under competition law on these grounds. In *Syfait II*, the ECJ confirmed this view, by holding that competition law applies to the pharmaceutical sector as well as it applies to other regulated sector⁴⁹⁵.

2. Savings from parallel trade of pharmaceuticals: do they exist? ...

It is now necessary to examine whether and how the existence of a favourable regulatory environment for parallel trade influences the pricing strategies of pharmaceutical companies in importing countries. To this purpose I will examine the traditional model of arbitrage considered by economic theory, where regulation on prices is absent. The latter will serve as *unconstrained benchmark* for the analysis of the outcome of arbitrage under price regulation, as it happens for parallel trade of pharmaceuticals.

2.1 *Optimal strategies in a world without parallel trade: price discrimination*

In a world without parallel trade, where national markets are perfectly segmented, the first-best solution to the maximisation problem of the manufacturer is to apply optimal prices in each country.

Economic theory developed different articulated definitions of price discrimination. The most accredited in the literature is the one given by Stigler's: there exists price discrimination when two or similar goods are sold at prices that are in different ratios to marginal costs⁴⁹⁶. It follows that price discrimination, in an economic sense, occurs also when identical units of a good are sold at the same price under different cost conditions. *Vice versa*, there is no price discrimination if the difference in price reflects the difference in the cost of serving different consumers, i.e. it is cost-based. Hence, strictly economically speaking, there is price discrimination only when the price difference is demand-based⁴⁹⁷.

⁴⁹⁵ See para. 67 of the *Syfait II* ruling, where the ECJ affirmed that the degree of price regulation in the pharmaceuticals sector could not preclude the EU rules on competition from applying just because the restrictive practice take place in a non harmonised area.

⁴⁹⁶ See STIGLER, *The Theory of price*, 1957, p. 209-215. This definition is also accepted in the legal literature. See, for instance, POSNER, *Antitrust Law*, 2001, p. 79-80.

⁴⁹⁷ See TIROLE, *The Theory of Industrial Organisations*, 1988, p. 134, who also specifies that it should not be inferred that price discrimination does not occur when differentiated products are sold to different

The economic literature acknowledges three conditions for price discrimination to be an optimal strategy: (i) firms should enjoy a certain degree of market power; (ii) firms should have information about reservation prices for each consumer (group); (iii) arbitrage should be absent, i.e. the firm successfully impedes that consumers who purchased the good at a low price resell it to consumers who bought it at a higher price⁴⁹⁸.

In the pharmaceutical sector, companies commonly apply 'third degree price discrimination'⁴⁹⁹, where prices differ across groups of consumers or geographic areas. Such type of price discrimination follows the Ramsey rule⁵⁰⁰, where low prices are charged to consumers with high demand elasticity, and high prices are charged to those consumers with low demand elasticity⁵⁰¹.

This turns out to be a second-best solution for those firms facing problems of fixed cost recovery, like in the pharmaceutical industry. By expanding the demand in markets with higher price elasticity, companies can spread the fixed cost over a larger number of units sold⁵⁰².

The analysis of case law previously conducted showed that European competition law does not preclude in principle an undertaking from setting different

consumers, as the use of different qualities of services is also partly an attempt to capture consumers' surplus by separating consumers in different groups.

⁴⁹⁸ See TIROLE, *The Theory of Industrial Organisations*, cit., p. 134 *et seq.*

⁴⁹⁹ This notation follows the well-known classification operated by PIGOU, *The Economics of Welfare*, 1920, p. 240-256, after which it is customary in economics to distinguish among first degree, second degree and third degree price discrimination. First degree price discrimination - a theoretical model that is unlikely to take place in practice because of absence of perfect information - occurs when a firm is able to charge to each consumer his reservation price for each unit of a given good, thereby ripping off completely the consumers' surplus and eliminating the deadweight loss eventually caused by pre-existing monopoly prices. If, on one hand, this result can be considered welfare enhancing, however on the other hand, it does not address distributional concerns and social costs resulting from 'rent seeking' behaviours raised by POSNER, *The social cost of monopoly and regulation*, J. Polit. Econ., 1975, no. 83, p. 807-828. Second degree price discrimination, occurs when a firm sets a price per unit that varies according to the quantity purchased by the buyer or when it applies a two part tariff composed by a flat fee plus a variable fee that depends again on the quantity purchased. In this way prices differ across unit of the goods but not across people, so that buyers enjoy some consumers' surplus. See TIROLE, *The Theory of Industrial Organisations*, cit., p. 134.

⁵⁰⁰ This concept was attributed to J. Robinson in 1933, but later on it has been recognized that Ramsey found this result before in the context of taxation. See RAMSEY, *A Contribution to the Theory of Taxation*, in *Economic Journal*, 1927, no. 37, p. 47-61.

⁵⁰¹ Therefore in the case of third degree price discrimination, prices do not differ according across the unit of the good, like for the second degree price discrimination, but among individuals or groups of consumers.

⁵⁰² See HAUSMAN and MACKEL-MASON, *Price Discrimination and Patent Policy*, in *Rand Journal of Economics*, 1988, no. 19(2), p. 253-265; DANZON and TOWSE, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, cit., p. 183-205. Finally see Guidelines OFT 414, *Assessment of Individual Agreements and Conducts*, para. 3.13;

prices in various Member States⁵⁰³. That is, uniform prices across Europe are not to be regarded as compulsory⁵⁰⁴.

Accordingly, geographical price discrimination cannot be regarded as illegitimate *per se*, as in itself it does not constitute an obstacle to trade between Members States or a barrier to freedom of movement of goods. Actually, it represents an incentive to intrastate trade. On the contrary, attempts to put obstacles to such a trade can represent a concern, as they run against integration and effective competition in the internal market⁵⁰⁵.

2.2 *Optimal strategies in a world with parallel trade*

The European policy on free movement of goods thus forces companies to find a second-best solution that allows them to maximise their profit under the constraint of parallel trade.

Standard economic theory generally predicts that a discriminating monopolist prevents arbitrage by *ex ante* charging a uniform price that eliminates any scope for cross border trade⁵⁰⁶. Consequently, consumers that previously enjoyed a lower price will be charged higher prices, while consumers that before were charged a high price, after the change will enjoy lower prices.

Contrary to first degree price discrimination, the welfare effect of third degree price discrimination still remains ambiguous in the economic literature⁵⁰⁷: in fact, the latter is welfare enhancing, with respect to a situation of uniform price, only as long as it

⁵⁰³ See Section 5.2 of Chapter II.

⁵⁰⁴ Cf. fn 428 *supra*.

⁵⁰⁵ See VICKERS, *When Discrimination is Undue?*, in *Regulating Utilities: Understanding the Issue*, 1998; RIDYARD, *Exclusionary pricing and price discrimination under art. 82 – an Economic Analysis*, ECLR, 2002, no. 23, p. 286; BISHOP, WALKER, *The Economics of EC Competition Law*, cit., p. 197, who affirms that if accompanied by barriers that prevent arbitrage, price discrimination can remove potential gains from trade.

⁵⁰⁶ See PHILIPS, *The Economics of Price Discrimination*, 1983; VARIAN, *Price discrimination and social welfare*, in *American Economic Review*, 1985, no. 75(4), p. 870-875; Id., *Output and welfare implications*, cit.; SCHWARTZ, *Third-degree price discrimination and output: Generalizing a welfare result*, in *American Economic Review*, 1990, no. 80(5), p. 1259-1262; BATTALIO and EKELUND, *Output Change under Third Degree Price Discrimination*, in *Southern Econ. J.*, 1972, no. 39, p. 285-290; FINN, *The Quantity of Output in Simple Monopoly and Discriminating Monopoly*, in *Southern Econ. J.*, 1974, no. 41, p. 239-43; MAULEG and SCHWARTZ, *Parallel Imports, Demand Dispersion and International Price Discrimination*, in *Journal of International Economics*, 1994, no. 37, who found that a regime of uniform pricing was globally sub-optimal with respect to third degree price discrimination; RICHARDSON and MARTIN, *An Elementary Proposition Concerning Parallel Imports*, in *Journal of International Economics*, 2002, no. 56, p. 233-245, who argued that neither a global policy of uniform pricing nor of full segmentation could be supported as a Nash equilibrium.

⁵⁰⁷ See SCHMALENSEE, *Output and welfare implications of monopolistic third-degree price discrimination*, in *American Economic Review*, 1981, no. 71(1), p. 242.

leads to an increase in the total output sold. That is, consumers who were not served before are served under price discrimination.

To the contrary, a switch from uniform pricing to price discrimination that leaves output unchanged triggers a reduction in consumer welfare. This shrink is given by a misallocation of output: some consumers with lower willingness to pay will stop buying the good once the price rose. The reduction in consumer surplus dominates the increase in monopoly profit and overall social welfare decreases⁵⁰⁸.

Therefore, only if it entails an increase in total output, price discrimination is Pareto-superior to price uniformity.

It is argued that in the pharmaceutical sector, differently from others, a uniform price is not attainable, due to the presence of regulation on prices⁵⁰⁹.

Anecdotal evidence seems to support this prediction. The first pharmaceutical company that applied a Single European Price, as a reaction to parallel trade activities over its products, was Merck and Co. Inc., which in the 1996 launched its protease inhibitor indinavir (Crixivan®) at a common EU price, denominated in European Community Units (ECUs)⁵¹⁰.

However, to date this example has remained an isolated case. Reasons are manifold.

Overall it appears that a policy of uniform price is hardly attainable in the long run. In fact, it may hold only at the launch of a drug and for ex-factory prices. Afterwards, price gaps may emerge again due to currency fluctuations and rebates asked by national authorities along time after the launch. For instance, a consistent convergence of prices was registered during the period between the mid-1986 and 1997. However, later on price differential re-appeared, because of government interventions that lowered down prices in countries of Southern Europe⁵¹¹.

Switching to a global uniform price policy for in-market products is equally

⁵⁰⁸ See LAYSON, *Third-degree price discrimination, welfare and profits: a geometrical analysis*, in *American Economic Review*, 1988, no. 78(5), p. 1131-1132; ID., *Market opening under third-degree price discrimination*, in *Journal of Industrial Economics*, 1994, no. 42(3), p. 335-340.

⁵⁰⁹ REY and VENIT, *Parallel Trade and pharmaceuticals*, cit., p. 167.

⁵¹⁰ Cf. DANZON, *The Economics of Parallel Trade*, *Pharmacoeconomics*, 1998, no. 13(3), p. 300.

⁵¹¹ In October 1997 in Greece a decree set pharmaceutical prices by reference to the lowest price charged in Europe; and in August 1996 in Spain there was a voluntary price freeze that lasted until 1998. Subsequently, devaluation of the Drachma, in Greece, and rebates asked by government, in Spain, fostered the divergent trend.

difficult. In fact, this would require either i) lowering prices in importing countries to the level of price charged in the exporting countries (plus the cost of arbitrage), or ii) raising prices in the exporting countries and simultaneously lowering them in the importing countries, until a point where the price gap is such that there is no longer scope for parallel trade, or iii) drop the exporting country⁵¹².

In the following analysis, I will examine the three mentioned pricing strategies, in order to understand which is the optimal response of pharmaceutical companies to parallel trade and what is the effect on drug prices, both in importing and in exporting countries.

2.3 *The impact of parallel trade of pharmaceuticals on price levels in importing countries*

Recent economic literature investigated the effect of the first pricing policy by assuming that pharmaceutical companies, if subject to competition, cannot influence the controlled price in the exporting country but can adjust the price in importing countries only⁵¹³. In this case, parallel trade brings harmonisation towards the bottom, i.e. high prices converge towards the controlled low price⁵¹⁴.

In fact, under such hypothesis⁵¹⁵, companies may respond to parallel trade in two ways.

If trade costs are high, companies find it more profitable to lower the price in the importing country up to the cost of arbitrage so that the latter never occurs (deterrence strategy). In the importing country, the price is reduced to the level of the price charged in the exporting country plus trade costs, while in the exporting country it remains unchanged due to regulation. Price pressure is obtained without parallel trade actually taking place, namely without real resources used in arbitrage activities. The deterrence strategy results in a per-unit revenue equal to the price in the exporting market plus the

⁵¹² I will leave this third choice aside for the time being, given that under EU pharmaceutical law there may be limits to this strategy. I will consider it again *infra* Section 2.4 of this Chapter.

⁵¹³ See GANSLANDT and MASKUS, *Parallel Imports of Pharmaceutical Products in the European Union*, in *Journal of Health Economics*, 2004, no. 23, p. 1035-1057, at 1050, where regulation is introduced by considering the price in the exporting country as given. Also, see MÜLLER-LANGER, *A Game Theoretic Analysis of Parallel Trade and the Pricing of Pharmaceutical Products*, in *German Working Papers in Law and Economics*, 2007-2-1200, Berkeley Electronic Press.

⁵¹⁴ REY and VENIT, *Parallel Trade and pharmaceuticals*, cit., p. 153-177, allege that, whilst this may be positive for consumers, companies may suffer too large profit losses that may endanger their investment in research and development.

⁵¹⁵ However, note that this result derives from the further simplifying assumption that pharmaceutical companies do not apply supply management strategies to restrict parallel trade.

trade cost.

The higher the cost of trade, the easier is the deterrence strategy, since the manufacturing firm does not need to reduce its price that much in the importing country to deter parallel trade. Price pressure takes place also in this case, but it is much lower, due to the high level of trade costs.

Vice versa, if trade costs are low, accommodation – i.e. the firm prefers to sell a smaller quantity at a higher price in the importing country, instead of precluding parallel trade – is the best response. The accommodation price falls with the volume of arbitrage. A larger quantity of parallel trade results in a lower price in the importing country, up to a point where it becomes more profitable to again deter parallel trade. It should be noted that in the case of accommodation, it is actual parallel trade, and not potential, that brings price pressure.

The volume of arbitrage also plays an important role in determining the impact that parallel trade has on prices. When there is an unlimited possibility of parallel import, the most likely and profitable reaction from the manufacturers is deterrence. Unlimited parallel trade, in fact, is capable of stealing the whole manufacturer's business in the importing country, and the firm would earn profit only in the exporting country. Instead, by deterring parallel trade, the manufacturer earns a larger profit. *Vice versa*, accommodation is more attractive when the potential volume of parallel trade is relatively small⁵¹⁶.

The development of the parallel trade industry in the last ten years seems to support the accommodation hypothesis: on the one hand, the flows of parallel imports have been growing, thanks to technological improvements and standards harmonisation that lowered the cost of trade; on the other hand, the volume of supplies shipped abroad remains limited to a certain volume, because of a) mandatory public services requirements that impose on wholesalers the satisfaction of the whole domestic demand first, b) supply restrictions imposed by manufacturers, and c) strategies spontaneously chosen by parallel traders in order to avoid the deterrence response from the manufacturer, which would eliminate any scope for imports.

As a consequence of the premise of low trade costs and endogenously limited

⁵¹⁶ GANSLANDT and MASKUS, *Parallel Imports of Pharmaceutical Products in the European Union*, cit., p. 1040; ZHONG, *Another Side of Parallel Trade*, cit., p. 9.

arbitrage, in certain occasions manufacturing firms have been accommodating parallel trade and the price in importing markets have been falling as the volume of parallel trade raised.

Substantiation of the accommodation hypothesis comes, for instance, from the empirical analysis performed in Sweden, where in the period between 1995 and 1998 an increase of parallel import activities (16% of the sales and 15% of commercialised products) and a correspondent decrease of home market prices (4%) or a diminution of the increase of prices have been observed. Roughly three-fourths of this effect was attributed to the lower prices of parallel imports and one-fourth to lower prices charged by the manufacturing firm⁵¹⁷.

Anecdotal evidence shows that the strategy of deterrence may also take place, when circumstances render it more profitable.

Merck Sharp & Dohme (hereinafter, 'MSD'), the UK subsidiary of Merck & Co. Inc., in August 2007 voluntarily cut by nearly a third of the price of its antihypertensive drug Cozaar®, the UK's sixth most prescribed drug. Such a reduction appeared to be strictly linked to the fact that parallel importers had attained a market share of up to 75% for the product in the UK, as the following table shows:

Table 6: Price cut operated by MSD on Cozaar in August 2007 matched with parallel import penetration in UK

	UK sales (£000) 3/06 - 3/07	Old price (£)	New price (£)	Price reduction	PI market share
Tabs					
25 mg	14.788	18,09	16,18	10,56%	0,00%
50 mg	52.455	18,09	12,80	29,24%	75,09%
100 mg	43.565	24,20	16,18	33,14%	57,27%
Comp tabs					
100/25 mg	1.524	24,20	16,18	33,14%	0,00%
50/12.5 mg	5.912	18,09	12,80	29,24%	60,58%

Source: EAEPC, 2008.

⁵¹⁷ GANSLANDT and MASKUS, *Parallel Imports of Pharmaceutical Products in the European Union*, cit., p. 1049 *et seq.*

The strategy of deterrence can be facilitated by regulation. When a general price cut is introduced in the UK market at the renegotiation of the PPRS, for instance, pharmaceutical companies have two options to meet this price cut: either they reduce all their price by the required percentage or they modulate their price by lowering the price for some drugs more substantially.

The analysis of the pharmaceutical prices after the last renegotiation of the PPRS in 2005 shows that companies applied the modulation option and that they lowered the prices of those drugs subject to parallel trade more than the renegotiation required, as the following table shows:

Table 7: Correlation between a reduction in parallel trade activities in UK and price reductions at the renegotiation of the PPRS in 2005

Product	PI % 2004	PI % 2005	Price cut
Lipitor	42.5	14.6	5-17%
Zoton	37.5	42.7	0-1%
Zyprexa	48.6	35.5	0-19%
Plavix	46.2	25.8	0%
Zoladex	66.5	49.2	0-31%
Efexor	28.9	30.8	0-2%
Cozaar	43.7	45.4	-10-0%
Seretide	16.9	17.5	7%
Aprovel	80.9	34.8	24-30%
Serevent	28.7	27.4	0-7%
Cardura	32.6	6.7	0-55%
Risperdal	48.4	39.4	8-14%
Lipostat	30.0	13.2	7%
Fosamax	27.5	42.7	0-1%
Aricept	62.2	62.1	7%

Source: IMS Health, Janice Haigh, Management Forum, Cambridge, 20th February 2005

It should be noted that price cuts higher than the mandatory 7% established in the new PPRS scheme correspond to the highest level of penetration of import in the UK market, thereby suggesting a correlation between these reduction and parallel trade⁵¹⁸.

As a result, parallel trade market share diminished dramatically for those price cuts that were more substantial.

From this it appears that parallel trade stimulates savings. This may happen both directly and indirectly.

Direct benefits accrue to consumers when manufacturers find it optimal to accommodate and parallel trade takes place in equilibrium. In this case, savings derive from the lower prices paid by patients that purchased parallel imported products, which in turn entail lower reimbursement costs for health care systems and lower premium for health insurance.

The indirect benefits may derive, both under accommodation and deterrence, from the competitive pressure put on manufacturers by parallel importers that drives down patented products prices, or decelerates their increase⁵¹⁹.

For instance, in the Cozaar case, it was estimated that the UK health care system would save an approximate £ 30.2 million per annum due to major price reductions for only one product, provided that that sale volumes of Cozaar products remain constant and that the Government claw back rate stabilises at 10%. In addition, by recouping 100% of the branded product market in the UK, MSD would gain about £ 30 million per annum in revenues despite reducing its price.

An illustrative example of the dynamic effect on prices is given by the following graph:

⁵¹⁸ This interpretation of price trends was expressed also by an EFPIA officer at the SMi conference on Parallel Trade in February 2009 in London, where he said: "[...] as an alternative to a 7% across the board cut, companies were allowed to modulate this across their product range and several chose to target brands with high PI penetration".

⁵¹⁹ Similarly see para. 5.98 of the OFT report on PPRS: "In the short term, parallel trading may provide savings for consumers (typically public purchasers) in higher price markets as a result of the lowering of prices. This may be brought about both as a direct result of the purchasing of parallel imported drugs (which will be cheaper), and by the effect that the increase in competition in the markets for these drugs has on the pharmaceutical manufacturer's pricing for domestically sourced products. In the UK, the Department of Health attempts to identify the savings made by pharmacies on parallel trade through the periodic Margin Inquiry. It then operates a clawback system whereby some of the savings made by pharmacies from the buying of parallel imported products are recovered by the NHS".

Graph 7: Dynamic gains from *intra*brand competition



Source: Pharmacy price list (Poland) - T. Dzitko – 3rd Annual CEE Pharmaceutical Challenges Conference, Budapest, June 2006

The red line identifies the development of the manufacturer’s price, while the green and the blue line indicate the price policy pursued by two parallel traders. From the graph it is apparent that the entry of the two competitors accelerated an existing downward trend.

2.4 *The impact of parallel trade of pharmaceuticals on price levels in exporting countries*

Until now I have considered only those models that assume that drug prices in exporting countries are fixed and that companies can have influence on them only in the importing countries. This assumption is a simple way of modelling the difference in pharmaceutical policies between Northern and Southern European countries: whilst the former apply more ‘market-oriented’ policies and allow free pricing to a certain extent, in the latter governmental intervention is more pervasive and price controls tighter.

It is true that the re-negotiation of prices at a higher level in countries that apply stricter budgetary control of pharmaceutical expenditures may not be always successful. Although there have been cases where companies managed to obtain higher prices (see *infra*), in general governments are reluctant to accept unjustified increases in price and

could threat to de-list products from the reimbursed products lists or to scale down the reimbursement level.

Still, pharmaceutical regulation, as described in Section 1, shows that for new products such increase in price may, instead, start taking place.

The analysis conducted there has shown that even under a scheme of statutory prices, pharmaceuticals pricing in all exporting countries considered (with the exception of Greece) have switched to negotiation systems. Under such pricing policy final prices depend on where the bargaining power resides. Economic investigation showed that the latter is influenced, among other things, by the presence of parallel trade.

When parallel trade is not allowed, if the bargaining power resides with the firm, the price level is positively correlated to the market size. If, on the contrary, the bargaining power resides with the government in the exporting country, the firm will accept a lower price as long as the market size is large. In fact, a larger volume of goods sold compensates the lower prices charged⁵²⁰.

However, in the presence of parallel trade, the negotiated price depends also on the level of trade costs. For a given market size, the price in the exporting country rises as long as trade costs fall. In fact, a falling transaction costs makes parallel trade more of a problem for the manufacturer, who tries to limit parallel trade activity by raising the price. *Vice versa*, higher trade costs that render parallel trade more difficult entail lower prices.

When trade costs are low, the firm is induced to bargaining harder in order to obtain a larger price that blocks arbitrage⁵²¹. As a result, prices in the exporting country rise with respect to a situation where parallel trade does not take place.

The 'bargaining harder effect' can be seen as the result of a change in the participation constraint of the pharmaceutical company due to parallel trade: without parallel trade, in the bargaining process the reservation price for the firm is equal to the

⁵²⁰ See SAUER, *A Model of Parallel Imports of Pharmaceuticals with Endogenous Price Controls*, Economics Bulletin, no. 6(36), p. 1-8, who find that when the firm has all of the leverage, the highest foreign price is achieved. As the government gains bargaining power, the foreign price decreases. When the government has all of the leverage, the firm is forced into marginal cost pricing.

⁵²¹ See TABATA, SHINKAI, TANAKA, and OKAMURA, *Parallel Imports, Drug Price Control and Pharmaceutical Innovation*, Discussion Paper no. 26 School of Economics Kwansei Gakuin University, 2005. In GROSSMAN and LAI, *Parallel Imports and Price Controls, Parallel imports and price controls*, in *RAND Journal of Economics*, 2008, no. 39(2), p. 378-402.

marginal cost; while with parallel trade, the reservation price is given by the price that entails the same profits the company would earn by serving only the importing market at a high price⁵²².

Economic theory, in fact, shows that under a switch from price discrimination to uniform price policy, serving the low-priced country may turn out to be unprofitable for the company⁵²³. In other words, it may be more lucrative to drop the low-priced market and supply only the high-price country at the highest price possible. In that case, low-priced countries, where arbitrage is likely to originate, might be abandoned.

In this sense, an increase in price in the exporting countries could be seen as a response from governments to the development of parallel trade, in order to avoid the possibility that the companies do not serve the market⁵²⁴. That is why price concessions from companies in the exporting countries should be less likely under parallel trade and negotiated price result higher.

Is the threat of cutting off supplies really credible?

From an economic point of view, it should be noted that the abandonment of a country occurs, for instance, when consumer demand in the country that enjoyed low prices under price discrimination is too small compared to the consumer demand in the country where high prices are charged⁵²⁵. Under pharmaceutical price regulation, however, this effect is diminished, because the reimbursement system grants an

⁵²² Or, equivalently, it could be explained as following: more lenient regulation on prices in exporting countries is caused by the prospect that the low price is exported in the importing country through parallel trade and undermines the innovation pattern there. In that case, the exporting country would not be able to free ride anymore on the research activity conducted in the importing country.

⁵²³ In traditional models this effect takes place because the price is too high and quantity purchased in the low-price country too low, therefore companies lose too much money. See MOTTA, *Competition Policy*, cit., p. 502 *et seq.* Note that manufacturers' profits decrease, because the switch impedes them to rip the whole consumer surplus. Therefore, the total welfare effect of a uniform price policy is on the whole positive only if consumers gain more than the manufacturers lose.

⁵²⁴ GROSSMAN and LAI, *Parallel Imports and Price Controls*, cit. *Contra*, see MATTEUCCI and REVERBERI, *Price Regulation and Public Service Obligations under International Arbitrage*, in *Journal of Regulatory Economics*; 2005, no. 28(1), p. 109, who showed, quite counterintuitively, that, by imposing public service obligation, regulators in the exporting country may be able to reduce prices in its country by exploiting parallel exports. The distributor is willing to accept the lower retail price proposed by the regulator in the exporting country, insofar it could recoup profits with exporting activities in the importing country. Such exporting activities are more profitable the larger is the gap between the exporting and the importing country, i.e. the lower is the price is the price asked by the regulator in the exporting country.

⁵²⁵ See ZHONG, *Another Side of Parallel Trade on Pharmaceuticals: Price, Supply and Social Welfare in the Exporting Country*, Mimeo, April 2006 available at <http://economics.ca/2006/papers/0247.pdf>, who finds the exporting country's minimum size that renders the firm indifferent between serving both markets or only the importing country under parallel trade.

adequate demand level to the company. Thus, the likelihood that a company does not launch a product in a low-priced country is also reduced, with respect to other sectors⁵²⁶.

From the legal perspective, in the pharmaceutical sector the withdrawing of a drug from a market after the launch is impossible without infringing the EU legal provisions on uninterrupted supplies, as well as competition law provisions. Companies are, however, entitled to decide not to launch a drug at all⁵²⁷.

The provision establishing the public service obligation cannot be interpreted as mandating companies to enter a specific market, as they have the right to decide not to enter a market at all (especially if they are offered a price that they consider to be too low⁵²⁸). However, if they choose to enter, they are obliged by law to grant 'appropriate and continuing' supplies, in compliance with competition law and the EU rules on free movement of goods⁵²⁹.

The research conducted has evidenced only few cases where pharmaceutical companies did not launch a product: one took place in Greece, where a pharmaceutical form of Zyprexa® has not been launched; other cases happened in Northern European

⁵²⁶ See fn 456 above about the legal provision establishing the public service obligation. In this respect the pharmaceutical market presents very different features with respect to other sectors, where the withdrawal of a product is always possible and it actually occurred, as a consequence of parallel trade. An emblematic case is the *Distiller* case, (see Commission decision 78/163/EEC in case IV/28.282 — *The Distillers Company Limited — Conditions of sales and price*) where the company, after the Commission's prohibition to hinder re-importation of its Scotch whisky in the UK market, it withdrew the product from the other EU countries. See KORAH, *Goodbye, Red Label: Condemnation of Dual Pricing by Distillers*, in *Eur. L. R.*, 1978, no. 3, p. 624.

⁵²⁷ Note that in this case governments could always issue a compulsory licence and impose to the company the introduction of the drug in the market, if the drug is considered essential for the protection of public health. Article 8.2 of the TRIPS Agreement states that "*appropriate measures (...omissis...) may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology*". Article 40 of the Agreement affirms the right of Members to specify in their legislation licensing practices or conditions that may be in particular cases constitute an abuse of intellectual property rights having adverse effects on competition in the relevant market and to adopt appropriate measures to prevent or control such practices. An example of such measures is compulsory licensing. The words 'compulsory licensing' do not appear in the TRIPS Agreement, but form part of the scope of Article 31, relating to 'other use without authorisation of the right holder'. See ANDERSON, *The interface between competition policy and intellectual property in the context of the international trading system*, *Journal of International Economic Law*, 1998, p. 655-678; ABBOTT, *First Report (Final) on the subject of Parallel Importations to the Committee on International Trade Law of the International Association*, *Journal of International Economic Law*, 1998, p. 607-636, at 622-623. However, note that no cases of compulsory licence have been registered in the EU so far.

⁵²⁸ See KANAVOS, *The Single Market for Pharmaceuticals in the European Union*, cit., p. 524, where he affirms that a medicine may have a license to be sold through the European centralised authorisation system, but may not actually be marketed everywhere because of inconclusive pricing negotiations (with the manufacturer opting not to launch in a given member state). In other cases, pricing may not be a necessary condition for launch and the manufacturer may opt to launch in the country at its preferred price in order to capture the private market. However, if reimbursement is sought, then the reimbursement price needs to be negotiated.

⁵²⁹ See AG Ruiz-Jarabo Colomer's opinion in the *Syfait II* case at para. 89.

countries.

It follows that the unsuccessful launch of pharmaceutical products can be considered a problem with marginal relevance in this context. But, while missed launches remain a sporadic case, delays in the launch of new products have been often observed almost in all Member States⁵³⁰.

A possible determining factor of delays in the launch of new products is, on the one hand, reference pricing. The simultaneous launch of a drug in all Member States would in fact influence price negotiation and impede the companies' price discriminating policy: low prices negotiated in some Member States could undercut negotiations elsewhere, thereby impeding to obtain higher prices. That is why low-price countries typically receive the products later than high-price countries.

Companies argue that parallel trade also plays a role in this context: some reported withholding or delaying launch of new products in traditional low-price countries of the EU, rather than accepting prices that would invite parallel trade and hence erode the prices that they can earn in other markets⁵³¹. An example at this regard is provided by the facts in the *Glaxo* case, where GSK claimed that the delay of several years in the introduction of its antimigraine product sumatriptan (Imigran®) in France was caused by parallel trade⁵³². The defendant claimed that in total, from 1972 until 1998 there were five delays of GSK products in Spain and five in France.

Some studies confirm this statement by finding that Spain, Portugal, Greece and Italy were facing the greatest number of delays in gaining access to modern medicines⁵³³. However, data provided by the European Commission do not match with this story: in fact, there appears to be a large number of cases of delay registered in importing countries too. For instance, in the same period, three delays in the launch of GSK products were registered in Sweden, eleven in the Netherlands, ten in Denmark, eight in

⁵³⁰ TABATA ET AL., *Parallel Imports*, cit., p. 107, study delays as a form of non-price discrimination or sabotage.

⁵³¹ See DANZON, *The Economics of Parallel Trade*, cit., p. 300. Similarly BALE, *The Conflicts between Parallel Trade and Product Access and Innovation: the Case of Pharmaceuticals*, in *Journal of International Economic Law*, 1998, p. 637-653.

⁵³² See the Commission Decision on *GlaxoWellcome*, cit., para. 174 *et seq.*

⁵³³ See BOOER, EDMONDS, GLYNN, OGLIALORO, *Economic Aspects of the Single Market in Pharmaceuticals*, in *ECLR*, 1999, no. 5, p. 262, mentioning the figures provided by a study of Europe Economics; DANZON, WANG and WANG, *The Impact of Price Regulation on the Launch of New Drugs – Evidence from Twenty-Five Major Markets in the 1990s*, in *Health Economics*, 2005, no. 14, p. 269.

Germany and in the United Kingdom⁵³⁴.

In sum, the issue of delays in the launch of drugs in national markets is largely open to speculations. However, while causes remain ambiguous, their effect is apparent.

Such strategy helps companies in strengthening their negotiation power *vis-à-vis* the authorities and may lead to the obtainment of higher launch prices also in countries that traditionally control prices more strictly. This confirms that the ‘bargaining harder effect’ hypothesis is highly plausible and may help understanding the empirical evidence that shows a rise in drug prices in exporting countries.

In fact, in the *Glaxo* case, there is evidence that between May 1997 and July 1998 the company managed to obtain substantial price increases for four out of eight products, which were claimed to be the prime candidates for parallel trade: Serevent®, Imigran® and Lamictal® and Ventolin®⁵³⁵.

The welfare effect of such a rise in drug prices depends on the policy objectives in which the government in the exporting country is interested in. When it is mainly concerned with the maximisation of consumer surplus, society will suffer a loss from parallel trade⁵³⁶. If, on the contrary, the government is not concerned only with consumer welfare but it has other policy objectives, like the contribution to R&D, a price that is above the firm’s marginal costs may not necessarily decrease total welfare in the exporting country⁵³⁷.

Overall, considering the effect that parallel trade may have on prices of exporting countries, it follows that this form of competition is capable of bringing prices for pharmaceuticals towards a medium price, instead of a bottom price.

The total effect on consumer welfare is indefinite, as it depends on how much consumer in the importing country gain and on how much those in the exporting

⁵³⁴ See the Commission Decision of 8 May 2001, in case IV/36.957/F3, *Glaxowellcome*, para. 176, on http://eur-lex.europa.eu/LexUriServ/site/en/oj/2001/L_302/L_30220011117en00010043.pdf.

⁵³⁵ See the Commission Decision on *GlaxoWellcome*, cit., para. 121 and 122.

⁵³⁶ TABATA ET AL., *Parallel Imports, Drug Price Control*, cit., p. 18, found that consumer surplus in the exporting country is lower under parallel trade. Similarly see also REY and VENIT, *Parallel Trade and Pharmaceuticals*, cit., p. 166, who say that national government in exporting countries cannot benefit from lower prices as they could under parallel trade.

⁵³⁷ See GROSSMAN and LAI, *Parallel Imports and Price Controls*, cit., p. 398, affirm that the higher prices in exporting countries are detrimental for the short-term consumer welfare there but are beneficial to consumers of both countries in the long-term, thanks to the extra-subsidy from the exporting country that sustain investments in innovation, partly relieving consumers in importing countries, which can enjoy lower prices.

country lose. In terms of profits, the price increase in the exporting country may compensate the profit loss suffered by the manufacturer in the importing country due to competition.

3. ... And how large are they? Competition and regulation in the pharmaceutical sector.

The above analysis shows that savings from parallel trade on pharmaceuticals in importing countries do exist. The relevant question at stake then should not pertain the existence of benefits from parallel trade, but rather their magnitude, namely, how much competitive pressure parallel trade puts on the market.

In other words, the key question is about who pockets the price differential and avail himself of the potential benefits coming from parallel trade⁵³⁸.

3.1 *Measuring the magnitude of savings from parallel trade of medicines*

Three empirical studies conducted by independent organisations attempted to quantify the savings entailed by parallel trade on pharmaceuticals but produced contradictory results at this regard.

A study performed by the university of York (hereinafter, the 'York study') quantified the resulting savings in five main European Member States: Denmark, UK, Germany, Sweden and the Netherlands. With regards to indirect savings, it found that absent competition, prices increased for on-patent drugs, whereas, with competition from parallel trade, prices for on-patent drugs decreased⁵³⁹.

The York study was subject to criticism in an IMS Health's evaluation of the report findings. Calculations were performed again and indicated that savings realized by payers were significantly lower: in particular, figures for Germany and UK were criticized, on the basis of an overestimation of the level of parallel trade in those countries⁵⁴⁰.

⁵³⁸ The Commission itself noted in its Communication of 1998 on the Single Market in Pharmaceuticals (1998) that, "*Unless parallel trade can operate dynamically on prices, it creates inefficiencies because most, but not all, of the financial benefits accrue to the parallel trader rather the health care system or patient.*"

⁵³⁹ See WEST, MAHON, *Benefits to Payers and Patients from Parallel Trade*, University of York, 2003, where the authors considered the competitive effect that parallel imports had on domestic prices in the period 1997-2002 and tried to quantify the resulting indirect savings.

⁵⁴⁰ The York study estimated a level of parallel trade of €2 billion in Germany and an amount of savings equal to €194 million. However, IMS estimated the level of parallel imports into Germany to be only €1.3 billion. Re-applying York's methodology to this revised parallel import figure, IMS estimated that the

Contradicting results with respect to the findings of the York study also came from the subsequent study performed by the London School of Economics (hereinafter, the 'LSE study'). The latter found in general little competitive effect and a very small price reduction for on-patent drugs subject to parallel import⁵⁴¹.

This result was later explained in a subsequent study performed by the University of Southern Denmark (hereinafter, the 'Pedersen study'). There it was argued that the small competitive effect associated with parallel trade was probably due to the very small and little relevant sample used and to the interpretation of the observed co-movement of prices. The study was based on the selection of six product categories that covered 21% of the branded medicines market. The between-country comparison of prices required that information for the same products were collected in all countries. Some products, however, were not subject to parallel import in all countries and not during the entire period. The savings, therefore, were estimated for 19 products only for the year 2002.

Furthermore, the market penetration of parallel imports of the selected products was relatively low, with two-thirds of the products having less than 20% of the parallel import market share.

On the basis of these remarks, the Pedersen study returned back to the method used in the York study and updated the data related to the direct and indirect savings for fifty products in the four main European countries: Denmark, Germany, United Kingdom and Sweden⁵⁴².

saving to payers in Germany is €126 million. The same was performed for UK, arriving at a figure of €201 million, instead of €342 million. See HAIGH, *Parallel Trade in Europe - Assessing the Reality of Payer and Patient Savings A Review of the York Health Economics Consortium report*, available at www.imshealth.com.

⁵⁴¹ See KANAVOS, COSTA-I-FONT, MERKUR, GEMMILL, *The Economic Impact of Pharmaceutical Parallel Trade - A Stakeholder Analysis*, LSE, 2004. Among other things, the study aimed at studying price convergence between countries. For this reason, the study looked at price co-variance. However, prices co-movement does not necessarily imply the absence of price effect. On the contrary, if there is co-movement, one should expect price competition *à la Bertrand*, where each player will undercut its competitor in order to capture the bigger or even the whole market share. In case where to prices co-movement does not correspond competition, then it is likely that one of the actors has market power.

⁵⁴² See PEDERSEN ET AL., *The Economic Impact of Parallel Import on Pharmaceuticals*, 2006. The study used a larger sample: it analyses the price series for 50 products and took into account the development of prices over time. The general assumption on which the study is based is that the manufacturers in the absence of competition from parallel imports will set their price equal to the maximum reimbursed price. Therefore, any deviation from this maximum in markets with parallel imports competition can be attributed to competitive effects from parallel imports.

Savings were found to be lower with respect to those indicated in the York study, because of changes in the relevant national legislation that diminished the incentives for parallel trade (see *infra*).

Here below are some of the results of three studies compared:

Table 8: Comparison between the findings of three studies measuring direct savings from parallel trade on pharmaceuticals in given years (in ml €)

	York study - 2001	LSE study - 2002	Pedersen study - 2004
UK	342	6.9	237
Germany	194	17.7	145
Sweden	47	3.8	45.3
Denmark	16	3	14.2
Total	599	31,4	441.2

Source: York study, 2002; LSE study 2003; Pedersen study, 2006.

A comparison among the results of the three mentioned surveys is, however, hard and not entirely appropriate, given the dissimilar methodology used and the different period considered⁵⁴³. It follows that empirical evidence regarding the magnitude of the savings entailed by parallel trade currently remains inconclusive.

Besides the differences in the methodology used, there are other reasons that contribute to explain these contradictory findings.

⁵⁴³ The York study and the Pedersen study used the same methodology. The calculation of direct savings results from the difference in medicine prices between the more expensive local product and the cheaper parallel-imported product. The measurement of indirect savings is based on the assumption about how prices developed in the absence of parallel imports and about the causal link between parallel imports and changes in the price of the direct import. The evolution of the original product's price before the entry of competition from parallel imports has been examined to predict the hypothetical evolution of the price in the absence of competition. This fictive or 'possible' price has been then compared to the actual price with competition from a parallel import to calculate the savings from the price differential. The LSE study covered the period 1997-2002. Direct savings were estimated using the intra-country price spread in pharmacy purchase price (originator price - parallel import price) and the quantity sold, assuming inelastic demand and using a hypothetical average price for parallel imports. The savings realised should also include the pharmacy profit margins and VAT. It is thus not surprising that the LSE study resulted in a low estimate of the direct savings in the 6 countries. If the selected brand drugs, covering 21% of the market, were representative for the rest of the market in terms of extent and price of parallel importing, then for the total market a rough estimate for the direct savings in pharmacy purchase price terms would be five times the provided figure. This is still considerably lower than the York study estimate, though.

The level of price of parallel imported products – and consequently the level of associated savings - very much depends on strategies implemented by manufacturers to defend their profits from competition. If, for instance, the manufacturer applies quota systems or supply restrictions, it limits the degree of freedom of parallel trader in setting its profit maximising price or in its ability to undercut the manufacturer. With limited volumes at his disposal parallel distributors are often unable to charge lower prices in the market of destination and lose part of their competitiveness⁵⁴⁴. As a consequence, savings from parallel trade decrease.

If, instead, the manufacturer decides to tolerate parallel trade in its distribution system and to adapt its price policy to the sensitivity of the market, the quantity of original products sold – and the consequent market share gained by parallel traders - depends on the size of the price sensitive and insensitive market segments. The bigger is this segment, the larger is the number of consumers that buy cheaper parallel imported products and the bigger are savings.

The latter increase even more if the manufacturer decides to enter into price competition with traders.

Also, the level and the distribution of savings deriving from parallel trade depend on the degree of wholesale and retail competition present in the importing market. Distributors can retain excess profits from exploiting price differences if there are barriers to entry to parallel trading, and if buyers of the imported drugs are unaware to their source and the sellers' margins. This may be the case where parallel imports are a very limited activity and if there are few competing traders in the markets. But economic theory suggests that, where parallel trade is significant and the number of traders increases, parallel traders' margins and prices would fall. And savings increase.

The incentive to charge low prices is sometimes strengthened by the product differentiation existing between parallel imported and original drugs. The former, in fact, by regulation must be clearly labelled and re-packaged as imports⁵⁴⁵. For this reason, the aesthetical appearance of parallel imported drugs is often very much dissimilar to that of original products. Hence, in order to persuade pharmacies and

⁵⁴⁴ See at this regard PEDERSEN ET AL., *The Economic Impact of Parallel Import on Pharmaceuticals*, cit., p. 31. Similarly KYLE, *Strategic Responses to Parallel Trade*, 2005, available at <http://www.duke.edu/~mkyle/Research%20Papers.htm>.

⁵⁴⁵ See *infra* Section 4.1 in Chapter I and *infra* Section 3.2 in Chapter II.

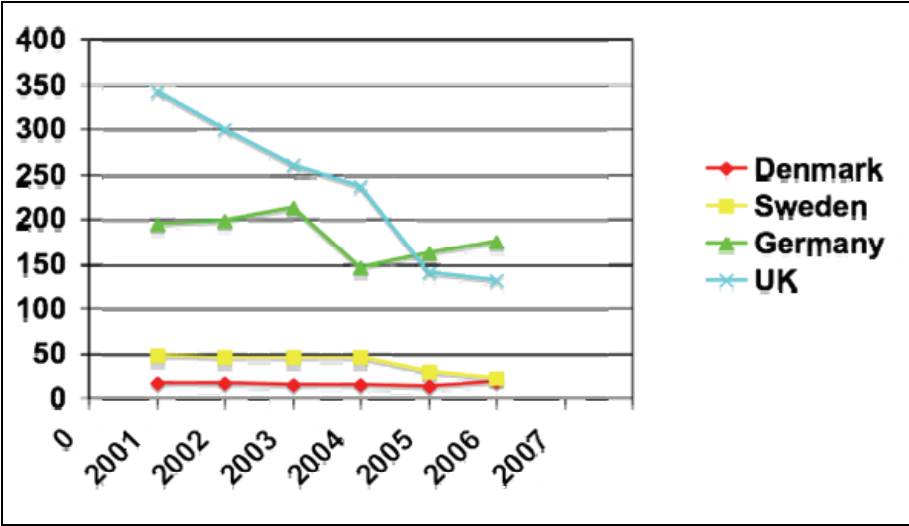
health authorities to accept the imported drug, traders may provide additional financial incentive to purchase an imported drug⁵⁴⁶. This may in turn lead to higher potential savings for the health care system.

3.1.1 Competition and regulation in pharmaceuticals

The regulatory environment influences the magnitude of direct savings too⁵⁴⁷.

The magnitude of direct savings appears to have continuously changed over the period 2001-2006 in Denmark, Germany, UK and Sweden, as it appears from the figure below.

Graph 8: Trend of direct savings from parallel trade from 2001 to 2006 (in ml €)



Source: EAEPC⁵⁴⁸

⁵⁴⁶ For instance, while in UK wholesalers generally sell to pharmacies with a discount of 8-12% on the official price, parallel traders sell with a discount of 10-15%.

⁵⁴⁷ Pharmacists margins vary from country to country and it is generally acknowledged by both national and EU Courts that they should not be calculated in such a way as to prevent importers from passing on any lower cost advantage. See, for instance, ECJ, 13 December 1990, in case C-166/89 *Nefarma Pharmaceutische Bedriff v. Commission*, where it was asked to consider the question of pharmacists' margins and their impact on imports; see also *R. v. Secretary of State for Social Services, ex p. Bomore Medical Supplies*, 1986 (English Court of Appeal).

⁵⁴⁸ Data for the years 2002, 2003, 2005 and 2007 were provided by the Secretary General of the EAEPC, in an interview in October 2007. Data for the years 2001 and 2004 are sourced from the York study and from the Pedersen study respectively. I already warned the reader that these figures have been contested. Still, they are the only ones that I could use to perform an evaluation of the trend of savings along time, because they

The explanation for these different trends are mainly to be found in the changes in the regulation that provides different incentives for stakeholders to supply parallel imported products.

For instance, in Denmark savings from parallel trade in 2003-2004 decreased compared to 2001. However, a new increase took place as of 2005, given that regulation was amended in three main aspects that are capable of stimulating parallel imports: (i) the scope for substitution increased, given that the new law obliged the pharmacies to offer the cheapest product; (ii) the reference price for reimbursement of drugs changed from the Average European price to the cheapest synonymous Danish product; and (iii) a new formula for the pharmacist price margin provided incentives for cheapest substitution.

Parallel imports accounted for 7% of the total turnover in the German market in the first half of 2003, but only for 4,5-5% in the first half of 2004. The main reason for this decline was probably the reduction in the mandatory quota of parallel imports from 7% to 5% at the end of 2003. Furthermore, as of 2004 the parallel importers' mandatory discount to sickness funds on the ex-factory price was temporarily increased from 6% to 16%, forcing the withdrawal of one third of parallel imported products from the German market. However, the reversion of the mandatory rebate to 6% and the new reimbursement system that moved from generic reference pricing to therapeutic reference pricing in 2004 inverted the trend in the subsequent years.

The upward trend in the direct savings from parallel trade registered in Sweden between 2001 and 2004 did not continue in the next years. The pharmaceutical reform and the general price development in the market reduced scope for parallel trade. The Pharmaceutical Benefit Act in October 2002 introduced a new reimbursement rule based on cost-effectiveness analysis to determine the reimbursement level of pharmaceuticals, and the mandatory substitution of the lowest-cost generic alternative. Generic substitution was rapidly implemented and the positive attitude developed by doctors encouraged generic penetration, which obviously reduced market share of parallel imported drugs.

come from the same source and they have been estimated in relation to a period of time that is sufficiently long to allow such analysis.

Secondly, medicine prices have generally decreased with 15% over the period 2002 to 2005, primarily due to ending of the patent period for a number of top-selling drugs⁵⁴⁹, which has opened up for generic products that compete with branded drugs (parallel imported as well as originals). The general decline in the market for brand drugs also reduced the potential savings from parallel trade.

Although it is not included in the graph above, it is also interesting to mention how pharmaceutical regulation in the Netherlands influenced the development of parallel trade. As a financial incentive to dispense generics and parallel imports, the Dutch government allows pharmacists to keep one-third of the price difference between a generic or parallel import and the branded equivalent. This was effective in encouraging the use of generics and parallel imports for the first year of the scheme. Thereafter, its effectiveness fell below expectations as pharmaceutical companies and wholesalers reacted by offering discounts and incentives for dispensing branded products.

This effect was countered further by the introduction of the 1996 pricing law. The price differentials between branded and generic products fell from 17 to 7% and from 16 to 5.7% for parallel imports. Some generic and parallel imported products were driven out of the market and problems of availability ensued. The pricing law meant declining incomes for pharmacists and, as a result, they started looking harder for discount bonuses⁵⁵⁰.

It clearly appears that regulation also impacts the degree to which manufacturers respond to increased competitiveness. And this in turn determines the magnitude of indirect savings.

While price negotiation aims at setting a maximum price under which competition is allowed, reference price systems put a minimum cap that blocks competition towards the bottom⁵⁵¹. Often pharmaceutical companies might not want to lower their domestic prices in response to competition for several reasons.

⁵⁴⁹ E.g.: Zocord®, Losec®, Cipramil®, Plendil®, Zolof®.

⁵⁵⁰ Cf. KANAVOS, *The Single Market for Pharmaceuticals in the European Union*, cit., p. 529.

⁵⁵¹ In Italy, for example, it has been observed the absence of any kind of price competition bringing prices below the reference point. See the reports from the Italian Competition Authority No. AS131/1998 *Determinazione del prezzo dei farmaci* and No. AS300/2005 *Disposizioni urgenti per il prezzo dei farmaci non rimborsabili dal SSN*. See also CERM, *Il decreto sui prezzi dei farmaci di fascia 'C' alla luce dell'attività di segnalazione dell'AGCM spunti per 'riflessioni riformiste'*, n. 4/0, 2005.

First of all, after a successful price war against a competitor, it is not always profitable to raise again prices, as, even in countries where pharmaceutical companies can freely price their products, the regulator might not increase correspondingly the price reimbursement level.

Secondly, a lower price for a given product could have a knock-on effect on other European markets through reference pricing, thereby causing a larger loss than the one suffered in the domestic market as a consequence of competition⁵⁵².

Therefore, health care and pharmaceutical regulation play a fundamental role in determining favourable competition conditions and, hence, the magnitude of the savings from parallel trade, as well as the identity of beneficiaries. Yet, the fact that the price difference may be pocketed by traders cannot be attributed to pharmaceutical price setting. It is rather the signal that the market is characterized by price rigidity. Parallel traders enjoy a certain degree of market power for the same reasons that pharmaceutical companies do. Having little constraints from the demand side, discipline on prices, and consequently traders' profit, is necessarily determined by appropriate *ad hoc* regulation that provides pass-on mechanisms.

4. The price harmonising function of parallel trade of pharmaceuticals

The conducted analysis suggests that parallel trade brings harmonisation of prices for pharmaceuticals.

However, the theoretical literature is divided in this respect.

Some models show a tendency of price convergence under parallel trade, because prices in exporting countries increase while in importing countries they decrease⁵⁵³.

There are models that found, instead, that, in some circumstances, parallel trade is an unambiguous force for price integration. This has been explained through the three-fold trade off that manufacturers face when they set prices in the importing and in

⁵⁵² This was the case of Pfizer in Germany, which, after the inclusion of its product Lipitor in the reference price system and the attribution of the lower reimbursement price of simvastatin cluster, still found to be rational not to lower its price to the reference and to lose most of its market share in Germany, as this would have avoided a larger loss in other markets due the reference price system.

⁵⁵³ See JELOVAC and BORDOY, *Pricing and Welfare Implications of Parallel Imports in the Pharmaceutical Industry*, in *International Journal of Health Care Finance and Economics*, 2005, no. 5, p. 5-21.

the exporting countries: they have to restrict parallel trade, avoid resources waste due to actual trade, and reduce the double-markup problem in the exporting country. These three competing interests were found to determine the counterintuitive result that retail prices could diverge (albeit wholesale prices converge) as a result of declining trading costs and as the volume of parallel trade increases⁵⁵⁴.

It is difficult to say which of the two predictions is more correct from an economic point of view, because drug prices are influenced by a lot of factors.

Market analysis indicates that there has been overall evidence of progressive price convergence during the period 1986-2001. This development can be ascribed to changes in pharmaceutical price regulation⁵⁵⁵. Other studies that show evidence of price convergence in the pharmaceutical market⁵⁵⁶ found explanation of this trend in the general integration process that has been activated since 1985, thanks to the EU directives that have been adopted to achieve a single pharmaceutical market.

As already mentioned, we can observe that some European countries that were traditionally characterised by strict regulation of drug prices are now introducing more lenient regulations. Italy and Portugal, for instance, recently moved their regulated prices towards the European average, while France allows freer pricing for innovative products⁵⁵⁷. That is why prices of new products at launch are in average higher than in the past in those countries where traditionally prices were low.

Symmetrically, we observe the recent introduction of tougher cost-containment measures (based on parallel trade, on reference pricing and on cost-effectiveness

⁵⁵⁴ See GANSLANDT and MASKUS, *Vertical Distribution, Parallel Trade, and Price Divergence in Integrated Markets*, in *European Economic Review*, 2007, no. 51(4), p. 943-970, where the authors develop a model of vertical pricing in which an original manufacturer sets wholesale prices in two markets that are integrated at the distributor level by parallel imports. Also, cf. the GC in the *Adalat* case, where the Court at para. 181 said: "Nor, finally, can the Commission rely in support of its argument upon its conviction, which is, moreover, devoid of all foundation, that parallel imports will in the long term bring about the harmonisation of the price of medicinal products."

⁵⁵⁵ See EUROPE ECONOMICS, *G 10: Recommendation XIV the economic case*, 2002, where it is showed that the standard deviation of pharmaceutical prices in some Member States between 1986 and 2001 reduced significantly.

⁵⁵⁶ See TIMUR, PICONE and DESIMONE, *The Single Market and Pharmaceutical Industry in the European Union: Is There Any Evidence of Price Convergence?*, in *iHEA 2007 6th World Congress: Explorations in Health Economics Paper*, available at SSRN: <http://ssrn.com/abstract=992975>. Using annual 1994-2003 IMS Health data from five EU countries on prices of drugs at the molecule level used to treat cardiovascular disease, the paper explains how the integration process has affected cross-country drug price dispersion in the EU and show that some convergence took place, with long-term price differences arising from country fixed effects.

⁵⁵⁷ See KANAVOS and COSTA-I-FONT, *Pharmaceutical parallel trade in Europe: Stakeholder and competition effects*, in *Economic Policy*, 2005, no. 45, p. 766.

analysis) in markets that conventionally applied free pricing, like Denmark, Germany, Sweden and the UK, with the purpose of capping prices.

As a result of these trends, a price corridor is likely to appear in the market.

However, some caveats to the foregoing conclusion are necessary.

In fact, the latter have provided a variety of instruments aimed at pursuing, *inter alia*, a policy of price convergence. This is the case, for instance, of reference pricing: this price setting mechanism is very much facilitated by the Transparency Directive and has the effect of bringing prices in different countries nearer to each other⁵⁵⁸.

Also, as long as the process of price setting mechanisms gets more transparent, it becomes easier for the Commission, and other stakeholders, to establish whether the Treaty rules on free movement and competition are properly respected, particularly if national laws favour domestic production over imports⁵⁵⁹.

Such control should promote the development of favourable regulatory conditions at national level⁵⁶⁰ for parallel trade to develop. Its growth should inject more competition in the distribution chain: this should bring the necessary competitive pressure capable of further reducing price gaps among countries and contribute to realise what is called the 'negative integration' of the internal market.

Still, parallel trade is not the main driving force behind the observed price

⁵⁵⁸ Convergence is taking place towards the bottom according to LOPEZ-CASASNOVAS and PUIG-JUNOY, *Review of the literature on reference pricing*, in *Health Policy*, 2000, no. 54(2), p. 87-123. Still, they affirm that reference pricing did not bring a large amount of savings to national health care systems, because of the increase in volume of products not covered by reference pricing.

⁵⁵⁹ For instance, parallel importers claimed, unsuccessfully, that PPRS scheme allows manufacturers to introduce deep discounts for prices of products under competition from parallel trade while maintaining high prices for other products. See the Sixth PPRS Report to Parliament (Department of Health 2002). The research-based industry has also used the Directive to challenge national schemes that use imported product prices as a benchmark, thus in their view discriminating against domestic products. See the complaint filed by the Danish pharmaceutical industry association (LIF), *Danish LIF complains to ECJ*, in *Scrip*, no. 2612, 16 January 2001, p. 3. The Commission launched infringement proceedings against the Greek government in relation to its so-called 'confirmation price' system and with regard to its failure to respect the timetables for price approval as imposed in the Directive. See *Commission threatens Greece with Court proceedings*, in *Scrip*, no. 2589, 3 November 2000, p. 7. Infringement proceedings were also initiated against Finland for its failure to provide for reimbursement procedures for certain categories of drugs. See *Finnish Scheme Challenged*, in *Scrip*, no. 2558, 19 July 2000, p. 6.

⁵⁶⁰ Several conditions are necessary in order for parallel trade to take place effectively: low trade cost, appropriate regulation that allows for fast market penetration and that provides pass on mechanisms, absence of supply restrictions, etc. At the same time, companies manage to circumvent the mechanism of reference pricing by simply implementing sequential launching of products, starting with the country where the higher price is likely to be obtained.

harmonisation wave – and this is the first caveat⁵⁶¹ –, but it is just one of the several tools used by the Commission to achieve this result. In this respect, it certainly contributes to the process of market integration that the Commission has been pursuing through different means, from direct measures, like Directives, to indirect incentives, like the enforcement of free movement and competition law rules, as well as a policy of price transparency.

Understood in this sense, *la raison d'être* that justified the favourable policy conventionally adopted at a EU level towards parallel trade can still be considered well founded.

The second caveat is about the necessary qualification that accompanies the term 'harmonisation' in the field of pharmaceuticals. It has been already shown that the market appears highly fragmented, especially at the level of prices. And in fact, whilst empirical evidence shows that on average the price gap among countries has been narrowing, for individual products price differentials still remain consistent⁵⁶².

The reasons of this diverging effect are manifold. But surely governmental intervention plays an important role in determining price trends: renegotiations, price freezes, and rebates asked by governments from time to time explain why, despite the efforts of the Commission, the market still appears non-harmonised at the level of prices.

In sum, it appears that the attainment of 'harmonisation' of prices in the pharmaceutical market is determined by two conflicting forces: on the one hand, the rules of the internal market push for price convergence and may also achieve it for a certain period, until regulation pulls in the opposite direction and may restore the situation existing previously to the period of convergence. That is why price harmonisation in the pharmaceutical market is still only partial.

For these reasons, one may wonder whether parallel trade (as well as other indirect measures of 'negative' harmonisation) is best suited to achieve price

⁵⁶¹ An opposite statement, i.e. finding a relationship of pure causation between parallel trade and trends of prices for drugs, is methodologically shaky. This problem of correlation generally affects many international comparative pricing studies, as it is difficult to isolate causal effects in the cross-country comparisons, because of the many factors influencing drug prices in a given market: differences in health system structure and financing, pharmaceutical subsidies, cost-containment policies, product mix and production costs, etc. KANAVOS and MOSSIALOS, *International comparisons of health care expenditures: what we know and what we do not know*, in *Journal of Health Services Research and Policy*, no. 4(2), p. 122–126.

⁵⁶² This is the outcome of a study by Janice Haigh from IMS, presented at the conference *Management Forum*, held in London, on February 2006.

harmonisation, or whether internal market integration in this field should rather be accomplished through approximation of national laws and health care systems, as the Commission has attempted to do in the first stage of its action.

This issue is relevant also from a strictly legal point of view. In a sector where legislative competence is reserved to Member States, the question of whether it is appropriate to pursue a policy of price harmonisation through the use of EU competition law rules arises.

4.1. The 'constitutional issue'

According to Article 168 TFEU, a high level of human health protection is a horizontal objective that must be ensured in the definition and implementation of all European policies and activities⁵⁶³.

However, paragraph 7 of the analysed provision imposes an important limit on the activities and policies that the EU can adopt in the field of public health. It establishes that the EU action in the field of public health has to fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. For this reason, the EU action shall limit itself to complementing national policies, encouraging cooperation between the Member States and, if necessary, lending support to their action⁵⁶⁴.

On the basis of such a division of competences in the field of health, price differences due to governmental regulation acquire further legitimacy under the architecture of the Treaty.

As outlined in Chapter I, differences in pharmaceutical prices derive from the different national objectives pursued by governments. Some of them focus on containing public healthcare expenditures and granting universal access to medicines by keeping prices low, while others permit high prices, in consideration of various factors: the weight that the pharmaceutical industry plays in their economy, the promotion of R&D,

⁵⁶³ The Treaty of Amsterdam introduced Commission competence on health care, albeit only to a limited extent. Before the introduction of a division of competence on health at a EU level, the EU slowly developed a complex, sophisticated system of pharmaceutical regulation on the basis of its general powers under Articles 100 and 100A EEC (now Art. 114 TFEU) to promote the internal market.

⁵⁶⁴ See para. 2 of the provision under examination. Note that under the new division of competences set by the Lisbon Treaty, the field of health remain a supporting competence.

as well as the higher purchasing power⁵⁶⁵.

As a matter of equity, as well as of efficiency, in fact, high-price countries may be charged higher prices for drugs, because they are better placed to finance more substantially the competitiveness of the industry. *Vice versa*, countries that have a low purchasing power should benefit from lower prices for pharmaceuticals⁵⁶⁶.

Also the regulatory means deputed to implement the policy choice vary to a great extent from country to country. As already noted, price regulation is not necessarily to be identified with price cuts or price/volume caps. But pharmaceutical regulation comprises also profit repayments, negotiations, reference pricing, etc.

Not only actual policies on prices for pharmaceuticals (should) reflect the economic wellbeing of a country, but they also signal the way a government has chosen to strike the trade off between low healthcare expenditures and generalised access to medicines and the remuneration of the production and distribution or the R&D effort⁵⁶⁷.

Given that governmental regulation on pharmaceutical prices reflects the different social, budgetary and industrial policies, the most efficient outcome would be that each government chooses the desired way of striking the trade off. From this point of view, it is claimed that parallel trade undermines such a choice, because it limits national authorities ability to control domestic prices through the chosen price-setting regime. In particular, by imposing a downward pressure on prices, it diminishes the contribution to R&D chosen by a given country⁵⁶⁸.

In other words, parallel trade would function like a negative externality that is imposed on the importing country: through a spillover effect, the low level of prices

⁵⁶⁵ What factors are considered in determining the reasonableness of the price for a medicinal product depends on whether the primary objective of the regulator is to achieve the lowest price possible as part of a cost-containment strategy or a price level that balances industry incentives and profitability with cost-containment goals. Some countries reward companies that contribute to the national economy or invest in R&D, but determining what contributions should be rewarded and how much is not necessarily evident. For example, albeit pricing mechanisms are established through a formula, other factors such as therapeutic value and prices in other countries may be taken into account without being formally stated. This generates lack of transparency in the price setting mechanisms. See MRAZEK and MOSSIALOS, *Regulating Pharmaceutical Prices in the European Union*, in MOSSIALOS ET AL., *Regulating Pharmaceuticals in Europe: striving for Efficiency, Equity and Quality*, 2004, p. 118.

⁵⁶⁶ See REY and VENIT, *Parallel Trade and pharmaceuticals*, cit., p. 153-177. Similarly, WHISH, *Competition Law*, cit., p. 507, points out that preventing price discrimination could pose distributional problems, by redistributing income from the poorer to the richer countries through trade.

⁵⁶⁷ See REY and VENIT, *Parallel Trade and pharmaceuticals*, cit., p. 161.

⁵⁶⁸ See REY and VENIT, *Parallel Trade and pharmaceuticals*, cit., p. 161.

applied in the exporting country is transferred to the importing country⁵⁶⁹.

In this sense, it is argued, price regulation that privileges low prices is liable of distorting the entire internal market. In fact, whenever a Member State decides to implement a low price policy for pharmaceuticals, this will influence the price policy of other countries across Europe, among other things, through parallel trade⁵⁷⁰.

It follows that a policy that encourages parallel trade, although in line with the objectives of the EU, may be in contrast with the policy objectives of a single Member State. This in turn may entail two considerations.

First of all, given that market fragmentation comes in the first place from different pharmaceutical regulations present in each Member State, it would not be appropriate to attribute the responsibility of market partitioning to companies⁵⁷¹.

Secondly, it may not be up to the Commission to achieve price harmonisation for pharmaceuticals through parallel trade, because it would violate the outlined division of competences in the field of health as set forth by the Treaty⁵⁷².

In other words, the choice of achieving harmonisation of prices for pharmaceuticals through competition law enforcement may be questionable. In this wake, the Court of First Instance in the *Adalat* case argued that the Treaty provides for other means to achieve the single market in those fields where fragmentation is caused by the exercise of Member States' sovereignty⁵⁷³.

Article 5 TEU provides that the EU shall act within the limits of powers

⁵⁶⁹ See REY and VENIT, *Parallel Trade and pharmaceuticals*, cit., p. 168.

⁵⁷⁰ See the opinion of AG Fennelly in the case *Merck v. Primecrown*, para. 47, where he recalled that in the absence of parallel levels of protection in both the exporting and importing Member States, EU law should not export the legislative policy of the former to the latter.

⁵⁷¹ See BOOER, EDMONDS, GLYNN, OGLIALORO, *Economic Aspects of the Single Market in Pharmaceuticals*, in *ECLR*, 1999, no. 5, p. 261. This argument clearly reminds the issue put forward by the defendant for the first time in *Consten and Grundig* and solved in *Deutsche Grammophon*.

⁵⁷² See KON and SCHAEFFER, *Parallel Imports of Pharmaceutical Products*, cit., p. 130.

⁵⁷³ See para. 179 of the ruling from the GC in the *Adalat* case, where the Court said that "under the system of the Treaty, it is not open to the Commission to attempt to achieve a result, such as the harmonisation of prices in the medicinal products market, by enlarging or straining the scope of Section 1 (Rules applying to undertakings) of Chapter 1 of Title VI of the Treaty, especially since that Treaty gives the Commission specific means of seeking such harmonisation where it is undisputed that large disparities in the prices of medicinal products in the Member States are engendered by the differences existing between the state mechanisms for fixing prices and the rules for reimbursement...". The Court mentioned previous case law that established such principle before: *Merck and Beecham*, para. 47, *Centrafarm v Winthrop*, para. 17, *Musik-Vertrieb Membran and K-tel International v GEMA*, para. 24, *Bristol-Myers Squibb and Others*, para. 46, where it was affirmed that that distortions caused by different price legislation in a Member State must be remedied by measures taken by the Community authorities.

attributed and of objectives assigned by the Treaty. Among the latter, Article 3(3) TEU indicates the establishment of the internal market. In particular, Article 26 TFEU provides that the EU shall adopt harmonisation measures that progressively allow its building. To this purpose, Article 114 TFEU establishes that the achievement of the objectives indicated at Article 26 TFEU should be obtained through the application of the procedure ex Article 294 TFEU⁵⁷⁴. In this context, the Council is the body that should adopt the necessary measure to approximate national laws.

In sum, one could wonder whether a policy that encourages and protects parallel trade of pharmaceuticals in order to indirectly wipe out the obstacles to market integration implemented by private parties, and bypasses the institutional provisions devoted to harmonisation purposes in the field of health, is legitimate and appropriate under the current structure of the Treaty.

In fact, while in other sectors that are under the competence of the EU, market integration can be achieved through the concurrent means of positive harmonisation, namely the enacting of EU legislation that forces national laws towards convergence, and negative harmonisation, namely the enforcement of freedom of movement of goods and competition law rules, such possibilities may not both be available when competence is reserved to Member States.

⁵⁷⁴ According to the assent procedure established by Art. 294 TFEU, the harmonisation measure should be approved by qualified majority by the Council, based on a proposal of the Commission and the opinion of the Parliament. Para. 3 and 4 of the provision read as follows. “2. *The Commission shall submit a proposal to the European Parliament and the Council.*

3. *The Council, acting by a qualified majority after obtaining the opinion of the European Parliament:*

- *if it approves all the amendments contained in the European Parliament's opinion, may adopt the proposed act thus amended,*

- *if the European Parliament does not propose any amendments, may adopt the proposed act,*

- *shall otherwise adopt a common position and communicate it to the European Parliament.*

The Council shall inform the European Parliament fully of the reasons which led it to adopt its common position. The Commission shall inform the European Parliament fully of its position. If, within three months of such communication, the European Parliament:

- (a) *approves the common position or has not taken a decision, the act in question shall be deemed to have been adopted in accordance with that common position;*

- (b) *rejects, by an absolute majority of its component members, the common position, the proposed act shall be deemed not to have been adopted;*

- (c) *proposes amendments to the common position by an absolute majority of its component members, the amended text shall be forwarded to the Council and to the Commission, which shall deliver an opinion on those amendments.*

4. *If, within three months of the matter being referred to it, the Council, acting by a qualified majority, approves all the amendments of the European Parliament, the act in question shall be deemed to have been adopted in the form of the common position thus amended; however, the Council shall act unanimously on the amendments on which the Commission has delivered a negative opinion. If the Council does not approve all the amendments, the President of the Council, in agreement with the President of the European Parliament, shall within six weeks convene a meeting of the Conciliation Committee.*

What is, in fact, argued is that market integration for pharmaceuticals should rather be achieved through positive harmonisation, i.e. EU legislation, only after that Member States have given their consensus on this choice through the appropriate legislative procedure.

4.2. 'Negative harmonisation' v. 'positive harmonisation' in the pharmaceutical market

These statements give rise to some observations.

First of all, it is questionable that the path towards harmonisation based exclusively on the institutional mechanism proposed by the GC in *Adalat* is a viable solution both from a political and from an efficiency point of view.

The history of the harmonisation efforts undertaken by the European Commission and Council disproves this feasibility.

Currently, the Commission holds the monopoly of the legislative initiative at a EU level, but it believes that in pharmaceuticals any action is left to Member States. Therefore it looks like it will not act⁵⁷⁵. This would be a first institutional *impasse* that may not be easily overcome.

From Member States' side, any harmonization attempt would be politically extremely difficult, given that health care is a sensitive policy area that is capable of determining the outcome of national elections. It follows that Member States are not willing to act either⁵⁷⁶. And this would be a second hurdle that may block the harmonisation process.

Under these circumstances, thus, the successful completion of the single market for pharmaceuticals cannot rely only on the approximation of national rules. The enforcement of the rules of the internal market, therefore, in my view appears an inevitable tool to deal with market fragmentation.

⁵⁷⁵ However, the *Tobacco Advertising* case demonstrated that appreciable distortions of competition could be tackled under Article 95 EC.

⁵⁷⁶ Cf. HANCHER, *Pricing European Pharmaceuticals: Can the Commission untie the Gordian Knot?*, in *Fifteen ways to price a pill*, *Eurohealth*, 2001, no. 7(2), p. 28, where she recalls that Commission's attempts to tackle the issue of price divergence at source by seeking to harmonise national rules on pricing and profit controls have not found much favour from either the Member States, who regard this as a matter of health policy and therefore of national competence, or from the research-based industry, who distrust attempts to set average 'European' prices for their products. See for instance, the failure of the efforts to reach consensus within the three Bangemann round tables described in the Commission Communication on the Single Market in Pharmaceuticals COM(98) 588 final of November 25th, 1998, p. 10-11.

Secondly, the call for positive harmonisation as the only legitimate policy tool in the pharmaceutical market assumes that Article 168 TFEU attributes to Member States the entire and exclusive responsibility in the health care sector. However, health care is not totally excluded from EU law⁵⁷⁷. In fact, internal market provisions inevitably influence Member States' health care policy. For instance, the Internal Market Council of May 18, 1998 concluded that the EU policy for pharmaceuticals should, *inter alia*, aim at ensuring the effective further improvement in the operation of the single market in this sector based on principles of free movement and competition⁵⁷⁸. It follows that the organization and delivery of health service are sovereign competences that have to be exercised by Member States in full respect of the provisions of the Treaty.

For instance, in the field of organisation and financing of social security, the ECJ affirmed that Member States have the power to autonomously organize their social security systems, especially given the lack of harmonisation at a EU level. Yet, in exercising this competence, Member States are required to do so in compliance with EU law, i.e. with the principle of free circulation of goods as well as competition law rules. Accordingly, recent case law strengthened access to cross-border health care⁵⁷⁹.

Certainly, given that access to health care is a fundamental right and that health services constitute a major component of the European social model and contribute to social and territorial cohesion in Europe, the application of the rules of the internal market should respect the right for the Member States to ensure the availability of high-quality health care accessible to the population, *without endangering the financial balance of*

⁵⁷⁷ For instance, see the EC Charter on human rights, which gives some competence also to the Community on health issues. In the literature, it is also advocated the need for Community health care policy, including patients' rights, and for an increased cross-border alliances (e.g., hospital care), and for a framework for cross-border care conditions (quality, equality medical practice, admission, accreditation, patients' rights, etc.). See DEN EXTER, *The EC Treaty and Access to Health Care*, presentation at conference about health care law in Toronto in 2004 available at www.law.utoronto.ca/documents/zhealthlaw04/denExter.ppt.

⁵⁷⁸ The Council also considered the goals of: facilitating the delivery of health care in Member States at levels at which are affordable and in ways which maximise patients' access to medicines; maintaining the regulation of the pharmaceutical sector to ensure the safety, quality and efficacy of medicines; and strengthening the competitiveness of the sector, in particular by encouraging R&D. The Council, nevertheless, recognised that there is a tension among these policy objectives.

⁵⁷⁹ See recent case law cross-border health care: ECJ, 8 April 1998, in case C-120/95 *Nicolas Decker v Caisse de maladie des employés privés*; ECJ, 7 August 1999, in case C-157/99, *B.S.M. Smits-Geraets v. Stichting Ziekenfonds VGZ*, and *H.T.M. Peerbooms v. Stichting CZ Groep Zorgverzekeringen*; ECJ, 12 July 2001 in case C-368/98 *Abdon Vanbraekel and Others v Alliance nationale des mutualités chrétiennes (ANMC)*; ECJ, 13 May 2003, in case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekering UA*, and between *E.E.M. van Riet and Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen*.

their national security systems⁵⁸⁰.

That fact that the EU must refrain from imposing a financial burden on Member States in areas where they retain competence, shows *a contrario* that internal market measures that represent a financial relief for national health care systems do not necessarily violate this Member States' right to secure their financial budgets.

This is valid *a fortiori*, as long as Member States choose to take advantage of these measures to achieve their own policy objectives. So, for instance, the mentioned *ad hoc* national regulation that aims at encouraging parallel trade of pharmaceuticals in their territory is a signal of the fact that Member States are actually willing to avail themselves of the internal market rules, insofar these allow them to contain health care expenditures⁵⁸¹. This happens especially in those countries that normally host the bulk of the European pharmaceutical industry where governments over time built a reputation of institutions prone to allow high prices.

These countries, intending to be important home markets for research-based products, have traditionally opted for higher prices and lower volumes of consumption. For this reason, they have been not willing to ask for lower prices, or they may not dispose of enough bargaining power to cut prices themselves⁵⁸².

Nevertheless, Member States realised over time that market pricing simply resulted in higher prices where the health care system was paying for the brand, without that the therapeutic value of products reflected their price. Already from the end of the nineties all Member States were concerned that, unless savings could be made elsewhere within existing expenditure level in the pharmaceutical sector or elsewhere in the healthcare system, the entry of new products onto the market would have represented

⁵⁸⁰ See Decker, para. 39.

⁵⁸¹ A doubt at this regard may be cast only for UK, where the claw back system was not implemented specifically to encourage parallel trade, but has such an effect only indirectly. However, cf. what the OFT affirmed in its report on PPRS as reported in fn 519 of this Chapter.

⁵⁸² See JUNOD, *An End to Parallel Imports of Medicines? Comments on the Judgment of the Court of First Instance in GlaxoWellcome*, in *World Competition*, 2007, no. 31(2), p. 300, where it is affirmed that parallel trade is rather used as a political justification to justify a price cut. *Contra* see REY and VENIT, *Parallel Trade and pharmaceuticals*, cit., p. 167 citing several cases where governments imposed a price cut: UK imposed a price cut in 1999 of 4.5%. Spain: 6% in 1999/2000. France: 2,5% in 2000. Italy 7% in 2003. Germany: 6% on ex-factory prices of product that are not subject to reference pricing.

additional calls on health budgets⁵⁸³.

So, Member States' financial need to contain pharmaceutical expenditures compelled them to take appropriate measures. At the same time, advances in health economics created a new awareness in health authorities, which realised that acting on the supply-side through statutory pricing only was insufficient and probably counterproductive⁵⁸⁴.

That is why new pharmaceutical policies are now looking at the demand-side, in order to stimulate price sensitivity in all relevant stakeholders. To this purpose, most of Member States enacted laws that aim at increasing substitution with cheaper products. Facilitating market penetration of parallel imported products contributes to this policy objective, especially during patent validity where price competition is lower⁵⁸⁵. Generic penetration serves the same purpose after patent expiry.

In light of this, it is true that there is a tension between a particular set of prices that have been chosen by a country to strike a particular national trade off⁵⁸⁶ and the

⁵⁸³ This was one of the concerns expressed at the Bangemann Roundtables. See Commission Communication Commission Communication on the Single Market in Pharmaceuticals COM(98) 588 final of November 25th, 1998, p. 9.

⁵⁸⁴ Total pharmaceutical expenditure is the sum of drugs dispensed, multiplied by their price. Consumption (i.e. prescribing) patterns are a determinant factor for pharmaceutical expenditures. For instance, demographic factors result in volume demand for healthcare and especially for pharmaceuticals increasing faster than population growth. Hence even if prices remained constant, expenditure would increase. In Sweden, real drug expenditures increased by 95 per cent between 1974 and 1993, due to a 22 per cent rise in the number of prescriptions – mainly due to newer, more expensive products – while relative prices decreased by 35 per cent (see JONSSON, *Pricing and reimbursement of pharmaceuticals in Sweden*, in *Pharmacoeconomics*, 1994, no. 6 (suppl. 1), p. 51–60). In France, numerous supply-side policies aimed at controlling drug prices have been used since 1975, achieving some of the lowest prices in Europe. However, with volumes unconstrained, pharmaceutical expenditures increased with the number of prescriptions (see LE PEN, *Drug pricing and reimbursement in France*, in *Pharmacoeconomics*, 1996, no. 10, suppl. 2, p. 26–36). In Spain, the relative price of drugs decreased by 39 per cent between 1980 and 1996, yet a 10 per cent increase in the number of items prescribed, mostly for new products (there was a 442 per cent increase in these) with little therapeutic gain, was associated with a 264 per cent increase in real drug expenditures over the same period (LOPEZ-BASTIDA, and MOSSIALOS, *Pharmaceutical expenditure in Spain: cost and control*, in *International Journal of Health Services*, 2000, no. 30(3), p. 597–616.). A similar picture emerges from Greece, where from 1994 to 2000, despite a 17 per cent decrease in relative prices, the number of prescriptions increased by 16 per cent while drug expenditures grew by 204 per cent (see KONTOZAMANIS, *The Greek Pharmaceutical Market*, Athens: Institute for Industrial and Economics Studies, 2001). These examples serve only to emphasize that while direct price controls may be effective in lowering drug price, pharmaceutical expenditures may nevertheless increase.

⁵⁸⁵ It follows that price of medicines is only one of the control variables affecting total pharmaceutical cost. However, even if much depends on policies that influence volume and prescribing habits of physicians, price is still felt by authorities to be a key variable. This, according to KANAVOS, *The Single Market for Pharmaceuticals in the European Union*, cit., p. 527, induces them to implement policies, among which there are incentives to parallel trade, that aim at constraining prices.

⁵⁸⁶ E.g. it is claimed that the PPRS in the UK is thought to have encouraged investments, not only by maintaining a stable and predictable regulatory environment, but also through higher prices that allowed

rules of the internal market. However, it's national governments in the first place that, having realised the opportunity provided by cross border competition, have departed from the initial choice by allowing parallel imports to access their market.

Health authorities, in fact, govern the marketing authorisation and the pricing and reimbursement system: in some countries, lacking any provision that establishes a final price and the related reimbursement level for imported products, parallel trade cannot have access to the market and it is unlikely to develop.

For instance, Italy lacks an appropriate and updated legislation for parallel trade⁵⁸⁷. In particular, nowhere it is established how to price parallel imported products and at what level the reimbursement price should be set. Given that in Italy prescription-only products are subject to statutory pricing and that the final price is negotiated together with the reimbursement price, its absence represents an implicit denial of access to the market for imports. As a matter of practice, AIFA has been asking for a rebate on the original reimbursement price from 5% to 10%⁵⁸⁸, or a reimbursement price equal to the generic equivalent. However, this price proved to be too low and caused the exit of the parallel imported product from the market⁵⁸⁹.

As a consequence, despite the release of eight marketing authorisations for the import of prescription-only products into Italy, no imported reimbursed product is marketed⁵⁹⁰.

It follows that parallel trade operates at a significant level only as long as

levels of research and development expenditures above the worldwide average. See MOSSIALOS, *An evaluation of the PPRS: is there a need for reform?*, in GREEN, *Should Pharmaceutical Prices be Regulated?*, London: Institute of Economic Affairs, 1997. Similarly, see para. 4.64 of the OFT report on PPRS: "*In the longer term, lower parallel imports means a higher proportion of NHS payments going to the company which originally developed the product, and this may be expected to benefit innovation*".

⁵⁸⁷ In Italy the Decree of 29 August 1997 regulates parallel imports. The European Commission in 2002 started an infringement procedure against Italy and released a reasoned opinion to the Italian Ministry of Health (2002/287/I) because the legislation was causing obstacles to cross border trade. The Commission asked the Italian government to review the Decree but to date no amendments were made to it.

⁵⁸⁸ This method may be not compliant with EU law, because it may discriminate among domestic products and imports. For instance, the European Commission already released a reasoned opinion to the Swedish (n. 2000/4158) and the Austrian (n. 2002/5316) Ministry of Health, which established a reimbursement price lower with respect to domestic products. The Commission considered those provisions against Articles 28 and 30 EC. Both States amended their reimbursement legislation.

⁵⁸⁹ This was the case, for instance, of Voltaren phials. The Italian importer had two marketing authorisations for the import of the product from France and from Spain (Det. AIFA n. 560 e 561 del 26/09/2005) but for both AIFA established that the reimbursement price was granted at the level of the correspondent generic. The importer could not market the product, because that price was not profitable.

⁵⁹⁰ Imports, on the contrary, take place for OTC products, given that they are free priced.

Member States autonomously decide to encourage it through appropriate national legislation⁵⁹¹. In this context, thus, governments are not entirely passive recipients of the Commission's policy on parallel trade.

I believe it is more accurate saying that importing countries rather apply an ambiguous attitude towards the pricing issue: they do not cut prices directly because they do not want to be accused to stifle innovation, but at the same time, given the financial constraints they are subject to, they choose to do it indirectly, for instance by allowing parallel imports.

This ambivalent policy is certainly exercised in accordance to the division of competence in the field of health at a EU level that gives full responsibility for drug prices to Member States. However, it inevitably generates the 'push-and-pull' effect that delays the accomplishment of price harmonisation in the pharmaceutical industry.

5. Anticompetitiveness by object or by effect?

The considerations expressed in this Chapter shed some light on the issue, presented at the beginning, of whether an agreement that restricts parallel trade on pharmaceuticals runs contrary to Article 101 TFEU in its effect, and not in its object, in consideration of the heterogeneous regulation of prices for drugs.

5.1. *The modernised approach to Article 101 TFEU and the Glaxo case*

For a long time, the influence of the ordoliberal thought led the Commission to consider a restraint to commercial freedom as a restraint to competition. This enlarged

⁵⁹¹ See KANAVOS, *The Single Market for Pharmaceuticals in the European Union*, cit., p. 527, who says that parallel trade increased at a significant level with the lowering of trade barriers, due to direct action of the Commission (Directive 70/50/EC of the 22 December 1969, where the Commission established important provisions aimed at eliminating all the national obstacles of legislative nature to cross border trade) and the work of the ECJ against discriminatory national regulation that favoured domestic products over imports. Until the end of the '90s health authorities or sickness funds were not really showing interest in parallel trade. Until then cross border trade was benefiting only the intermediaries involved. Afterwards, maybe encouraged by the ruling in *Decker*, started promoting parallel trade in order to benefit from lower prices and enacted specific laws that allowed them to translate such lower prices into savings for the health care system.

very much the scope of Article 101(1) TFEU⁵⁹² and triggered the criticism of a large part of legal scholars⁵⁹³.

Indeed, improvement in the economic understanding of the functioning of markets made clear that a restriction to commercial freedom is not necessary or sufficient to find a restriction to competition. Accordingly, EU Courts, starting from *Société Technique Minière*, rejected a formalistic application of the provision and called for a deeper market analysis based on the legal and economic context in which the agreement under scrutiny operates before a violation of Article 101(1) TFEU – either by object or by effect – is alleged.

In line with the mentioned case law, the old formalistic policy has been abandoned, and a new approach has been later on embraced by the Commission. The latter in its *Guidelines on the application of Article 81(3) of the EC Treaty* (now Article 101(3) TFEU) (hereinafter, the '*Guidelines on Art. 81(3)*') indicated that the anticompetitiveness of an agreement arises only if damaging effects in terms of output, prices, innovation and the variety or quality of goods and services can be found (even only potentially) in the market⁵⁹⁴.

So, for instance, the Commission starts its analysis of an agreement from the joint market shares of the parties, in order to check whether these exceed the thresholds set out in the Commission's *de minimis* Notice⁵⁹⁵. But this is in itself insufficient for the

⁵⁹² This also entailed a huge workload for the Commission under Article 101(3) TFEU, as ROUSSEVA, *Modernizing By Eradicating: How the Commission's New Approach to Article 81 EC Dispenses with the Need To Apply Article 82 EC to Vertical Restraints*, in *Common market law review*, 2005, no. 42(3), p. 589.

⁵⁹³ *Ex multis* see KORAH, *The Rise and Fall of Provisional Validity: the need for a Rule of Reason in EEC Antitrust*, in *Northwestern J. of Intellectual Law and Business*, 1981, p. 320; FORRESTER and NORALL, *The laicization of Community Law: Self-Help and the Rule of Reason: How Competition Law is and could be applied*, in *CMLR*, 1984, no. 21, p. 11; BRIGHT, *Deregulation of EC Competition Policy: Rethinking article 85(1)*, in HAWK, 1994 *Fordham Corp. L. Inst.*, 1995, p. 505-527; WAELEBROEK, *Antitrust Analysis under Article 85(1) and Article 85(3)*, in HAWK, 1994 *Fordham Corp. L. Inst.*, 1995, p. 693-793. These commentators claimed that Art. 101(1) TFEU should have been applied on the basis of the *rule of reason* parallel to the application of the Section I of the Sherman Act. The issue of whether there exists a rule of reason under European competition law will be discussed at length in Chapter V.

⁵⁹⁴ See the Communication from the Commission – Notice – Guidelines on the application of Article 81(3) of the Treaty, OJ C 101, 27.4.2004, p. 97-118, para. 16 and 24.

⁵⁹⁵ See the Commission Notice on agreements of minor importance that do not appreciably restrict competition under Article 81(1) of the Treaty (OJ C 368, 22.12.2001 – hereinafter the '*de minimis* Notice'). The thresholds are set as following: the joint market share of parties should not exceed the 10% if they are competitors, and 15% if they are not competitors.

finding that an agreement is caught by Article 101(1) TFEU. The individual assessment of the likely effects produced by the agreement is, on the contrary, required⁵⁹⁶.

By reference to this approach, the GC in the *Glaxo* case recalled that the ‘restriction to competition’ considered in Article 101(1) TFEU refers to the concept of *effective competition*, i.e. the degree of competition necessary to achieve the goals of the Treaty⁵⁹⁷. The latter is necessarily determined by the legal and economic context that characterises the market where the agreement takes place. The analysis of such circumstances should drive, according to the Court, the examination of *both the object and the effect* of an agreement⁵⁹⁸.

The particular features of the pharmaceutical market, according to the Court, would cast some doubts about the existence of a restriction to competition by object. More specifically, regulation on prices impeded to presume that parallel trade would bring real competition in the market. Hence, in the absence of any presumption of negative effects on competition, the agreement could not be caught under Article 101(1) TFEU without an analysis of the actual effects on the market.

While this principle may seem to be an application of that strand of the case law that rightly requires the analysis of the legal and economic context before an infringement is alleged, *de facto* it is only paying lip service to this case law, and, instead, it is indirectly upsetting it.

Various reasons support this statement.

5.1.1. *An effect-based approach?*

An effect-based approach in the application of competition law rules is surely to be welcomed. However, the application provided by the GC leaves any interpreter greatly puzzled.

The Court acknowledged that the agreement was intended to limit parallel trade and partition the common market. However, this was not considered sufficient for an infringement of the provision to be alleged⁵⁹⁹. In fact, the Court affirmed that even when

⁵⁹⁶ See the Guidelines on Art. 81(3) EC, para. 24.

⁵⁹⁷ See *Metro I*, para. 20-21.

⁵⁹⁸ See para. 109-111 of the *Glaxo* ruling.

⁵⁹⁹ See para. 119 of the *Glaxo* ruling, where the Court said that “... *the application of Article 81(1) EC to the present case cannot depend solely on the fact that the agreement in question is intended to limit parallel trade in medicines or to partition the common market, which leads to the conclusion that it affects trade between Member States...*” (emphasis added).

an agreement has an anticompetitive object, but it does not appear to have effects on consumers, it cannot fall within the scope of Article 101(1) TFEU. *Rectius*, no matter the fact that the agreement has an anticompetitive object, if there are indicia of absence of any anticompetitive effect, it should be ascertained that they concretely exist, in order to prohibit it⁶⁰⁰.

Actually, this reasoning – quite illogically – leads to affirm that an agreement with an anticompetitive object that does not have anticompetitive effects (which may well be the case, as I will show *infra*) is not anticompetitive in its object anymore.

Such convoluted principle seems to suggest that the absence of any anticompetitive effect of the market renders irrelevant the fact that the agreement has an anticompetitive object. But this equals to say that the provision under examination should be applied only when agreements have negative effects on consumers⁶⁰¹.

From a legal standpoint, however, this view cannot be supported.

The rationale of Article 101 TFEU is, in fact, designed according to the paradigm of consumer welfare. Therefore, only agreements that are welfare reducing should be caught under the provision. This means that welfare-enhancing factors deriving from the characteristics of the market where the agreement takes place should be taken into account in the anticompetitive assessment⁶⁰². Case law also confirms that there exists a restriction to competition within the meaning of Article 101(1) TFEU when, without the agreement, consumers enjoy a larger quantity of cheaper products⁶⁰³. On the contrary, there is no restriction when the market situation does not appear to be different when the agreement is implemented⁶⁰⁴.

⁶⁰⁰ See JUNOD, *An End to Parallel Imports of Medicines*, cit., p. 298, who rightly wonders how it is possible that an agreement that has an anticompetitive object does not have anticompetitive effects.

⁶⁰¹ See JUNOD, *An End to Parallel Imports of Medicines?*, cit., p. 297.

⁶⁰² Note that this interpretation of Art. 101 TFEU came from its reading in conjunction with Art. 3(1)(g) EC, which has been excised from the text further to the Lisbon Treaty. Cf. NAZZINI, *Article 81 EC between Time Present and Time Past*, cit., p. 504; GYSELEN, *The Substantive Legality Test under Article 81-3 EC Treaty – Revised in Light of the Commission's Modernization Initiative*, in *European Integration and International Coordination, Studies in Transnational Economic Law in Honour of Claus-Dieter Ehlermann*, 2002, p. 181. The economic approach purported in the case law has then been definitely adopted in the new block exemption and in the Guidelines on Art. 81(3) EC, para 13.

⁶⁰³ For instance, in *Consten and Grundig* it was verified that the implementation of the agreement led to higher prices of 20%. See KORAH, *EEC Competition Policy- legal form or economic efficiency*, in *Current Legal problems*, 1986, no. 39, p. 85-109, at 93.

⁶⁰⁴ See ODUDU, *Demonstrating Restrictive Effect*, in *ELR*, 2001, no. 26, p. 262.

However, this cannot substantiate the interpretation that, in the analysis of whether an agreement has as its object or effect the restriction of competition, account of the disadvantage for the final consumers should always be taken⁶⁰⁵. The notion of restriction of competition includes also cases where an agreement may only have the potential and tendency to produce an impact on competition, and not only those agreements that concretely harm consumers⁶⁰⁶.

Accordingly, in its decision on the *Glaxo* appeal the ECJ recalled that Article 101 TFEU aims to protect not only consumers, but also the structure of the market and competition as such, because the latter is thought to be by definition the best method to serve consumer welfare.

An opposite interpretation would deprive the category of ‘restriction by object’ as one of the alternative criteria under Article 101(1) TFEU of part of its practical effectiveness and significance.

For instance, if one accepts the view expressed by the GC in the *Glaxo* case, only restrictions to competition downstream are caught by the provision, while restrictions upstream would never fall within Article 101(1) TFEU. In fact, in the latter case it is more difficult to show a detrimental effect on consumers, especially if downstream competition is not effective. But without the proof of consumer harm, the agreement would not be prohibited.

However, some restrictions that operate at an upstream market level are capable of adversely affecting the final consumer⁶⁰⁷. These are precisely restrictions of competition by object, which are considered as such because by their very nature they put at risk consumer welfare. Among horizontal agreements, price fixing, output limitation and market sharing agreements are generally considered by the EU Courts and the Commission to have this effect. As regards vertical agreements, the examined category includes, in particular, fixed and minimum resale price maintenance and

⁶⁰⁵ Cf. ECJ, 6 October 2009, in case C-501/06 P *GlaxoSmithKline v. Commission* (hereinafter, ‘*Glaxo appeal*’), para. 63.

⁶⁰⁶ See the opinion of AG Trstenjac in the *Glaxo appeal*, para. 104 and 108.

⁶⁰⁷ See the opinion of AG Trstenjac in the *Glaxo appeal*, para. 113-115, where she observes that “[...] as the distance from the market level at which the final consumer asks for the end product increases, the analysis of whether the restriction of competition at the upstream market level has an appreciable adverse effect on the final consumer would probably also be more difficult. Beyond a certain distance, such an analysis would probably be barely feasible without carrying out a market analysis. With a market analysis, however, the dividing line between restriction of competition by object and restriction of competition by effect would be crossed”.

contractual clauses providing absolute territorial protection, as well as restrictions on passive sales⁶⁰⁸. These agreements are immediately caught under Article 101(1) TFEU⁶⁰⁹.

Agreements that are anticompetitive by object, in fact, constitute a sort of 'pure conduct offence'⁶¹⁰, i.e. the conduct is sanctioned as such and not only when it has a negative effect on the market. Such strict treatment is justified on experience showing that these clauses have a very high potential to produce negative effects on the market: they reduce output and raise prices, leading to a misallocation of resources and to a reduction in consumer welfare⁶¹¹.

In other words, the category of restriction of competition by object embodies a *presumption* of effects⁶¹². That is why when agreements between undertakings are considered to be anticompetitive 'by object', it is unnecessary for the purposes of applying Article 101(1) TFEU to demonstrate any actual effects on the market. Once it has been established that an agreement has as its object the restriction of competition, there is no need to take account of its concrete effects⁶¹³.

Obstacles to parallel trade do enter this definition: the features of the legislation on pharmaceutical pricing at a national level, as well as market analysis support the presumption that cross border trade brings, not only in abstract, but concretely, benefits to consumers. And, as held by the ECJ in its decision on the *Glaxo* appeal, none of the characteristics of the pharmaceutical market is capable of casting doubt on this presumption.

⁶⁰⁸ Restrictions that are blacklisted in block exemptions or identified as hardcore restrictions in guidelines and notices are generally considered by the Commission to constitute restrictions by object. See the Guidelines on horizontal cooperation agreements, cited in note, paragraph 25, and Article 5 of Commission Regulation 2658/2000 on the application of Article 81(3) of the Treaty to categories of specialisation agreements (OJ L 304, 5.12.2000, p. 3). (29) See Article 4 Commission Regulation 2790/1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices (OJ L 336, 29.12.1999, p. 21) and the Guidelines on Vertical Restraints, cited in note, paragraph 46 *et seq.*

⁶⁰⁹ Extensively on the role that market integration plays within European competition law see WILS, *Rule of Reason*, cit., p. 62-66, who *inter alia* recalls that economic models that show the positive effects of vertical restraints do not take into account the objective of the Community. Similarly, GYSELEN, *Vertical Restraints in the Distribution Process: Strength and Weakness of the free rider rationale under EEC Competition Law*, in CMLR, 1984, no. 21, p. 651 affirms that free rider issues do not bear market integration overtones.

⁶¹⁰ See *European Night Services*, para. 136.

⁶¹¹ See the Guidelines on Art. 81(3) EC, para. 21.

⁶¹² Cf. NAZZINI, *Article 81 EC between Time Present and Time Past: a Normative Critique of 'restriction of competition' in EU Law*, in CMLR, 2006, no. 43, p. 497.

⁶¹³ See the Guidelines on Art. 81(3) EC, para. 20.

A restriction to parallel trade thus is a restriction by object. And the way to the ‘modernization’ of Article 101 TFEU according to an effect-based approach chosen by the General Court cannot be sustained, as it does not find any legal or economic ground.

5.1.2. ... Or an *ad hoc* exception for the pharmaceutical sector?

By narrowing the scope of the principle set forth by the Court to the pharmaceutical sector only, a second interpretation of the *Glaxo* ruling may be envisaged.

The Court first acknowledged that agreements restricting parallel trade normally run against Article 101(1) TFEU in their object⁶¹⁴. But then it questioned the validity of this statement in the pharmaceutical sector: the underlying justification for the departure from traditional analysis of restrictions to parallel trade, as I recalled several times, is the presence of regulation on prices.

It follows that the presumption of illegality of restrictions to parallel trade is valid in all sectors but the pharmaceutical market⁶¹⁵. Differently stated, it may seem that the GC was attempting to tailor an *ad hoc* departure from the traditional application of competition rules only for the pharmaceutical sector⁶¹⁶.

Such exception, although in abstract it is a legitimate policy choice, nevertheless, appears founded on a misconception: the belief that regulation on prices drives out any competition mechanism. Such statement is not supported by the analysis conducted in this Chapter: as previously stressed, the presence of regulation is not sufficient to exclude in principle that parallel trade can put pressure on prices of original products. On the contrary, national pharmaceutical legislations that encourage parallel trade create the virtual conditions for this effect to take place. The existence of savings corroborates the finding.

In this sense, the pharmaceutical market is not ‘special’ under competition rules: while the economics of the sector - very large sunk costs, a high degree of uncertainty characterising the discovery process, the lengthy of the administrative procedures,

⁶¹⁴ See para. 115-116 of the *Glaxo* ruling, where the Court affirmed that “...agreements which ultimately seek to prohibit parallel trade must in principle be regarded as having as their object the prevention of competition. [...] agreements that clearly intend to treat parallel trade unfavourably must in principle be regarded as having as their object the restriction of competition”.

⁶¹⁵ Similarly, see SOUTO SOUBRIER, *The Concept of an Agreement and Beyond: How to Block Parallel Imports of Pharmaceuticals to Protect the Hearth of Competition*, in BELLAMY and CHILD, *European Community Law of Competition*, 2008, p. 132.

⁶¹⁶ Similarly, JUNOD, *An End to Parallel Imports on Medicines?*, cit., p. 296, fn 20.

governmental intervention on prices, all together - may distinguish it from other markets, regulation as such does not appear sufficient to exclude that traditional market mechanisms take place and to justify an exception from competition rules⁶¹⁷.

In fact, there are many regulated sectors where products and services judged 'essential' to consumers – like tobacco products, books, postal and banking services – are subject to price regulation *and* competition law. In such cases, the fact that prices are regulated in different ways and differ from State to State does not normally constitute a reason to claim a departure from the traditional judgement of anticompetitiveness, due to the specificity of the sector. Indeed, the existence of price regulation is not a sufficient reason to treat a regulated sector differently from others.

Secondly, a standard of anticompetitiveness grounded on the presence of regulation of prices for pharmaceuticals and on the 'specificity' of the pharmaceutical sector easily proves to be unworkable and creates problems of consistency in the application of competition rules for the way it is crafted.

For instance, given that it is based on the assumption that regulation of prices excludes competition, and since such regulation is not present everywhere, Article 101(1) TFEU would then apply in a different way according to the Member State considered.

To substantiate this objection it is enough to just depart from a two-countries setting and consider a broader context where trade flows in and out from Member States. For instance, while parallel trade *into* UK may appear to not have any beneficial effect on British patients because pharmacies are reimbursed on the basis of the prices negotiated in the PPRS scheme⁶¹⁸, parallel trade *from* UK, say, into Denmark, where pharmaceuticals prices are free and reimbursement covers the level of the price of the cheapest equivalent (i.e. the imported product under patent validity), would be presumed to bring benefits to Danish patients⁶¹⁹.

⁶¹⁷ The GC seems to contradict itself at para. 105 where it affirmed that "[...] In accordance with the case-law [...], it is only where the sector in which the agreement is applied is subject to regulations which preclude the possibility of competition that might be prevented, distorted or restricted by that agreement that Article 81(1) EC is inapplicable."

⁶¹⁸ Although recall that the claw back system indirectly allows the NHS in UK to translate the lower prices charged to pharmacists, also by parallel traders, into savings.

⁶¹⁹ However, as the GC itself acknowledged later on at para. 130, a deeper look into the mechanism of the system reveal that such economic benefits come indirectly in the form of discounts (the claw-back system),

In this case, the positive effects of parallel trade are more apparent and there should be no need of ascertaining their actual existence. Under these conditions, a dual pricing system would have again an anticompetitive object.

However, it appears that such 'elastic' notion of 'restriction by object' cannot be supported under European law. Either a restriction is by object or it is by effect. In order to fall within the second category, it should be demonstrated that the presumption of negative effects is false and unsupported by empirical evidence.

The analysis of regulation conducted so far, however, shows that, no matter the magnitude of savings (an aspect that plays a role at a subsequent stage of the analysis, under the balancing of anticompetitive effects with pro-competitive effects), these do exist. Their existence ultimately rests on the abstract possibility provided by the regulatory environment to have competition from parallel trade, notwithstanding governmental price controls. It has been shown in this Chapter that such conditions for competition to take place are present, and actually endeavour to encourage it.

Having excluded the validity of this alternative interpretation of the *Glaxo* ruling, and in light of the considerations expressed in the preceding sub-section, it follows that the legal principles that guided the previous jurisprudence on parallel trade still apply and that restrictions to parallel trade of pharmaceuticals remain restrictions by object.

The only way to reconcile this, to my opinion, inevitable conclusion with the effect-based rationale of the provision under discussion is to interpret the reasoning of the Court as an attempt to provide defendants with the possibility to escape the strict treatment reserved to hardcore restrictions, through the rebuttal of the presumption of the existence of a restriction to competition, where economic and legal circumstances allow it⁶²⁰. This is the interpretation that appears to be privileged, for several reasons that will be discussed at length in the last Chapter.

which are designed by taking into account the ability of wholesalers and pharmacies to buy part of their supply at cheaper price from parallel importers.

⁶²⁰ See, for instance, GC, First Ch., 14 July 1994, in case T-77/92 *Parker Pen Ltd v Commission of the European Communities*, para. 39, where the Court held that even " [...] an agreement according absolute protection escapes the prohibition laid down in Article 85 of the Treaty where it affects the market only insignificantly, regard being had to the weak position of those concerned on the market for the product in question."

6. Conclusions

This Chapter analysed the effects of parallel trade in terms of lower drugs prices for consumers in the short term, starting from the legal assessment operated two recent cases before EU Courts. Both the Court of First Instance of the *Glaxo* case on dual pricing, and the AG Jacobs in the *Syfait* case, where parallel traders were subject to refusal to supply, affirmed that corporate conducts aimed at obstructing parallel trade were not to be considered necessarily anticompetitive.

The main thesis underlining this new approach to limitations to parallel trade on pharmaceuticals, proceeds as follows: under price controls, parallel trade could not be presumed to bring about any effective pressure on prices of original products and consequently benefits for consumers.

This Chapter showed that price regulation cannot be presumed to impede price competition in importing markets and that benefits from parallel trade do exist, as confirmed by the fact that health care systems in the importing countries generally take appropriate measures in order for public finances to benefit from the presence of cheaper products in the market.

The investigation conducted tried to face the issue at stake by re-formulating it. It is believed, in fact, that the relevant question related to parallel trade on pharmaceuticals is not whether it entails savings for consumers but rather how large they are. Country-specific regulation and market dynamics could, in fact, impede the full exploitation of the potentials that parallel trade displays and fail to entirely pass savings on to consumers, thereby allowing traders or other stakeholders along the distribution chain to pocket them.

Negotiation procedures seem to be the most efficient pass-through mechanism that avoid the appropriation of benefits from parallel trade from third parties. When parallel trade takes place in equilibrium, the latter plays like a threat that increases the bargaining power of authorities and insurance funds *vis-à-vis* the companies in price negotiations for domestic products. It follows that, by helping regulators to convince manufacturers to charge lower prices, parallel trade can serve the purpose of achieving allocative efficiency goals.

However, empirical evidence about the magnitude of savings brought about by parallel trade of pharmaceuticals appears to be rather inconclusive to date. As well as there are no clear-cut results about the effect that parallel trade brings in terms of price harmonisation. Some empirical evidence registered a price convergence during the period of 1986-2001. Yet, this evidence is not robust enough to make any conclusion on this point.

It rather appears that, whilst on average prices are converging, specific products are priced at a very different level across countries. This does not necessarily mean that the theoretical rationale of the Commission's policy towards parallel trade, price harmonisation, is flawed, because evidence does not underpin it. It rather appears that parallel trade is one of the many tools used by the Commission (and welcomed by those Member States that want to use them to achieve their policy objectives in the field of pharmaceuticals) to achieve 'negative harmonisation' in a market where 'positive harmonisation' is currently experiencing an *impasse*. These tools, which are represented by the rules of the internal market, compete with an opposing force, regulation. The latter often pulls in a direction contrary to harmonisation, thereby nullifying the harmonisation action eventually deriving from the enforcement of the rules on free movement of goods and on competition law.

These considerations have important antitrust implications. In this respect, my focus was on issues related to Article 101 TFEU and in particular on whether agreements restricting parallel trade of pharmaceuticals are to be considered anticompetitive in their object or only in their effects, insofar they are present in the market.

Although an approach to competition rules that bans or allows corporate practices depending on the effects of the latter on the market is certainly correct, the change of the anticompetitive assessment of agreements restrictive of parallel trade does not appear justifiable under the 'specificity' of a sector, i.e. on the presence of regulation on prices.

The reference to the intervention of governments on drug prices as a basis for an exception in the anticompetitive analysis only for the pharmaceutical sector is flawed. In fact, the analysis conducted showed that despite regulation competition works and parallel trade of pharmaceuticals brings savings to patients.

This means that the presumption of negative effects from restrictions to parallel trade can be upheld also for pharmaceuticals. An opposite interpretation would, in fact, lead to exclude restrictions in the upstream market, which do not have immediate effect on consumers, from the scope of Article 101 TFEU, and to reduce the category of 'restriction by object' to empty words.

CHAPTER IV

Parallel trade and pharmaceutical innovation: the emergence of the 'efficiency defence' in European competition law⁶²¹

Introduction

The second line of arguments used by pharmaceutical companies to justify their practices restrictive of parallel trade was based on efficiency grounds.

They claimed that profits' erosion caused by parallel trade may slowdown the innovation pace, by decreasing the future profitability of R&D projects and consequently undermining their incentive to innovate and bring new drugs in the market. In this sense, parallel trade may have an adverse effect on consumer welfare in the long term.

The impediment to parallel trade was thus aimed at indirectly keeping alive the incentives to innovate, a key factor for pharmaceutical companies' competitiveness, as well as a means to provide consumers with new and better drugs. For this reason, the defendants maintained, first of all, that actions taken to stop parallel trade had a positive effect on consumers in the long run.

Secondly, the defendants argued that actions against parallel trade were proportioned. Given that this type of competitive pressure would benefit neither patients nor national health care systems, because the price differential is almost entirely pocketed by the intermediaries, the elimination of parallel trade caused little consumer harm in the short term, as opposed to the long run positive effect arising from the stimulation of innovative activity.

⁶²¹ This Chapter builds on my article *Parallel Trade and Pharmaceutical R&D: the Pitfalls of the Rule of Reason*, in *European Competition Law Review*, 2008, no. 29(11), p. 649-665.

Such allegations had important implications for the legal assessment performed before the EU Courts in both cases under examination.

In the *Syfait I* case AG Jacobs supported the idea that a dominant pharmaceutical company does not necessarily abuse its dominant position by refusing to supply in full the orders placed with it by wholesalers, even when this has an anticompetitive effect, i.e. when parallel trade is eliminated.

In his view, the refusal to supply could be regarded simply as a legitimate business behaviour finalized to the protection of commercial interests from the negative effects that parallel trade had on profits and on the incentive to invest in innovation. Thus the conduct was not to be considered abusive, because it stimulated dynamic efficiency.

However, I shall recall that the *Syfait I* case was dismissed on procedural grounds by the ECJ, while the merit was dealt with only in the opinion of the AG Jacobs. Moreover, his approach has been challenged in *Syfait II*, which revisited the issues of *Syfait I*. In that case, both the AG Colomer and the ECJ contradicted AG Jacobs' analysis and conclusions.

The AG Colomer, also embracing a more economic approach to legal analysis, considered whether recouping financial resources through to the elimination of competition provided by parallel trade would have served the purpose of stimulating innovation to the benefit of consumers, and would therefore have constituted a valid 'objective justification' for the refusal to supply.

However, he concluded that there was insufficient evidence that the defendant's conduct would have led to efficiency gains, given the absence of empirical support necessary to justify such conduct as against the negative effects caused on competition.

The Grand Chamber of the ECJ, differently from what both AGs argued, wiped away the R&D issue entirely, but it acknowledged that parallel trade threatens companies' commercial interests, insofar it potentially reduces their profits. For this reason, the Court left open the possibility for a pharmaceutical manufacturer to justify its refusal to supply where the orders are 'out of the ordinary', in relation to the requested volume of products and to the size of the exporting market and the existing commercial

relationships between the pharmaceutical manufacturer and the wholesaler concerned⁶²².

The efficiency defence did not find a concrete application in the *Glaxo* case either.

There the defendant contended that dual pricing contributed to technical and economic progress, through the increase of the amount of resources to be spent in R&D, and to the efficiency of the productive and distributional system, by impeding the diversion of products from their traditional distribution channels.

However, the European Commission did not consider this argument sufficiently proved to meet the first condition set forth by Article 101(3) TFEU to obtain the exemption for the agreement⁶²³.

But the GC held that the Commission, in denying the exemption, did not adequately consider all the economic aspects of the case, especially with regards to the *possibility* that the extra-profits entailed by dual pricing could have translated into larger investments in R&D⁶²⁴. Therefore, the GC annulled its decision in that part and required a new evaluation from the Commission.

In appeal, the ECJ held that the GC did not commit any error of law in affirming that the Commission's decision was vitiated by a failure to carry out a proper examination. The ECJ also agreed that the Commission had considered the loss in efficiency associated with parallel trade, but it did not take account of all the relevant evidence produced by GSK regarding about the gain in efficiency procured by dual pricing⁶²⁵.

Interestingly, the Court somewhat provided a *modus procedendi* for the Commission to analyse the request of exemption based on efficiency grounds⁶²⁶. However, the link between parallel trade and R&D has not been discussed in the merits.

It follows that the issue of the impact of parallel trade on pharmaceutical innovation is still open⁶²⁷.

⁶²² See para. 67-70 of the *Syfait II* ruling.

⁶²³ See the decision of the Commission in cases IV/36.957/F3 *Glaxo Wellcome (notification)*, IV/36.997/F3 *Aseprofar and Fedifar (complaint)*, IV/37.121/F3 *Spain Pharma (complaint)*, IV/37.138/F3 *BAI (complaint)*, IV/37.380/F3 *EAEPIC (complaint)*, of the 8 May 2001, from para. 147 onwards.

⁶²⁴ See para. 301-303 of the *Glaxo* ruling.

⁶²⁵ See para. 131 of the ECJ decision in the *Glaxo* appeal.

⁶²⁶ See para. 128-129 of the ECJ decision in the *Glaxo* appeal.

⁶²⁷ See para. 70 of the *Syfait II* ruling, where the Court said: "... without it being necessary to examine the argument raised by GSK AVEE that it is necessary for pharmaceuticals companies to limit parallel exports in order to

The debate surrounding the discussion of this specific issue before EU Courts has been quite partisan and sensitive. On the one hand, the Commission, supported by parallel traders, has been firmly rejecting the claims of the industry as a pretext to put in place market partitioning behaviours. On the other hand, however, companies' arguments are largely underpinned by the findings of part of the economic literature.

This Chapter intends to contribute to this debate, by providing an answer to the questions left open by the jurisprudence.

To this purpose, the main focus of the analysis will be on the existence of a link between parallel trade on pharmaceuticals and innovation.

To date there exists a large amount of literature of reference, especially in the fields of HE and of IO, which investigated the determinants of innovation in the pharmaceutical sector. Wiggins (1981), Grabowski and Vernon (1981) investigated that variables determining the R&D expenditures firms' decisions; Myers (1992), Scherer (1993, 2001), and Giaccotto, Rexford, Santerre and Vernon (2005) examined the link between pricing, profitability and pharmaceutical R&D; Danzon (1997) and Vernon (2003, 2005) used those findings to examine the effect on R&D investment potentially created by the introduction of price controls in US.

Still, the question of whether parallel trade can be included among the variables influencing the innovation activity of a pharmaceutical company has been explored to a more limited extent. To my knowledge, only Danzon (1998) discussed the effect of parallel trade on the level of investment in pharmaceutical innovation. The other studies available either provide information about the impact of pharmaceutical parallel trade on profits only, without any specific implication for innovation (Ganslandt and Maskus, 2001; Ahmadi and Yang, 2000), or they look into innovation issues but do not focus on the pharmaceutical market (Valletti, Szymanski, 2004; Grossman and Lai, 2006; Li and Robles, 2007).

Beside the unambiguous results provided by the economic literature about the link between parallel trade and innovation, also, the application of the above-mentioned

avoid the risk of a reduction in their investments in the research and development of medicines, it is sufficient to state that, in order to appraise whether the refusal by a pharmaceuticals company to supply wholesalers involved in parallel exports constitutes a reasonable and proportionate measure in relation to the threat that those exports represent to its legitimate commercial interests, it must be ascertained whether the orders of the wholesalers are out of the ordinary..." (emphasis added). The underlined incipit could be interpreted as if the Court is disregarding the R&D argument, but also as if the economic theory supporting GSK's allegations is taken for granted and accepted.

findings to the field of antitrust is almost entirely lacking. Apart from Veljanovski (2007), who dismissed the link between parallel trade and innovation as empirically unsubstantiated, to my knowledge no comprehensive studies on how efficiency gains can enter the antitrust scrutiny of restrictions to parallel trade on pharmaceuticals have been undertaken so far.

The debate in its general features is not new: already in the '70s the Chicago School (Bork, 1978; Posner, 2001) was supporting a more economic analysis into antitrust law, aimed at seeing corporate behaviours in their long-term pro-competitive aspects. Still, Chicagoans believed that the goal of antitrust should be understood as the improvement of both allocative and productive efficiency. In their view, innovation activities and technological progress should not be given any weight in antitrust analysis, because they involve resources that cannot be measured in terms of willingness to pay.

This scepticism most probably determined the hostility, or conscious disregard, of US Courts and antitrust agencies towards efficiencies through the '60s and the '70s. Spurred by the advances of the Post-Chicago School, however, this attitude evolved into an explicit acknowledgement of their importance, albeit often accompanied by the inability to account for them (Leary, 2002). Its more prominent scholars (Hovenkamp, 2002) regard efficiencies as part of the antitrust scrutiny. Thus, for instance, when dominant firms raise their rivals' costs, inquiry on a possible business justification should be made, or in case of foreclosure, it should be ascertained whether the practice results in substantial efficiencies.

From then on, US competition law scholars and Courts attempted to find ways of giving significance to efficiency gains deriving from anticompetitive corporate practices within the legal assessment.

In Europe, where the Chicago School had much less influence, the developments of the Post-Chicago trend had very limited application. The latter mainly took place within Article 101 TFEU, while the enforcement of Article 102 TFEU remained partially alien to any kind of economic analysis. The process of modernisation of European competition law is now urging the Commission and the European Courts to abandon

this formalism and to convey economic analysis into the legal scrutiny of the abuse of dominant position.

The new cases on parallel trade on pharmaceuticals constitute an attempt of evolution towards this direction. However, how and to what extent efficiency gains can guide the legal assessment is still far from being clear. This vagueness appears to be even more pronounced in the cases under discussion, because European Courts did not really give any clear guidance in this respect.

For this reason, the examination of the existence of a link between parallel trade and pharmaceutical innovation will not be dealt with as such. Its unravelling is rather finalised to ascertain whether the findings of economic theory about this relationship can provide a basis for the development of a workable exemption/justification to restrictions of parallel trade under efficiency grounds.

This Chapter is organised as follows.

Section 1 analyses whether the structure of EU competition law provisions leaves scope for the consideration of efficiency gains in the antitrust assessment, how these have been concretely conveyed into legal analysis in the past cases and why such operation has not been successful so far.

Section 2 reviews the old theoretical debate among economists – underlining the efficiency defence – about the best market structure, competition or monopoly, needed to spur innovation. This overview traces the advances in economics starting from the Schumpeterian theory of constructive destruction to the more recent developments in the IO literature and their application in the empirical literature in health economics, in order to provide the reader with a good grasp of the salient elements and conclusions, if any, of the academic discussion about this issue.

Section 3 then focuses on the relationship between patents, profits and firms' incentive to invest in innovation, by disentangling the main finding of the mentioned literature, that the higher is the expected return from the development and commercialization of a new drug, i.e. the higher are expected profits, the higher is the incentive for the company to engage in that project in the first place. The literature that investigates the link between parallel trade, profits and innovation is examined.

Such analysis aims at ascertaining whether it is possible to rely on a *presumption*

of existence of positive effects in terms of increased innovation coming from restrictions to competition, and specifically to parallel trade. Stated differently, this Section looks at whether efficiency gains can be considered a redeeming virtue *per se* to anticompetitive corporate conducts, or whether it is necessary to demonstrate case-by-case the existence of overall positive effects from such practices.

Section 4 examines how the consideration of efficiency gains practically enters the antitrust assessment. This question is relevant especially in relation to Article 102 TFEU, whose modernisation is still at an early stage. The Section discusses four different options, in order to find the test for efficiencies that better suits the rationale of the provision and takes into account economic teaching at the same time.

Section 5 concludes.

1. The 'efficiency defence' in the European competition law

The European Courts and the Commission agree on the fact that competition law cannot focus only on allocative efficiency goals. Put it differently, economic welfare cannot be restricted solely to price related issues, as consumers are concerned also with the level of quality, variety and safety of products⁶²⁸. It follows that also efficiency gains appear to be essential to improve consumers' living standards⁶²⁹.

1.1. The four-partite test under Article 101(3) TFEU

In the *Guidelines on Art. 81(3)*, the Commission expressly say that: "*The aim of the Community competition rules is to protect competition on the market as a means of enhancing consumer welfare and of ensuring an efficient allocation of resources. Agreements that restrict competition may at the same time have pro-competitive effects by way of efficiency gains. Efficiencies may create additional value by lowering the cost of producing an output, improving the quality of the product or creating a new product.*"⁶³⁰

The analysis of efficiency gains is, in fact, devolved upon this paragraph⁶³¹, which explicitly offers the possibility that *any* agreement⁶³² restrictive of competition is

⁶²⁸ See LANDE, *Proving the Obvious: the Antitrust Laws were Passed to Protect Consumers (Not Just to Increase Efficiency)*, in *Hastings Law Journal*, 1999, no. 50, p. 962.

⁶²⁹ See AGHION and HOWITT, *A Model of Growth through Creative Destruction*, cit., at 349, where it is affirmed that progress involves the creation of a new product rather than an old product at a cheaper price.

⁶³⁰ See *Guidelines on Article 81(3) EC*, para. 33.

⁶³¹ The next chapter traces the stages of the intense theoretical debate that animated legal scholars for long time about whether efficiencies should enter the antitrust analysis in the first paragraph of Art. 101 TFEU,

exempted from the application of Article 101(1) TFEU, provided that it brings about pro-competitive effects and or efficiency gains.

In particular, Article 101(3) TFEU establishes that in order for an anticompetitive agreement to be exempted, the latter should *cumulatively*: i) contribute to the improvement of the production or distribution system or to the promotion of technical and economic progress; ii) be such that also consumers equally benefit from a fair share of the economic advantages; iii) not impose to involved undertakings restrictions that are not indispensable to the achievement of this goal; iv) not allow the undertaking to completely eliminate competition in a substantial part of the market.

The first two requirements are positive, whereas the second ones are negative.

1.1.1. The two positive requirements

According to the case law, the first requirement is satisfied when efficiency claims are substantiated, so that the following can be verified: their nature, the link between the agreement and the efficiency gains, their likelihood and magnitude and how and when they are going to be achieved. Unsubstantiated claims are rejected⁶³³.

At this stage the analysis of the link between the agreement and the efficiencies is limited to examining whether the latter are likely to follow from the former, i.e. whether they result from the economic activity object of the agreement or whether they have a general efficiency-enhancing effect (suitability test)⁶³⁴.

The existence of efficiencies must be appreciable in an *objective* way. This has a twofold implication: first of all, any subjective benefit is irrelevant. This means that gains should have a positive impact on the market and on competition, and not merely on the undertaking⁶³⁵.

according to a *rule of reason*, or in the third. The jurisprudence and the Commission opt for the second interpretation. See GC, 15 September 1998, in joined cases T-374/94, T-375/94, T-384/94, T-388/94 *European Night Services v. Commission of the European Communities*, para. 22-24, 107, 111, 113, 119, 132, and subsequently GC, III Ch., 18 September 2001, in case T-112/99 *Métropole Télévision (M6), Suez-Lyonnaise des eaux, France Télécom and Télévision française 1 SA (TF1) v Commission of the European Communities*, para. 72-74. The following analysis in this Chapter is performed under this hypothesis.

⁶³² See *Matra Hachette*, para. 85: “[...] in principle, no anti-competitive practice can exist which, whatever the extent of its effects on a given market, cannot be exempted, provided that all the conditions laid down in Article 85(3) of the Treaty are satisfied and the practice in question has been properly notified to the Commission”.

⁶³³ See the Guidelines on Art. 81(3) EC, para. 53-57.

⁶³⁴ See the Guidelines on Art. 81(3) EC, para. 53.

⁶³⁵ See *Consten and Grundig*, cit., para. 13, where the Court said: “... whether there is an improvement in the production or distribution of the goods in question ... cannot be identified with all the advantages which the parties to the agreement obtain from it in their production or distribution activities”.

Secondly, the existence of such pro-competitive effects has to be proven convincingly⁶³⁶. This means that between them and the agreement there must be a *causal link*, whose evidence must be *direct and effective*⁶³⁷. In other words, to substantiate the claim of a positive effect on productive efficiency it is not sufficient to speculate about the existence of such efficiencies but it is necessary that the latter is supported by empirical and factual evidence⁶³⁸. It follows that claims must not only be plausible: they must be credible⁶³⁹.

For this reason, the *Guidelines on Art. 81(3) EC* require that the party who claims the existence of efficiency gains should prove it⁶⁴⁰. Therefore, not only the defendant has to demonstrate that they derive directly from the economic activity object of the agreement, but he or she also has to calculate or estimate the probability and the amount of such gains in order to ascertain how and when such gains will be obtained⁶⁴¹.

The second condition required by Article 101(3) TFEU, i.e. the attribution of an adequate part of such gains to consumers, is strictly linked to the first one. In fact, if efficiencies positively impact the market, then also consumers must benefit from them. For instance, if the agreement consents the company to produce a better or a new product, consumers interested in buying it may benefit from it.

The ECJ established that '*the productive efficiency gains should present noticeable objective advantages such as to compensate for the inconveniences resulting there-from the level of competition.*'⁶⁴² That is, benefits deriving from the latter must be such that they

⁶³⁶ See ECJ, 17 January 1984, in joint cases C-43/82 e C-63/82 *VBVB and VBBB v Commission of the European Communities*, para. 52; ECJ, V ch., 7 January 2004, in joint cases C-204/00, C-205/00, C-211/00, C-213/00, C-217/00 and C-219/00 *Aalborg Portland and Others v Commission of the European Communities*, para. 78.

⁶³⁷ See GC, II Ch., 27 February 1992, in case T-19/91 *Société d'Hygiène Dermatologique de Vichy v Commission of the European Communities*, para. 93. The Guidelines on Art. 81(3) EC at para. 54 indicate that indirect effects are too indeterminate to be taken into account. However, FAULL and NIKPAY, *The EC Law of Competition*, 2007, p. 304, affirm that the use of the term '*as a general rule*' in that paragraph implies that indirect effects can be taken into account, but that their evidence must be proven convincingly.

⁶³⁸ See KLEIN, *A Stepwise Approach to Antitrust Review of Horizontal Agreements*, available at <http://www.usdoj.gov/atr/public/speeches/Jikaba.htm>. Also, see the Guidelines on Vertical Restraints, 2000, OJ C291/1, para. 136; the Guidelines on Art. 81(3) EC, para. 51, 56-58; the Guidelines on the Applicability of Article 81 of the EC treaty to Horizontal Cooperation Agreements, 2001, OJ C 3/2, para. 32.

⁶³⁹ In this regard, ODUDU, *The Boundaries of EC Competition Law: the Scope of Article 81*, 2006, p. 143, affirms that the credibility of a plausible productive efficiency claim is affected by how the market power is obtained. For instance, if the company intends to restrict competition the claim is not credible.

⁶⁴⁰ See *Remia*, para. 45. See also art. 2 of Reg. (EC) 1/2003 of 16 December 2002, which establishes that the burden of proof in the context of Art. 101(3) TFEU is on the party that claims the exemption.

⁶⁴¹ See the Guidelines on Art. 81(3) EC at para. 56.

⁶⁴² See *Consten and Grundig*, para. 348 e 349; GC, ch. II enlarged composition, 8 June 1995, in case T-7/93 *Langnese Iglo GmbH v Commission of the European Communities*, para. 180; ECJ, 29 October 1980, in case C-

compensate the detriment caused to competition and to consumers. This second condition, therefore, provides for the so-called '*bilan économique*'.

It should be noted that this balancing exercise does aim at weighing the consumer welfare against the producer welfare, i.e. it does not apply the Kaldor-Hicks criterion, where a policy option is considered efficient as long as total welfare increases.

For instance, consider an agreement that entails significant production efficiencies but also higher prices and lower output. According to the Kaldor-Hicks criterion, the agreement should not be prohibited, if producers gain much more than consumers lose. In this case, in fact, society in its whole is better off.

However, in mandating that agreements should never be detrimental for consumers, the balancing exercise rather follows the Pareto criterion⁶⁴³. Accordingly, an agreement that entails higher prices for consumers would not pass the test under Article 101(3) TFEU, unless it is proved that consumers are compensated with improvements in quality⁶⁴⁴.

1.1.2. The two negative requirements

The third condition established by the third paragraph of Article 101 TFEU requires that the restrictions contained in the agreement must be reasonably necessary. That is, there must be a strong connection between the allocative efficiency loss and the productive efficiency gain and no alternative options that are less restrictive are

209/78, *Van Landewyck SARL and Others v Commission of the European Communities*, para. 139. See also the Guidelines on Art. 81(3) EC at para. 43. On the difficulties of performing such balance see MANZINI, *The European Rule of Reason – Crossing the Sea of Doubt*, in *European Competition Law Review*, 2002, p. 392-399; VAN DEN BERGH and CAMESASCA, *European Competition Law and Economics: a comparative perspective*, 2006, p. 252. As ODUDU, *The Boundaries of EC competition law*, cit., p. 148-151, affirms, consumers face an increase price or cannot afford buying the product if Art. 81.3 EC is applied. In other words, they are asked to make a sacrifice: invest in future cost reductions and innovations by paying more for current consumption. Therefore, since it is consumers that invest in the creation of production inefficiency, they should benefit from it.

⁶⁴³ VAN DEN BERGH and CAMESASCA, *European Competition Law and Economics*, cit., pp. 30 and 41 *et seq.*, seems to suggest this hypothesis.

⁶⁴⁴ See the Guidelines on Art. 81(3) EC, para. 86. The Guidelines, however, do not give any guidance about how this comparison should be performed: in fact, not only it is difficult to determine what is the loss for consumers from higher prices, but it is also difficult to compare such loss with the potential gains from improved quality. Also, considering that consumers may have different willingness to pay and different preferences for quality, such measurement becomes even more complicated. See NICOLAIDES, *The Balancing Myth: The Economics of Article 81(1) & (3)*, in *Legal issues of Economics Integration*, 2005, no. 32(2), p. 138, affirms that this suggests that it will be difficult to apply the second conditions to agreements concerning new or improved products, which are to be sold at higher prices. RBB ECONOMICS, *Art or Science? Assessing Efficiencies under the Commission's Article 81(3) Notice, Brief 15*, available at http://www.rbbecon.com/publications/downloads/rbb_brief15.pdf, affirm that measuring the extent to which an improved product enhances consumer welfare equals to compare 'apples and pears'.

available (indispensability test)⁶⁴⁵. Once it has been ascertained that the agreement is necessary in order to produce the efficiencies, the indispensability test is applied to the individual restrictions contained in the agreement. A restriction is considered necessary if its elimination would impair the production of efficiencies through the agreement⁶⁴⁶.

The indispensability condition necessarily entails that *possible* links between restrictions and profitability of parties are not accepted.

Also, profitability as such cannot be relevant under European competition law. As it will be illustrated later, it acquires significance only as long as it translates into gains for consumers, in terms of new or better quality of products.

The GC indicated in the *Vichy* case⁶⁴⁷ that the profitability of an investment made by a producer in connection with the launch of a product or a range of new products, depending on the specific circumstances of the case in question, might be one of the pro-competitive effects that could be taken into account in the balancing exercise. However, profits made by undertakings belong in principle to shareholders. Therefore, in order to acquire relevance under competition law, they have to be passed on to consumers, for instance in the form of investments in R&D, quality improvements, service amelioration, etc. In other words, the increase in profitability brought about by an agreement ought to be taken into account only where it serves the purpose of fostering an investment, which gives rise to benefits to consumers. It follows that, as it will be made clear in the following Sections, *profitability is relevant only to the extent it contributes to the materialisation of the efficiency gains*.

Finally, the fourth condition contained by the analysed provision requires that the agreement does not entirely eliminate competition in the market. At this regard, the criteria used by the European Courts and the Commission does not refer only to market share of companies operating in the market, but also to the ability and the incentive of competitors to actually compete with the defendant⁶⁴⁸.

⁶⁴⁵ See GC, 28 February 2002, in case T-86/95, *Compagnie Generale Maritime v. Commission*. For this reason, PAPPALARDO, *Il diritto comunitario della concorrenza*, cit., p. 129-130 observes that the burden of proof for the companies is quite relevant, given that the indispensability is based on prediction, which therefore require discretion.

⁶⁴⁶ See the Guidelines on Art. 81(3) EC at para. 79.

⁶⁴⁷ See *Vichy*, para 94.

⁶⁴⁸ For instance, if competitors have capacity constraints or have high production costs, their competitive response is limited. See PAPPALARDO, *Il diritto comunitario*, cit., p. 132.

From the above analysis it clearly appears that the wording of Article 101(3) TFEU allows for the consideration of efficiency gains. However, the underlining conditions for their admission are very strict.

In particular, an overview of the Commission practice and of the case law illustrates that hardcore restrictions, like price fixing and import or export bans, very seldom pass this test, especially with regards to the indispensability criterion⁶⁴⁹.

1.2. The objective justification to abusive conducts by dominant companies

The way efficiency gains enter the antitrust scrutiny of dominant companies' conducts under Article 102 TFEU is much less clear.

First of all, what can constitute 'objective justification' is not entirely plain. The Treaty does not provide any list of defences that can be considered objective justifications. Therefore, the concept was filled in with practical significance by European Courts.

This interpretative work never led to identify an exhaustive list of objective justifications. The Commission, however, has been recently suggesting the creation of such list. Unfortunately, not always in a consistent manner.

The new *Guidance on its enforcement priorities in applying Article 82 EC to abusive exclusionary conduct by dominant undertakings* (hereinafter, '*Guidance on Art. 82 EC*') affirm that an abusive conduct can be justified in two cases: when the conduct is objectively necessary, i.e. on the basis of factors external to the company, or when it produces substantial efficiencies⁶⁵⁰.

However, previously the *DG Competition Discussion Paper on the application of Article 82 of the Treaty to exclusionary abuses* (hereinafter, the '*Discussion Paper on Art. 82 EC*') had indicated that there are three types of objective justification: the objective necessity defence, the meeting competition defence and efficiency gains that outweigh the anticompetitive effect⁶⁵¹.

⁶⁴⁹ The rationale is that such restrictions may facilitate collusion and reduction of *interbrand* competition. See the Guidelines on Art. 81(3) EC at para. 45-46, 79. VAN DEN BERGH and CAMESASCA, *European Competition Law and Economics*, cit., p. 45, observe that the policy with respect of hardcore restrictions is determined by the single market imperative that expands the scope of antitrust provisions in EU.

⁶⁵⁰ See the *Communication from the Commission on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, 9.2.2009, C(2009) 864 final (hereinafter the '*Guidance on Art. 82 EC*'), at para. 28 *et seq.*

⁶⁵¹ See the *DG Competition Discussion Paper on the application of Article 82 of the Treaty to exclusionary abuses*, December 2005, p. 24 *et seq.*. Cf. LOEWENTHAL, *The defence of 'Objective Justification' in the Application of Article*

From the analysis of the EU case law, instead, it appears that the legal doctrine of 'objective justification' refers to three different conceptual categories⁶⁵²: (1) legitimate business behaviour, which encompasses the concepts of both 'competition on the merits'⁶⁵³ and 'defence of commercial interests'⁶⁵⁴, (2) objective factors out of the control of the dominant company⁶⁵⁵, and (3) efficiency gains⁶⁵⁶.

The first case where reference was made to the concept of objective justification was *Sirena*, where the Court affirmed that the fact that the excessive price charged for a product was not justified by any objective criteria was a determining factor in the finding of abuse⁶⁵⁷.

A landmark case that established the first of the three mentioned objective justifications was *United Brands*. In that occasion the ECJ acknowledged that a dominant company was entitled to take reasonable steps to protect its commercial interests and that this could operate as a ground for justification of its conduct. However, the Court added two qualifications: (i) the protection of the commercial interest should be the genuine reason behind the behaviour and (ii) any action taken to this purpose should be proportionate to the threat to which the company is subject⁶⁵⁸.

Few months later, the ECJ had the occasion of discussing the notion of objective justification based on causes external to the dominant company. In *BP*, the Court affirmed that a general shortage of petroleum products caused by an economic shock justified a practice that at first sight looked discriminatory, i.e. the reduction of supplies to occasional customers only⁶⁵⁹.

82 EC, in *World Competition*, 2005, no. 28(4), p. 464, who refers that the Director General of DG Competition at the 30th Annual Conference on International Antitrust Law and Policy at the Fordham Corporate Law Institute affirmed that the three objective justifications are the legitimate business behaviour, the objective necessity and the efficiency gains that outweigh the anticompetitive effect.

⁶⁵² The first two prevailed in the case law, while the third one has been emerging only recently.

⁶⁵³ See *Hoffmann-La Roche*, para. 90.

⁶⁵⁴ See *United Brands*, para. 189.

⁶⁵⁵ See ECJ, 29 June 1978, in case C-77/77, *Benzine en Petroleum Handelsmaatschappij BV and others v Commission of the European Communities* (hereinafter, 'BP'), where the Court affirmed that the petrol shock was considered a *force majeure* that justified the refusal to supply.

⁶⁵⁶ See *Irish Sugar*, para. 189, where the Court held that in order for the protection of a dominant company's interests to be an objective justification to the abuse, it should be based '*on criteria of economic efficiency that were consistent with the interest of consumers*'.

⁶⁵⁷ See *Sirena*, para. 16-17.

⁶⁵⁸ See *United Brands*, para. 189-190.

⁶⁵⁹ See *BP*, para. 33. Note that the Court neither the AG used explicitly used the concept of objective justification. The AG, in particular, alluded to it and pointed out that the Commission should have better clarified it in its decision.

However, this appears to be the only occasion where the Court accepted an external cause to justify a dominant company's abusive behaviour. In *Hilti*, for instance, the ECJ refused the arguments put forward by the defendant, who opposed that safety considerations were justifying the practices of tying and price discrimination applied to the cartridge strips and nails for which production and commercialisation the company was dominant⁶⁶⁰. The Court, in fact, believed that the defendant's action were not guided by a genuine concern about safety, but were rooted in the willingness to impede the entry of competitors in the market for cartridges⁶⁶¹.

The first judgment where efficiency gains were considered a possible objective justification to abusive conducts was in *Irish Sugar*. The company was charged with the allegation of applying discriminatory rebates to impede imports of sugar from Northern Ireland to Southern Ireland. The Court of First Instance considered that the company was entitled to protect its commercial interests on the basis of criteria of economic efficiency consistent with the interest of consumers⁶⁶². However, the Court saw in the policy of rebates applied by the company an illegitimate cross-subsidization and therefore did not consider the indicated efficiency criterion satisfied.

EU case-law on refusal to supply by dominant companies suggests that an 'objective justification' can immunize the conduct from the application of Article 102 TFEU provided that it complies with three requirements in order to be admitted: the conduct has to pursue a legitimate aim, be reasonable – i.e. suitable to the proposed goal –, and proportionate to the threat posed by its competitors⁶⁶³.

These filters have probably been applied too strictly by the jurisprudence and determined the little role that economics has played in the assessment of abusive conducts from dominant companies.

⁶⁶⁰ Similarly in *Tetrapack I*, para. 83, neither the Commission nor the Courts accepted public interest concerns as an objective justification, as they believed that is not for an undertaking to autonomously take steps to protect public safety or public health, as these are taken care of by the national legislation of Member States.

⁶⁶¹ See GC, II Ch., 12 December 1991, in case T-30/89 *Hilti AG v Commission of the European Communities*, para. 117.

⁶⁶² See *Irish Sugar*, para. 189.

⁶⁶³ See *United Brands*, para. 189-190, where the ECJ affirmed that the application of the proportionality principle to Article 102 TFEU presupposes that the conduct of the dominant company is suitable and necessary and not excessive means to the protection of its commercial interests. See the opinion of AG Kirschner in *Tetra Pak I* at para. 67, where he stated that the examples of abusive conduct mentioned in paragraphs (a) to (d) of Art. 102 TFEU have a common feature: they refer to a conduct that pursues a legitimate end of making profits through disproportionate means.

Economic considerations, in fact, have been taken into account in few cases involving the application of Article 102 TFEU. However, although their role in the antitrust scrutiny has been explicitly recognised by the EU jurisprudence, economic considerations have practically never worked out as an objective justification to anticompetitive restrictions. European Courts, in fact, have been either reluctant to take them into account or have tended to narrow down the relevance of economic arguments⁶⁶⁴.

Recently, however, the claim for a much greater use of economic theory in antitrust analysis can potentially enlarge the scope of the application of the concept of 'objective justification' based on dynamic efficiency gains arising from anticompetitive conduct⁶⁶⁵.

The *Microsoft* case, where the Commission applied what in the literature has been defined as an 'incentive balance test'⁶⁶⁶, represents the first attempt to include efficiency considerations in the antitrust analysis.

The Commission found Microsoft to have abused its dominant position by refusing to supply to competitors information regarding the interoperability between Windows pc and non-Microsoft work group servers, thereby leveraging its dominant position in the market for pc operating systems onto the market for work group servers. Microsoft claimed that its refusal was objectively justified by the need to protect its IPRs and preserve its incentive to innovate. Microsoft's efficiency arguments were not rejected

⁶⁶⁴ See GC, 28 February 2002, in joined cases T-191/98, T-212/98 and T-214/98, *Atlantic Container Line*, where the Court at para. 1112 said explicitly that '... because Article [82] of the Treaty does not provide for any exemption, abusive practices are prohibited regardless of the advantages which may accrue to the perpetrator of such practices or third parties'. *Inter alia*, see ECJ, 16 December 1975, in joined cases C-40 to 48, 50, 54 to 56, 111, 113 and 114-73, *Coöperatieve Vereniging "Suiker Unie" UA and others v Commission of the European Communities*, where Courts always identified efficiency gains solely with cost saving effects. The result of such a restrictive attitude was that not in a single instance the Courts applied this defence to a dominant undertaking accused to have infringed Article 102 TFEU by the Commission. On the contrary, see US case law, where 'competition on the merits' is understood as efficiency-enhancing conducts irrespective of the fact that aim at excluding a rival. See *Aspen Skiing*, cit., where the Supreme Court held that a conduct is predatory and does not constitute competition in the merits if it excludes or attempts to exclude a rival on a basis other than efficiency.

⁶⁶⁵ See AG Jacobs' opinion in the case C-7/97 *Bronner GmbH and Co. KG v. Mediaprint Zeitungs und Zeitschriftenverlag GmbH & Co. KG Oscar Br.* Among proponents of the efficiency defence as an objective justification see SHER, *The Last of the Steam-Powered Trains: Modernizing Article 82*, in ECLR, 2004, no. 5, p. 243; TEMPLE LANG, *Anticompetitive Abuses under Article 82 Involving Intellectual Property Rights*, in EHLERMANN and ATANASIU, *The European Competition Law Annual 2003: What is an Abuse of a Dominant Position?*, p. 589 et seq., and GYSELEN, *Rebates: Competition on the Merits*, cit., p. 287 et seq.

⁶⁶⁶ See VEZZOSO, *The Incentive Balance Test in the EU Microsoft Case: a Pro-Innovation 'Economic-Based' Approach?*, in ECLR, 2006, no. 27, p. 382.

but questioned in the merits: the Commission, and subsequently the Court, balanced the negative effects that an obligation to supply would have on Microsoft's incentive to innovate against the general positive effect on innovation that it would have on the market as a whole. The latter was found to benefit more than Microsoft would lose from the duty to deal. For this reason, the company was held liable and fined⁶⁶⁷.

However, the GC rejected the argument that the Commission had used such a test in the application of the 'legitimate commercial interest' criterion. According to the GC, the Commission rightly dismissed Microsoft's arguments not applying a balancing test but simply because the latter did not sufficiently prove that if it 'were required to disclose the interoperability information that would have a significant impact on its incentives to innovate'⁶⁶⁸.

It is apparent that at present, except for the *Guidance on Art. 82 EC*⁶⁶⁹, there is no clear indication about the role that efficiencies have within the antitrust assessment of abusive conducts from dominant companies.

The analysis of the *Syfait* saga, and of the arguments put forward by AG Jacobs about the relationship of parallel trade and pharmaceutical innovation, thus, provide an additional intellectual stimulus to put forward policy proposals about the crafting of an objective justification based on efficiencies to abusive conducts from a dominant company.

2. Innovation in the pharmaceutical market

2.1 The economics of innovation

Economic efficiency is a heterogeneous concept, which can be divided into allocative efficiency, productive efficiency and dynamic efficiency⁶⁷⁰. It is largely agreed

⁶⁶⁷ See Commission decision in the case COMP/C-337.792 *Microsoft*, of 24 March 2004, as confirmed by the GC, 11 November, 2007, in case T-201/94, *Microsoft Corp. v. Commission of the European Communities* (hereinafter the '*Microsoft ruling*').

⁶⁶⁸ See para. 697-711 of the *Microsoft* ruling.

⁶⁶⁹ Cf. Section 4 of this Chapter, where the Commission's proposal to account efficiencies is discussed.

⁶⁷⁰ Productive efficiency is the relationship between the output of a good and the input of resources used to make them. In this process, technology and technical efficiency play a great role: technology represents the method with which inputs are transformed in outputs; whereas, technical efficiency describes the maximization of outputs given a certain amount of inputs, using a given technology. The adoption of the frontier technology among the existing ones, especially if it allows the firm to be more efficient in production, is included in the concept of productive efficiency. The adoption of an entirely new technology, instead, represents an innovation and thus refers to the concept of dynamic efficiency.

both in the economic and the legal literature that all of them should be encouraged in order to improve consumer welfare. However, economists share the view that the dynamic efficiency, i.e. innovation, has a particularly important role in improving social welfare⁶⁷¹. That is why policy makers should ensure that firms are given the right incentives to invest in R&D.

In this task, competition policy plays an important role. For instance, competition influences innovation, insofar it preserves R&D lines that compete among each other, or as long as it provides the incentive to market actors to engage in efficient innovation.

Nevertheless, regulating dynamically competition industries from an antitrust standpoint is difficult, because market analysis necessarily looks at long-term aspects.

Such difficulty is aggravated by the fact that economic theory did not develop a formal model that captures the benefits of innovation on social welfare, as it has been done for the paradigm of perfect competition. The main reason behind this theoretical gap is that any measurement of innovation necessarily requires the evaluation and the comparison of actual and hypothetical situations.

Still, economic theory has been constantly confronting itself with this issue.

There are two main strands of the economic literature dealing with the question of what are the sources of economics development.

The first one is represented by the growth theory. The traditional growth theory, mostly dealing with the rate of technological change and estimating its value for society, claims that capital accumulation is the main driver of such change⁶⁷².

However, such statement has been criticised by the endogenous growth theory, by showing that an increase in capital accumulation cannot by itself generate persistent increases in the standards of living. It is rather the institutional environment that

⁶⁷¹ Solow's model of economic growth, also known as the '*Solow-Swan neo-classical growth model*', allows the determinants of economic growth to be separated out into increases in inputs (labour and capital) and technical progress. Using his model, Solow calculated that about four-fifths of the growth in US output per worker was attributable to technical progress. Such finding drew economists' attention to dynamic efficiency issues. See SOLOW, *Technical Change and the Aggregate Production Function*, in *Review of Economics and Statistics*, 1957, no. 39, p. 312-320. See also KENDRICK, *Understanding Productivity*, 1977.

⁶⁷² The growth theory was built on decreasing return to capital, perfect competition, perfect knowledge and exogenous technology. As savings generated by capital are saved, capital will raise, marginal product of capital will decrease, investments are made, until a point where economy cannot grow anymore simply by accumulating capital. At this point a technological change occurs and the marginal productivity of capital increases, spurring savings and investments, which raise the volume of capital. The marginal productivity of capital falls until a new technological change occurs.

supports technological change⁶⁷³. In these models, technological progress is no longer taken to be at a fixed rate but it is endogenously influenced, as a result of investments. Capital incorporates not only physical and human capital but also the accumulation of knowledge, assumed to be the basis of technological progress. The possibility of excluding for some time third parties from accessing information allows the firm behind the discovery to make monopoly profits through the commercialisation at a price higher than zero. New technology is developed in view of the prospect of such profit and it is its quest that makes long-term growth feasible.

However, growth theory only provides some indications about the sources of economic growth: endogenous technological change, partly privately owned technology, imperfect market structures, etc. However, the theory does not give any insight about the mechanisms that generate innovation out of these inputs.

It was the second strand of the literature mentioned that on a microeconomic level investigated at length the effect of market characteristics, competition mechanisms, and the impact of institutions, on innovation. In particular, it found that, among others determinants of the intensity and direction of R&D investment, market structure is fundamental in determining the degree of appropriability of returns on innovation for firms.

2.2 *Market structure as a determinant of innovation*

The traditional economic paradigm that guides antitrust enforcement is the neoclassical model of perfect competition. It describes a Pareto-optimal equilibrium⁶⁷⁴ where resources are perfectly allocated through trade and where price equals marginal cost, so that no dead weight loss occurs (allocative efficiency), and firms operate at the lowest cost possible without making losses (productive efficiency). It is well known that

⁶⁷³ ROMER, *Beyond Classical and Keynesian Macroeconomic Policy*, in *Policy Options*, 1994, available at www.Stanford.edu/~promer/policyop.htm.

⁶⁷⁴ The term is named after Vilfredo Pareto, an Italian economist who used the concept in his studies of economic efficiency and income distribution. *Pareto efficient situations* are those in which any change to make any person better off would not make anyone else worse off. Given a set of alternative allocations of goods or income for a set of individuals, a change from one allocation to another that can make at least one individual better off without making any other individual worse off is called a *Pareto improvement*. An allocation is defined as *Pareto efficient* or *Pareto optimal* when no further Pareto improvements can be made. Under certain idealized conditions, which will be listed in the text, Kenneth Arrow and Gerard Debreu (See ARROW and DEBREU, *Existence of a Competitive Equilibrium for a Competitive Economy*, in *Econometrica*, 1954, no. 22(3), pp. 265–90) mathematically showed that a system of free markets leads to a Pareto efficient outcome (so called *first welfare theorem*).

this equilibrium takes place only under certain strict conditions: in order to have perfectly competitive markets there should be many sellers and many buyers; the former should be able to decide the price of the products they sell but not to influence the market price; low barriers to entry/exit should characterise the market; products should be homogeneous; consumers should have perfect information about products and prices; transaction costs should be low; and no externalities should exist.

It is generally acknowledged that many of the above-listed conditions are rarely fulfilled or feasible in real markets. Therefore, perfect competition does not represent itself a policy objective to be achieved by competition law but rather a benchmark, a paradigm that serves the purpose of providing regulators with a term of comparison when analysing real markets⁶⁷⁵.

All firms have, in fact, some degree of market power, i.e. they may have influence on the market price, erect barriers to entry, differentiate their products from others, etc.⁶⁷⁶. For this reason, antitrust authorities rather pursue a second-best objective where competition is not perfect but *workable*, i.e. a market situation where a certain degree of monopolistic power exists but there is sufficient competition between near-monopolies to protect the buyers from abuse⁶⁷⁷.

Still, the findings of the neoclassical model underpin much of modern antitrust enforcement and any deviation from that paradigm is generally subject to scrutiny, in order to ascertain whether the distortions to productive or allocative efficiency are severe.

So for instance, regarded in absolute terms, the distortion caused by patents poses antitrust concerns, insofar it represents a departure from the paradigm of perfect competition.

2.2.1 Market power as a driver of innovation

However, in markets characterised by technological change, supra competitive prices do not necessarily signal a malfunctioning of the market. On the contrary, they may provide financial resources to develop new and better products to invest in new technologies that may lower future production costs. Also, the market power provided

⁶⁷⁵ See VISCUSI, VERNON, HARRINGTON, *Economics of Regulation and Antitrust*, 1995, p. 73; GELHORN and KOVACIC, *Antitrust Law and Economics*, 1994, p. 52 et seq.

⁶⁷⁶ See MOTTA, *Competition Policy*, cit., p. 41.

⁶⁷⁷ CLARK, *Towards a Concept of Workable Competition*, in *American Economic Review*, 1940, no. 30, pp. 241–256.

by patents, which allows supracompetitive prices and profits, is the result of successful product development, rather than the indication of a market failure.

Therefore, what would merely look as above-margin pricing in the model of perfect competition is a means to reward inventive activity and to keep the pace of technological change going in innovation markets. It follows that the model of perfect competition cannot in this case provide a useful yardstick for the regulator⁶⁷⁸. In fact, in presence of large sunk costs, pricing at marginal cost is a short way to bankruptcy.

That is why regulators should not be concerned about market power in innovation markets. There, competition primarily occurs *for* the market rather than *in* the market⁶⁷⁹: the most successful innovator will gain the whole market; but it will dominate it only for some time. In fact, incumbents are continuously replaced by other successful entrepreneurs that introduce new and better products in the market.

This virtuous rent-seeking model traces its roots back to Schumpeter⁶⁸⁰, who explored the relationship between the market structure and R&D investment⁶⁸¹.

According to the Schumpeterian theory of creative destruction, the process of transformation that accompanies radical innovation is necessarily linked to the existence of temporary market power. In Schumpeter's cyclical vision of capitalism, innovative entry by entrepreneurs was the force that sustained long-term economic growth through the 'destruction' of existing companies, yet ultimately succumbing to the pressure of

⁶⁷⁸ The idea that the model of perfect competition is of limited applicability in innovation-based markets is captured as following by DASGUPTA and STIGLITZ, *Uncertainty, Industrial Structure and Speed of R&D*, in *Bell Journal of Economics*, 1980, no. 11(1), p. 27: "competition in R&D necessitate imperfect competition in product markets".

⁶⁷⁹ Competition for markets may to different degrees found in computer software, communication network, mobile phones, biotechnology and pharmaceuticals. See EVANS and SCHMALENSEE, *Some Economic Aspects of Antitrust Analysis in Dynamically Competitive Industries*, NBER Working paper no. 8268, 2001, p. 2.

⁶⁸⁰ See SCHUMPETER, *The Theory of Economic Development: an Inquiry into Profits, Capital Credit, Interest and the Business Cycle*, 1934; ID., *Capitalism, Socialism and Democracy*, cit., pp. 84-92, at 99-106.

⁶⁸¹ Note also the investigation started in the same years by the 'Harvard School', which developed the first framework of economic theory with an impact on antitrust policy. See BAIN, *Barriers to New Competition*, 1956, who introduced the Structure-Conduct-Performance (SPC) paradigm. Also in that theory market structure was the fundamental variable determining the conduct of market participants, such as price, R&D and advertising. The SPC paradigm was criticised and overturned by the Chicago School, which, reappraising the price theory, formulated a more dynamic model based on the rational behaviour of firms. Under this framework, it is firms' conduct that shapes the market structure and not *vice versa*. See BORK, *The Antitrust Paradox*, 1978. The Chicago School approach has been revisited by the Post-Chicago thought, which supported the idea that firms do not merely respond to external conditions, but they also strategically act in order to shape their environment to modify market structures and competitors' conducts. It follows that market structure and conduct influence each other in a bidirectional sense. See WILLIAMSON, *Antitrust Policy*, in *The New Palgrave – A direction of Economics*, 1987.

new inventions commercialised by competing entrants.

At the centre of this virtuous circle there is the monopolist. According to Schumpeter the latter is the engine of technological development, because it has superior incentives to achieve innovation. This occurs for two reasons: first of all, from an *ex post* perspective, competition dissipates resources, while monopoly secures financial resources for long-run investment planning. Also, economies of scale, i.e. size, enhance the opportunity to have enough resources to fund large R&D projects. Finally, a strong pre-existing market position endows the company with less fear of rivals that may copy its new ideas⁶⁸². From an *ex ante* standpoint, a monopolistic structure of the market grants inventors the appropriability of the returns from the investment in R&D, providing the incentive to engage in innovation in the first place⁶⁸³. So the engine of the inventive activity is the prospect of being a monopolist in the market.

The theoretical IO literature⁶⁸⁴ and the endogenous growth literature strand⁶⁸⁵ have been supporting the Schumpeterian view. All models predicted that more intense product market competition reduces the rents of those firms that successfully enter the market (i.e. innovate), and therefore it discourages firms to enter the market in the first place⁶⁸⁶.

Also, empirical studies confirm that historically important innovations were

⁶⁸² For the scope of the present work I will leave the two last mentioned aspects aside, as they are not central to the analysis of the efficiency defence. For references about the literature that dealt with the issue of size, see the empirical evidence that questions that fact that large firms may be more efficient innovators, and support the hypothesis that both small and large firms contribute for a large share of innovation, although to different extents. Empirical evidence confirms that incumbents prefer other forms of innovation to those chosen by entrants, aspiring to preserve their position rather than fundamentally change the market. Breakthrough technology may be more attractive for small challengers than for big incumbents. Still the latter play an important role in the innovation process: after the development of a successful idea, big companies transform it in marketable products through improvements. Such incremental innovation is still very important for society. See AHN, *Competition, Innovation and Productivity Growth: a Review of Theory and Evidence*, OECD Economic Department Working Papers, no. 37, 2002, p. 10.

⁶⁸³ Among the other scholars of the Austrian School, see VON MISES, *Human Action*, 1949, who emphasized the role of entrepreneurial profit-seeking speculation.

⁶⁸⁴ See SALOP, *The Noisy Monopolist: Imperfect Information, Price Dispersion, and Price Discrimination*, in *The Review of Economic Studies*, 1977, no. 44, p. 39-406; DIXIT and STIGLITZ, *Monopolistic Competition and Optimal Product diversity*, in *American Economic Review*, 1977, no. 67, p. 297-308; DASGUPTA and STIGLITZ, *Industrial Structure and the Nature of Innovative Activity*, in *Economic Journal*, 1980, no. 90, p. 266-293.

⁶⁸⁵ See, *inter alia*, GROSSMAN and HELPMAN, *Innovation and Growth in the Global Economy*, 1991; ROMER, *Endogenous Technological Change*, in *The Journal of Political Economy*, 1990, no. 98(5), Part 2.

⁶⁸⁶ As DASGUPTA and STIGLITZ, *Industrial Structure and the Nature of Innovative Activity*, cit., p. 300, put it, "ex post competition drives out ex ante competition".

spurred by the opportunity of profits⁶⁸⁷.

The policy conclusions to be logically drawn from these findings are the following. First of all, patent protection raises monopoly rents and encourages innovation, whereas increased competition destroys those rents and discourages R&D. Secondly, the regulator should not be concerned with monopolistic or oligopolistic market structures: these are also subject to the threat of potential entrants that may replace the incumbent product with a substitute⁶⁸⁸. Therefore, concentrated market structures do not necessarily harm consumers. On the contrary, they may benefit them in the long term, through the discovery of new and better products.

From these considerations it follows that, in order to spur innovation, the enforcement of patent law should be prominent with respect to competition law in technological markets.

2.2.2 *Competition as a driver of innovation*

However, other strands of the economic literature point at opposing results and policy conclusions.

Some scholars found that market power might also give rise to productive inefficiency. The first source of such inefficiency is determined by the rent-seeking behaviour of the monopolist, i.e. the waste of resources used by the incumbent to maintain its monopoly position in the market⁶⁸⁹. The second source of inefficiency is the x-inefficiency: in the absence of competitive constraint, managers do not have enough incentives to reduce costs, i.e. to innovate⁶⁹⁰.

Similarly, Arrow demonstrated that, particularly where products are protected by IPRs, the incentive to invest is lower under monopoly than under competition,

⁶⁸⁷ See AHN, *Competition, Innovation and Productivity Growth: a Review of Theory and Evidence*, OECD Economics Department Working Papers, no. 317, 2002, p. 14.

⁶⁸⁸ See BAUMOL, *The Free-Market Innovation Machine: Analyzing the Growth Miracle of Capitalism*, 2002, who support the idea that oligopolistic competition among large firms is an important source of innovation.

⁶⁸⁹ See POSNER, *The Social Costs of Monopoly*, cit., p. 821-822 affirms that all super-normal profit will be dissipated in the effort to achieve and protect market power. However, TIROLE, *The Theory*, cit., p. 76-78, contests that, while rent-seeking behaviour wastes resources, it is unlikely that all super-normal profit are dissipated in such effort.

⁶⁹⁰ See LEIBENSTEIN, *Allocative Efficiency vs. 'X-Efficiency'*, in *American Economic Review*, 1966, no. 56(3), p. 392-415. However, the managerial slack hypothesis is difficult to test: principal-agent models do not show unambiguously that competition reduces managerial slack (see GROSSMAN and HART, *An Analysis of the Principal-Agent Problem*, in *Econometrica*, 1983, no. 51(1), p. 7-45; SCHARFSTEIN, *Product-Market Competition and Managerial Slack*, in *RAND Journal of Economics*, 1988, no. 19(1), p. 147-155) but there exists from evidence that individual firms' productivity is higher in more competitive markets (see NICKELL, *Competition and Corporate Performance*, in *Journal of Political Economy*, 1996, no. 104, p. 724-746).

because differential profits are lower for the incumbent than for the entrant⁶⁹¹. In other words, the additional profit that an incumbent monopolist can get from the development and the commercialization of an innovation will not be so large, compared to what the entrant can earn by replacing the incumbent entirely thanks to the new product (this is known as ‘replacement effect’, because the monopolist replaces itself instead of developing a new business)⁶⁹².

Such effect varies depending on the type of innovation. If innovation follows the investment in R&D with a high degree of certainty and the firm that invests the most will be the first at innovating, then the incumbent has a stronger incentive in investing in R&D to preserve its market position. On the contrary, if there is a high degree of uncertainty from the innovation process and the innovation is drastic, competitors have a larger incentive to engage in R&D. For incremental improvements of existing products, the incumbent still has superior incentives to innovate with respect to the entrant⁶⁹³.

It follows that more intense product market competition can enhance innovation⁶⁹⁴.

For instance, in an industry where there are efficient and inefficient firms, competition will drive the latter out of the market. In addition, under competition the number of conducted projects, of products and technologies possible is larger. The market will allow only the best ones to exist. This increases the industry productivity through a process of entry and exit from the market⁶⁹⁵.

⁶⁹¹ ARROW, *Economic Welfare and the Allocation of Resources for Invention*, in *Essays in the Theory of Risk-Bearing*, 1976, p. 157. In the same wake GILBERT and NEWBURY, *Preemptive Patenting and the Persistence of Monopoly*, in *American Economic Review*, 1982, no. 72, p. 514-526; GILBERT, *Looking for Mr. Schumpeter: Where are we in the Competition-Innovation debate?*, 2005.

⁶⁹² This approach seems to be at the basis of Commission’s antitrust policy. See the Guidance on Art. 82 EC at para. 30, where it is clearly said that an abusive conduct entailing efficiency gains is allowed only if, *inter alia*, it does not eliminate effective competition. This choice is motivated in the paper by affirming that rivalry between undertakings is an essential driver of economic efficiency, including dynamic efficiencies in the form of innovation, and that in its absence dominant undertakings lack adequate incentives to continue to create and pass on efficiencies.

⁶⁹³ The same findings may be true, under vertical differentiation, for firms that have different production costs. The enlargement of market share for low cost companies encourages their entry in the market. Also, high cost firms will be also induced to innovate in cost reducing technology in order to compete with the low cost firms. See AGHION and SCHANKERMAN, *On the Welfare Effect and Political Economy of Competition Enhancing Policies*, 2003.

⁶⁹⁴ See GEROSKI, *Market Structure, Corporate Performance and Innovative Activity*, 1995.

⁶⁹⁵ See JOVANOVIC, *Selection and the Evolution of Industry*, in *Econometrica*, 1982, no. 50(3), p. 649-70. However, see MOTTA, *Competition Policy*, cit., p. 54, for a small mathematical example that shows how too many competing firms in the market may reduce overall welfare.

Accordingly, the regulator should create an appropriate environment that ensures the presence of the necessary conditions for competition to appear. So for instance, potential competition should be spurred through the elimination of barriers to entry in a market, so that incumbents refrain from misusing their market power⁶⁹⁶. This policy objective should then be prominent with respect to patent policy.

Despite the efforts of theoretical and empirical investigation, the relationship between market structure and innovation process remains unclear.

Scherer and Ross found that in a model of two firms engaging in R&D for a new product, when the incumbent has an advantage from the fact that he is already present in the market, both firms increase the speed of development under competition: the incumbent does not want to incur large losses by losing the whole market share, which the entrant wants to capture. The more firms competing, the smaller the market share to be conquered in the market, until a point where it yields too little revenue to cover the R&D expenditures⁶⁹⁷.

Empirically this mechanism has been captured through an inverted-U relationship between competition and innovation⁶⁹⁸.

In those sectors where firms compete at the same level, more competition may foster innovation and growth, because it increases the incremental profits from innovating. That is, firms invest in R&D in order to be pioneers and escape competition⁶⁹⁹. On the contrary, in sectors where leaders and laggard firms compete, competition discourages the latter firms from innovating, as it reduces too much their rents from catching up with the leaders. Therefore the Schumpeterian effect of competition should dominate.

The overall effect depends on the number of sectors involving competing companies operating at the same technological level and of those where unlevelled firms compete. If the first type of sector prevails, the escape competition effect is likely to dominate the Schumpeterian effect. *Vice versa*, the latter effect is likely to dominate the

⁶⁹⁶ See the theory of contestable markets: BAUMOL, PANZAR, and WILLIG, *Contestable Markets and the Theory of Industry Structure*, 1982.

⁶⁹⁷ See SCHERER and ROSS, *Industrial Market Structure and Economic Performance*, 1990, p. 635.

⁶⁹⁸ See AGHION, BLOOM, BLUNDELL, GRIFFITH and HOWITT, *Competition and Innovation: An Inverted U Relationship*, AIM research Working Papers, 2004.

⁶⁹⁹ They affirm that this should be particularly true in sectors where incumbent firms are operating at similar technological levels.

escape competition effect, when a larger fraction of sectors has innovation being performed by laggard firms.

Thus patents and monopolistic-like structures of the market are not the only drivers of innovation. On the contrary, there are sectors where competition is a catalyst for innovation, and sectors where both patents and competition play a role.

Game-theoretical models also attempted to explain firms' strategic actions with regard to R&D investments. Regardless of the specific underlining assumptions (the structure of the market, the existence of a patent race, of spillover effects, repeated or non-repeated games), they all provide two basic findings: first of all, the quest for profits is an important innovation driver, *ceteris paribus*, in a stand-alone context; secondly, competitive threat, in terms of lost competitiveness and profits if the competitor innovates and the incumbent does not, is also conducive to technological progress⁷⁰⁰.

2.2.3 *Interim conclusions*

In sum, despite the large number of studies conducted, evidence is essentially inconclusive about the more appropriate market structure and the level of concentration that is best suited to encourage the optimal level of innovation.

Since technological opportunities, the character of innovation and the mechanisms of appropriation vary largely from industry to industry, there is no general conclusion able to offer clear guidance for policy⁷⁰¹.

The only indications that economics provided so far are the following. On the one hand, competition is necessary to spur firms' incentive to innovate. On the other hand, though, excessive competition may pose problems of appropriation of the benefits of an invention. Hence, some degree of appropriability of the returns from an invention is necessary to keep the pace of innovation going⁷⁰².

⁷⁰⁰ See *inter alia* WICKELGREN, *Innovation, Market Structure and the Holdup Problem: Investment Incentives and Coordination*, in *International Journal of Industrial Organizations*, 2004, no. 22, p. 693.

⁷⁰¹ Some prominent scholars attempted to give guidance by saying that '*what is needed for rapid technical progress is a subtle blend of competition and monopoly with more emphasis on the former than on the latter, and with the role of monopolistic elements diminishing when rich technological opportunities exist*'. See SCHERER and ROSS, *Industrial Market Structure and Economic Performance*, cit., p. 660.

⁷⁰² See the Commission's Industrial Property Rights Strategy, where it is affirmed that a strong industrial property rights system is a driving force for innovation, stimulating R&D investment and facilitating the transfer of knowledge from the laboratory to the marketplace. See Commission Communication of 16 July 2008 on an Industrial Property Rights Strategy for Europe, COM(2008)465 final.

2.3. Market structure and pharmaceutical innovation

The drug industry represents a meaningful example of the Schumpeterian mechanism of competition.

The pharmaceutical industry is characterised by a lengthy discovery process, by high regulatory hurdles, but in particular, by significant investments in innovation, which are sunk by the time of product launch and negotiation.

The European pharmaceutical industry annually spends 26 billion Euros on R&D projects. As already indicated in Chapter I, it is claimed that the cost of developing new drugs has increased significantly in recent decades and reached approximately the amount of \$800 million in 2003 compared to \$400 million in the early 1990s⁷⁰³. R&D costs increased 7.4% annually in real terms from the 1980s to the 1990s⁷⁰⁴. The reasons of this increase have been ascribed to the advent of molecular biology for the basic research, which require the use of expensive technology, to the higher complexity of products, to the higher hurdles imposed by regulation, etc.

It is also submitted that R&D represents a large part of the cost of developing and producing new drugs. The pharmaceutical industry claims that a firm's total expenditures in R&D cover a substantial part of its sales⁷⁰⁵. Furthermore, R&D is a global joint cost. That is, its level does not change depending on the number of consumers supplied and it cannot be allocated to specific products in specific countries. Still, they must be covered in the aggregate, in order for a firm to develop new drugs and stay in

⁷⁰³ See DIMASI, HANSEN and GRABOWSKI, *The price of innovation: new estimates of drug development costs*, in *Journal of Health Economics*, 2003, no. 22, p.151. As reported in fn 15 in Chapter I, this measurement has been heavily criticised by a US consumer advocacy group, Public Citizen, as well by other independent analysts on three grounds. First of all, the Di Masi study considered the cost needed to develop 68 drugs which were highly innovative: clearly this cost cannot be attributed to me-too drugs, whose development take much less time and cost also much less to firms. Secondly, the figure of \$800 million dollar is the *capitalized cost*, namely it is an opportunity cost, i.e. the amount of money that the firm would have earned by investing resources in the stock exchange rather than in R&D; Public Citizen affirms that thus measure is inappropriate, because it takes the perspective of investors rather than the firm itself. Thirdly, the Di Masi figure does not take into account that pharmaceutical firms enjoy a tax credit for R&D expenditures, which amount to 50% for orphan drugs. If these adjustments are applied, the figure that comes out is about \$200 million dollars. See ANGELL, *The Truth about Drug Companies*, cit., p. 32-36, supporting Public Citizen's view; at the same time, see ADAMS, *Estimating the cost of new drug development: is it really \$802 million?*, in *Health Affairs*, 2006, no. 25(2), p. 420-428, whose estimates instead vary from around \$500 million to more than \$2,000 million, depending on the therapy or the developing firm.

⁷⁰⁴ The cost of pharmaceutical research, according to the report *Innovation in the pharmaceutical sector - A study undertaken for the European Commission*, delivered by Charles River Associates in 2004, p. 11, had a five-fold increase for clinical trials and of 60% for pre-clinical trials.

⁷⁰⁵ R&D expenditures amount to the 45,9% of sales of US pharmaceutical firms and to the 31,1% of sales of EU pharmaceutical companies. See EFPIA, *The Pharmaceutical Company in Figures*, 2008, p. 3-4.

the market.

For this reason, it is claimed that a competitive structure of the market would yield earnings that are inadequate for companies to cover their costs. Pricing at marginal cost, in fact, would fail to provide the necessary revenues to pay for R&D. For instance, it has been calculated that if purchasers would pay only for the marginal cost of production of drugs, the revenue shortfall would cover only the 70% of total costs of such production⁷⁰⁶. This outcome would impede companies' to preserve incentive to invest in research in the long run.

That is why most of developed countries grant patents on pharmaceutical products: the exclusivity right granted by law enables firms to charge prices above marginal cost that are shielded from competitive pressure exerted by perfect substitutes, i.e. generics. Pharmaceutical firms claim that this allows them to recoup their costs through an adequate return on investments and to keep alive their incentive to spend money on innovation⁷⁰⁷.

Thus, the pharmaceutical market is one of those sectors where competition shows up in the form of the Schumpeterian 'rent-seeking' model explained above, with competitors competing for the market rather than in the market⁷⁰⁸.

The dynamics of competition in the market for drugs can be effectively symbolized by a race. Companies compete on the same R&D project to arrive first at the patent. The monopoly profits earned by the commercialization of the protected product is the prize earned by the winner of the race.

But the patent-race winner enjoys the market exclusivity only for a certain period, until better products enter the market, compete with the pioneer product and eventually replace it. Hence, the regulator should not be concerned with market power, since the latter will be disciplined by the existence of other innovators, which can

⁷⁰⁶ Consistently with this finding see GRABOWSKI and VERNON, *Brand loyalty, entry and price competition in pharmaceuticals after the 1984 Act.*, in *J Law Econ*, 1992, no. 35, p. 331-350, who found that prices of generics, which incur minimal cost of R&D and promotion, ultimately fall to roughly 25% of the price of the originator product in the US. If prices cover all costs except R&D, the shortfall would be roughly 30%.

⁷⁰⁷ See GRABOWSKI and VERNON, *The determinants of pharmaceutical research and development expenditures*, in *J. Evol. Econ.*, 2000, no. 10, p. 201-215.

⁷⁰⁸ See SCHERER, *Industry Structure, Strategy, and Public Policy*, in *Review of Industrial Organization*, 1998, no. 13(3), p. 378-379; ID., *The link between gross profitability and pharmaceutical R&D Spending*, in *Health Affairs*, 2001, no. 20, cit., p. 220, who expressly makes this comparison: as profit opportunities expand, firms compete to exploit them by increasing their R&D investments and perhaps also promotional costs until the increases in costs dissipates most if not all supranominal profit returns.

become future competitors.

In addition, high technological opportunities characterising the pharmaceutical market, in fact, favour entry and competition on innovation. The patent-race hypothesis is, in fact, an oversemplification, as it tends to conceive firms like black-box production functions. Firms do not only learn from their own experience, but also from other stakeholders present in the market: customers, suppliers, competitors, universities, etc. The notion of innovation as a vertical process, where the pace starts from basic research, and through more specialized R&D, arrives to final products, is not universal. Often, innovation takes the features of a process where networks, feedback mechanisms and linkages among firms and between firms and institutions take place⁷⁰⁹.

The pharmaceutical market very much resembles this model: firms necessarily have to confront themselves with the scientific community in the process of discovery of a new molecule deemed to target a certain disease; this generates substantial knowledge spillovers at the level of research, thereby increasing the technological opportunities, as well as investments in R&D⁷¹⁰. This, together with the increasing number of strategic alliances among pharmaceutical and biotechnological companies, increases complementarity of assets and inputs that may enable firms to innovate more rapidly and efficiently and compete among them⁷¹¹.

In competition law parlance, this would mean that in the pharmaceutical market entry is very much facilitated by the existence of a wide variety of technological opportunities. In other words, each drug has many potential substitutes capable of exerting pressure its price, i.e. the pharmaceutical industry is characterised by a fierce *interbrand* competition.

Under these conditions, it may look harmful to inject additional competition in the market through the stimulus of *intra*brand competition, as this may greatly dissipate profits and endanger investments.

Stated differently, the encouragement of *intra*brand competition would come at the expenses of *inter*brand competition. Instead, the sacrifice of *intra*brand competition

⁷⁰⁹ See JORDE and TEECE, *Innovation, Cooperation and Antitrust*, in JORDE and TEECE, *Antitrust, Innovation, and Competitiveness*, cit., p. 48.

⁷¹⁰ See COCKBURN and HENDERSON, *Racing to Invest? The Dynamics of Competition in Ethical Drug Discovery*, in *Journal of Economics and Business Strategy*, 1994, no. 3(3), p. 481-519, at 505.

⁷¹¹ See JORDE and TEECE, *Innovation, Cooperation and Antitrust*, cit., p. 49; GLADER, *Innovation Markets and Competition Analysis*, *EU Competition Law and US Antitrust Law*, 2006, p. 35.

would leave to companies the necessary resources to invest in new drugs that may compete with those already existing in the market and would thus increase *interbrand* competition.

However, it should be considered that *interbrand* competition can take place and spur technological progress only if competitors can actually enter the market. Only in perfectly contestable market, an incumbent monopoly is not able to exploit its market power to the detriment of consumers, because the threat of entry induces it to adopt an efficient behaviour. However, markets may display an array of entry barriers. These are present especially in markets for knowledge-based products, where network effects, high risk, large sunk costs, lengthy R&D process, regulatory hurdles, IPRs, etc., reduce the possibilities of entry⁷¹².

For instance, some drugs have been developed to cure only a particular disease. In that case product markets have reduced dimensions, while concentration is high. This, especially for highly specific products, is due to the large investments in R&D necessary to develop such products. The huge amount of resources necessary to discover a new molecule and the high level of risk associated with the inventive activity constitute a natural barrier to entry. The small number of companies having such resources to enter a potential market on the one hand, and the patent protection (strengthened by the dossier protection, the supplementary protection certificate etc.) on the other, reduce and delay the possibilities of penetration of the market from new entrants, especially if they are not endowed with sufficient financial resources.

In sum, when the market is characterised by narrow product segments with little opportunity for demand substitution⁷¹³, as it may be for pharmaceuticals, the number of competing technologies available for each product may be limited even though the industry as a whole displays seemingly infinite technological opportunities.

Under these circumstances, where *interbrand* competition may not be effective, a concentrated market structure may pose antitrust concerns.

⁷¹² See BOUND ET AL., *Who does R&D and who patents?*, in *R&D, Patents and Productivity*, 1984, p. 21, 28, 29. See GLADER, *Innovation Markets and Competition Analysis*, cit., p. 18, fn 5 and accompanying text. Cf. Section 1.1 in Chapter I.

⁷¹³ Cf. Section 6 in Chapter I.

These considerations show that patent enforcement is surely very important to spur pharmaceutical innovation⁷¹⁴. However, a policy that enforces pharmaceutical patents *tout court* does not consider that the industry is already structurally endowed with features that provide firms with high post-innovation appropriability⁷¹⁵.

In the pharmaceutical industry, in fact, market power in terms of size and availability of financial resources, plays an important role at the pre-innovation stage, by allowing firms to face the lengthy and costly regulatory process⁷¹⁶. After the innovation reaches the market, because of effectiveness of patents and of the natural barriers to entry, the appropriability issue is less crucial for innovation⁷¹⁷.

The reason why pharmaceutical companies fear that competition may reduce their profits too much is linked to the phase that the industry is experiencing at present. Several patents covering 'blockbuster' medicines (i.e. medicines whose annual global turnover exceeds US\$ 1 billion), which account for a substantial part of the sales and profits of big pharmaceutical companies, expired or are about to do so in the next years. And only few new breakthrough innovations that can grant a substantial flow of financial resources have been recently invented. This creates uncertainty about the expected profits to be earned in the future and makes companies extremely concerned about the revenues coming from the current best-selling products.

This explains why drug producers are so much distressed about their profitability and about any factors that can eventually erode it, like parallel trade.

2.4. *R&D patterns in the pharmaceutical sector*

It has already been mentioned that economic literature identifies two dimensions in the appropriability issue: one refers to the financial resources actually available to conduct R&D at the time of the investment decision; the other one is related to the prospect of profits deriving from the investment. With regards to this latter aspect, generally it is affirmed that when companies foresee their inability of recovering invention costs due to the inadequate protection of information, they do not invest

⁷¹⁴ Cf. fn 237 in Chapter II for arguments that question the indispensability of patents to spur pharmaceutical innovation.

⁷¹⁵ See LEVIN ET AL., *Appropriating the Returns from Industrial Research and Development*, in *Brookings Papers on Econ. Activity*, 1987, p. 783, at 797.

⁷¹⁶ See DANZON, *The Pharmaceutical Industry*, in *The Encyclopaedia of Law and Economics*, 2000, p. 1055, at 1083.

⁷¹⁷ See CARRIER, *Two Puzzles Resolved: of the Schumpeter-Arrow Stalemate and Pharmaceutical Innovation Market*, in *Iowa Law Review*, 2008, no. 93, p. 393-450.

(enough) in innovation⁷¹⁸.

The innovation process follows the sequence below:

Patent → Profits → R&D activity → Innovation → Patent → ...

Patents provide financial resources that allow recouping the cost of previous inventive activity, as well as investing in new projects. Such investment in R&D activity leads to a new product that is in turn patented. And the innovation cycle continues.

The relation between profits and the R&D activity results crucial in this context. This link is, in fact, bilateral: the amount of money that the firm obtains from the commercialisation of a protected product influences the intensity of the R&D activity, i.e. in simple terms, how much money is available for investment in R&D ('cash-flow effect'); this investment is, however, in turn influenced by the amount of money that the firm expects to earn from the commercialisation of the new product ('expected profit effect'). In other words, the expectations that firms have about their future profitability have an impact on R&D patterns.

In particular, firms will undertake the most profitable investment projects first – those offering the highest risk-adjusted expected rate of return – and continue to undertake additional investment projects so long as the expected rate of return from the next project exceeds the firm's marginal cost of capital. The last project to be undertaken is the 'marginal project', beyond which any other investment is not worth it.

If, for any reason, the profitability of the 'marginal R&D project' decreases until a point where the marginal cost of capital is not covered any longer, it is likely to be dropped and what was the next-to-the-least-profitable R&D project becomes the new 'marginal project'. As a result, the total number of projects undertaken by the firm may decrease.

These findings should apply also to the pharmaceutical sector.

Economic literature amply explored the impact of the expected return from drug innovation on R&D intensity, and between the latter and the level of innovation, and

⁷¹⁸ Cf. *infra* Section 1 in Chapter II. See also DAM, *The Economics underpinning Patent Law*, in *J. Legal Studies*, 1994, no. 27, p. 247.

found that profit expectations and cash flows are generally found to be the principal explanatory variables of firm-level pharmaceutical R&D investment⁷¹⁹.

With regards to the latter aspect, while for most corporations R&D spending does not depend upon internal cash flows, pharmaceutical R&D is almost entirely internally generated⁷²⁰. That means that profits earned by a company through the commercialization of its products are the source of funds that support those investments. Lower profits, therefore, would yield lower financial resources available for R&D.

Also, the literature indicates that the distribution of pharmaceutical firms' profits is highly skewed: a minority of products confers blockbuster profits, while the majority returns less than the capitalized cost of R&D⁷²¹. This little profitable fraction of products is composed in large part from newly launched, patented, pharmaceuticals⁷²², which are generally reimbursed products, and therefore subject to price regulation, at least outside US. Any regulatory intervention on prices then affects exactly that fraction of products and may be liable of reducing profits to a large extent, as well as the level of investments in R&D.

As with regards to the effect of profit expectations on R&D incentives in the pharmaceutical sector, a large part of the literature confirms that there exists a positive correlation between the expected return from drug innovation and the level of

⁷¹⁹ See WIGGINS, *The Pharmaceutical Research*, cit., p. 55-83; GRABOWSKI and VERNON, *The Determinants of Industrial R&D expenditures in the pharmaceutical industry*, in *Drugs and Health*, 1981, no. 10, p. 201-215; MYERS, *The Inter-relationship between Pharmaceutical R&D and profit*, in *Journal of Research in Pharmaceutical Economics*, 1992, no. 4, p. 79; SCHERER, *Pricing, Profits, and technological progress in the pharmaceutical industry*, in *Journal of Economic Perspectives*, 1993, no. 7(3), p. 97; SCHERER, *The link between gross profitability*, cit., p. 216. However, see COCKBURN and HENDERSON, *Racing to invest?*, cit., p. 421, where interviewed managers claimed that in planning their investment programs they focused on three criteria: the size of the unmet medical need, the scientific potential of a field, and the idiosyncratic capabilities of their researchers.

⁷²⁰ Basic economic theory predicts that firms invest in capital up to the point where the expected marginal efficiency of investment is just equal to the firm's marginal cost of capital. In a neoclassical world, with perfect information and well-functioning capital markets, the supply of funds would be constant at the real market rate of interest, implying that firms consider the source of investment finance irrelevant. See MODIGLIANI and MILLER, *The cost of capital, corporation finance and the theory of investment*, in *Am. Econ. Rev.*, 1958, no. 48, p. 261-297. Recent research, however, both theoretical and empirical, suggests the source of finance does matter, and cash flows, because they have a lower cost of capital relative to external debt and equity, exert a positive influence on firm investment spending. HUBBARD, *Capital market imperfections and investment*, in *J. Econ. Literature* 1998, no. 37, p. 193-225. This is particularly true in the pharmaceutical industry, where the difficulty in finding external funding raises, due to the uncertainty that characterises pharmaceutical R&D. Cf. Section 1.1 in Chapter I.

⁷²¹ SCHERER, *The link between gross profitability*, cit., p. 216.

⁷²² DANZON, *Price Regulation for Pharmaceuticals: Global vs National Interests*, The American Enterprise Institute Press, 1997.

investment in R&D⁷²³.

For instance, recent investigation suggests that, provided that other determinants of innovation are held constant, a 10% increase in the growth of real drug prices is associated with nearly a 6% increase in the growth of R&D intensity⁷²⁴.

That is why it is claimed that the greater a firm's exposure to price regulation that lowers drug prices, the lower a firm's expected returns to R&D, the lower its incentive to invest in R&D in the first place.

In sum, any pharmaceutical policy that shapes prices for drugs may affect the level of investments in R&D in a twofold way: it influences the expected returns to R&D and has also a cash flow effect. If such regulation has the effect of lowering prices, it may discourage investments, because expected profits may be perceived by pharmaceutical companies to be too low to recoup the investment; and it leaves the company with less money available for investment in R&D⁷²⁵. For instance, it has been calculated that regulating pharmaceutical prices in the US could lead to a decline in R&D intensity of between 23.4% and 32.7%. Of this decline, the cash flow effect accounts for between 44% and 60% of this drop, and the expected profit effect account for between 56% and 40%⁷²⁶.

It could be argued that, similarly, parallel imports, as a form of price competition that lowers pharmaceutical prices and profits, could reduce the resources available for R&D⁷²⁷.

⁷²³ See WIGGINS, *The Pharmaceutical Research and Development Decision Process*, in *Drugs and Health: Issues and Policy Objectives*, 1981, p. 55-83; GRABOWSKI and VERNON, *The Determinants of Industrial R&D expenditures*, cit., p. 201-215; MYERS, *The Inter-relationship between Pharmaceutical R&D and profit*, in *Journal of Research in Pharmaceutical Economics*, 1992, no. 4, p. 79; SCHERER, *The link between gross profitability*, cit., p. 216.

⁷²⁴ GIACCOTTO, REXFORD, SANTERRE AND VERNON, *Drug Prices and research and Development Investment Behaviour in the Pharmaceutical Industry*, in *Journal of Law and Economics*, 2005, no. 48, p. 195-214.

⁷²⁵ See SCHERER, *Pricing, profits, and technological progress*, cit., p. 97-115; GRABOWSKI, *Health Reform and Pharmaceutical Innovation*, 1994; HELMS, *Commentary, in Competitive Strategies in the Pharmaceutical Industry*, 1996; GREEN, *Is price regulation necessary: a summary of arguments*, in *Pharmacoeconomics*, 1998, no. 14(Suppl. 1), p. 137-142; VERNON, *Drug research and price controls*, in *Regulation*, 2002-2003, no. 25(4), p. 22-25.

⁷²⁶ VERNON, *Examining the link between price regulation and pharmaceutical investment*, in *Health Economics*, 2005, no. 14, p. 1-16. However, the author pointed out that figures represented only a lower bound, because other factors influence pharmaceutical profitability and it has been assumed that margins will fall below margins existing outside US.

⁷²⁷ MASKUS, *Parallel Imports*, CU Working paper, 2000; LI AND MASKUS, *Parallel imports and cost reducing research and development*, CU working paper, 2002; VALLETTI and SZYMANSKI, *Parallel Trade, International Exhaustion and Intellectual Property Rights: a Welfare Analysis*, in *Journal of Industrial Economics*, 2006, no. 54(4), p. 499-526; BARFIELD and GROOMBRIDGE, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, in *Fordham Intell. Prop. Media & Ent. L.J.*, 1999, no. 10, p. 185.

Pharmaceutical firms recoup their sunk costs by charging above cost prices that are differentiated on the basis of the price sensitivity of groups of consumers, according to the Ramsey rule. This allows firms to solve their maximisation problem by earning a larger profit that does not distort consumption patterns in the markets served.

However, parallel trade undermines the pricing policy of a discriminating firm. This, pharmaceutical companies claim, may entail an overall profit that is not sufficient to cover all the costs the firm incurred to discover and develop a new drug, including the cost of failed projects⁷²⁸.

It follows that, through the elimination of parallel trade, pharmaceutical companies would avail themselves the ability to fully exploit the value of their patent, thereby stimulating further research and promoting dynamic efficiency.

The policy conclusion to be drawn from pharmaceutical companies' allegations is that behind restrictions to parallel trade there is an important business justification: the preservation of the competitiveness of the company in terms of innovative activity. For this reason, they should not be prohibited under competition law rules.

This conclusion has consequences of overriding importance, not only for the policy to be adopted towards parallel trade, but also for the application of EU competition law in general.

For instance, it may imply that *any* restriction of competition that allows diversion of revenue from 'non innovative stakeholders' (like consumers) to 'innovative firms' is presumed to always entail an improvement in innovation and on this basis should escape the application of competition rules.

If applied to abusive conducts, such an interpretation would imply, for instance, that the presence of *ex ante* efficiencies *always* justifies a refusal to supply by a dominant undertaking to its rivals. To this purpose, in fact, the defendant should merely object that

⁷²⁸ However, the theoretical literature is not unambiguous with regards to the effect of parallel trade on manufacturers' profits. Recent literature, in fact, identified some conditions, like the presence of price regulation, where the effect of parallel trade on profits, and on innovation, can be positive. See AHMADI and YANG, *Parallel Imports: Challenges from Unauthorized Distribution Channels*, in *Marketing Science*, 2000, no. 19(3), pp. 279-294; RAFF AND SCHMITT, *Why Parallel Trade may raise Producers Profits*, CESIFO Working paper No. 1503, 2005; PECORINO, *Should the US allow prescription drug reimports from Canada?*, University of Alabama Economics Working Paper No. 01-01-04, 2002, finds this result under the assumption that demand function is identical in the two markets. GROSSMAN and LAI, *Parallel Imports and Price Controls*, in *RAND Journal of Economics*, 2008, no. 39(2), p. 378-402, achieve this result by finding that parallel trade increases prices in the exporting country. From this, overall profits increase, and so does the money invested in R&D.

its refusal to deal with rivals increases its overall expected profits and that such a profit increase will necessarily bring about the efficiency benefit of increasing the *ex ante* incentive to innovate. This would indicate that an IPR owner *never* has a duty to supply.

However, the principle that a dominant company never bears a duty to deal with its rivals, as much as the notion that it always has such a duty, does not find any legal ground⁷²⁹.

The opposite statement would equal to grant a blank immunity to IPRs owners, on the basis that the limited duration and scope of these rights already reflects a trade off between the exclusion of competition and the promotion of innovation⁷³⁰.

Such a minimalist vision of antitrust law, which should not intervene at all in the market where private incentives to innovate are at stake⁷³¹, implies that innovation is a policy objective that has relevance as such, and not as long as it promotes consumer welfare. But this inevitably contrasts the fundamental principles that found the EU competition law system as a whole, whose main objective is the protection of consumer welfare⁷³².

It is thus clear that pharmaceutical companies' claim about the potential impact of parallel trade on R&D incentives has an economic justification. Still the deriving policy conclusions in the field of European competition law should be carefully designed, in order to make sure that efficiency claims appropriately fit the law.

3. Patents, profits and incentive to innovate in the pharmaceutical sector

The claim on which defendants based the alleged efficiency of restrictions of parallel trade can be subdivided into two stages: firstly, they recall the existence of a

⁷²⁹ ELHAUGE, *Defining Better Monopolisation Standards*, cit., p. 310, reads into US Supreme Court case law the principle that *ex ante* efficiencies virtually give the right to refuse to supply in all cases to IPRs owners, except when such refusal is discriminatory towards rivals.

⁷³⁰ In No. 00-62 CSU, *LLC v. Xerox Corp.*, the DOJ opposed categorical antitrust immunity for refusals to license in its brief to the Supreme Court opposing certiorari. See Brief for the United States as Amicus Curiae at para. 10 (expressing "serious concerns about such a holding" and stating that the U.S. "would not be prepared to endorse it").

⁷³¹ Cf. AREEDA, *Essential Facilities: An Epithet in Need of Limiting Principles*, in *Antitrust Law Journal*, 1989, no. 58, p. 841; CARRIER, *Unraveling the Patent-Antitrust Paradox*, in *University of Pennsylvania Law Review*, 2002, no. 150, p. 761-845, at 816 *et seq.* who affirmed that in those sectors where both patents and competition play an important role in stimulating innovation, like the pharmaceutical market, competition rules should not apply, in order to avoid interference with patent incentives and discouragement of innovation.

⁷³² Cf. *supra* fn 391 and accompanying text.

positive correlation between the general level of current profits, or the expected profitability of the products, and expenditure on research and development; secondly, they submit that those factors (level of current profits, profitability of the products) are adversely affected by parallel trade.

Reverting the logic, restrictions to parallel trade increase profits, and such increment spurs innovation.

However, this reasoning has one main drawback: it requires the assumption that all rewards bring the same incentive effect, as if innovation were a one-size-fits-all concept. In my opinion this hypothesis is overly simplistic and needs some refinement. To this purpose, I will firstly analyse the impact of parallel trade on profits, and then I will examine the effect on innovation.

3.1. *The impact of parallel trade on profits*

It has already been pointed that the granting of a patent does not necessarily give rise to a monopolistic profit⁷³³. The patent puts the owner in the virtual condition to obtain it, but the concrete level of profitability of a new product depends on several variables affecting market conditions: the presence of competitors, barriers to entry, product differentiation, brand loyalty, successful marketing, etc.

Some firms consistently profit more than others from their R&D activities, because they are more successful at penetrating the market⁷³⁴. This in turn depends on the competitive advantage that the firm enjoys in the market: tangible and intangible assets, as well as the capabilities in discovering, developing, and marketing and the know-how. In fact, given that technological progress is essentially the process of using resources to learn or acquire new knowledge, it is very important how quickly the firm is able to go down the learning curve.

Profitability is also determined by the advantage of being a 'market pioneer'. This is particularly important in markets like the pharmaceutical sector, where customer (*read: doctors'*) familiarity and brand loyalty have helped companies in maintaining

⁷³³ See *infra* Section 3.2 in Chapter II.

⁷³⁴ See VERNON, *Drug research and price controls*, cit., p. 14; VERNON, *The relationship between price regulation and pharmaceutical profit margins*, in *Appl. Econ. Lett.*, 2003, no. 10, p. 467–470.

significant market shares long after they entered the market for the first time⁷³⁵.

Therefore, the profitability of R&D investments varies from firm to firm and cannot depend solely on the degree of price competition, which the firm is going to be exposed to⁷³⁶. Other variables play an important role. In the pharmaceutical market price regulation is one of the most important.

Given the long period that is typically necessary (10-15 years) in order to develop new molecules and to bring them onto the market, as well as the complex regulatory context in which the pharmaceutical industry operates, the reasons that could lead to a lower profitability of an R&D project can be manifold. For instance, the 'domino effect' of reference pricing systems is capable of reducing profits not only in the European market but also at a global level. Furthermore, the expiry of one or more patents and the subsequent arrival of generics on the market force companies to lower their prices in order to sustain competition, thereby reducing profits.

The second factor that influences the most the profitability of a pharmaceutical R&D investment is marketing and promotional activity. Advertising and marketing cover a large part of pharmaceutical companies' expenditure. From recent estimates it appears that US pharmaceutical companies spend almost twice as much on promotion as they do in R&D⁷³⁷. The market success of many pharmaceutical products is driven by

⁷³⁵ For two years after the expiration of patents, the average market share of pioneers in the pharmaceutical market was 51%. See WILLIAMSON, *First-Mover Advantage from Pioneering New Markets: a Survey of Empirical Evidence*, in *Rev. Ind. Org.*, 1994, no. 9, p. 1, at 5.

⁷³⁶ The literature on the theory of the firm finds substantial theoretical arguments to support the existence of heterogeneities in firm R&D capabilities. See PENROSE, *The Theory of the Growth of the Firm*, 1959; BARNEY, *Firm resources and sustained competitive advantage*, in *J. Manage.*, 1991, no. 17(1), p. 99-120. COCKBURN and HENDERSON, *Racing to Invest?*, cit., p. 482, similarly affirms that by examining ethical drug discovery - research intended to identify promising new drugs - rather than drug development, they find that investment levels are very weakly correlated across firms. This has been interpreted by the authors as consistent with the hypothesis that adjustment costs and firm heterogeneities play a significant role in determining investment patterns. See also the US DEP'T OF JUSTICE & FED. TRADE COMM'N ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY, 3.2.3, where it is said that "the capabilities to engage in the relevant R&D can be associated with specialized assets or characteristics of specific firms".

⁷³⁷ See GAGNON and LEXCHIN, *The Cost of Pushing Pills: a New Estimates of Pharmaceutical Promotion Expenditures in the United States*, in *PLoS Med*, 2008, no. 5(1), p. 29 contesting IMS' and PhRMA's findings that pharmaceutical firms spend more on research and development (R&D) than on marketing: US\$29.6 billion on R&D in 2004 in the US as compared to US\$27.7 billion for all promotional activities. See IMS HEALTH, *Total U.S. promotional spend by type*, 2004. The study compared estimates performed by IMS and CAM in 2004. CAM reported total promotional spending in the US of US\$33.5 billion. See CAM GROUP, *Total U.S. promotional activity for 2004*, from CAM USA Newsletter, 2005. However, the authors found that both estimates are incomplete and that the real amount of resources invested in marketing is US\$57.5. However, see CALFEE, *The Role of Marketing in Pharmaceutical Research and Development*, in *Pharmacoeconomics*, 2002, no. 20 (Suppl. 3), pp. 77-85, and KWONG and NORTON, *The Effect of Advertising on Pharmaceutical Innovation*, in

huge marketing operations, which determine the profitability of a product much more than competition⁷³⁸.

It follows that price competition (*read*: parallel trade) is only a concurrent factor that determines the expected profits deriving from an R&D investment. In other words, parallel trade is not the only determinant of the possible reduction of the value of a patent and of the discovery rate of new drugs. Conversely, parallel trade can only have an *incremental impact* on firms' profits and, on the basis of the magnitude of such incremental impact, potentially also on innovation⁷³⁹.

3.1.1. When parallel trade increases manufacturers' profits

Such incremental impact on profits has been traditionally believed to be negative, as much of the relevant literature affirmed⁷⁴⁰. Recent literature has been questioning this finding under certain hypothesis, though.

Ahmadi and Yang⁷⁴¹ show that parallel trade may extend the global reach of patented products and increase global profits. This is because parallel trade enables a manufacturer to further segment consumer groups. The model shows through a three-stage Stackelberg game that the market can be segmented into three groups when parallel trade occurs⁷⁴² – a) those customers who continue to purchase the product from authorised dealers because they value the warranty and service levels; b) customers who previously purchased the product from authorised dealers but switch to the parallel trader due to the lower prices; and c) new customers who purchase from the parallel trader attracted by lower prices. Parallel trade increases sales but its effect on profits depends on the relative sizes and profitability of these three groups. If the profits from group c) exceed the losses from group b) then aggregate profits will increase.

Rev. Ind. Org., 2007, no. 31, p. 221-136, both supporting the thesis that pharmaceutical advertising has a positive effect on product innovation.

⁷³⁸ This for instance the case of Prozac. At the expiry of the patent, Ely Lilly got the patent on the weekly Prozac and with a massive operation of marketing managed to keep doctors prescribing it instead of the cheaper generic version of the daily Prozac.

⁷³⁹ One can read this also in para. 277 of the *Glaxo* ruling, where it stated that the *Frontier Economics II* study found that a connection existed between the general level of current profits or the expected profitability of the products and decisions on research and development, and that those factors were affected by parallel trade, although admitting that parallel trade was not the main factor underlying decisions on research and development.

⁷⁴⁰ Among many see MALUEG and SCHWARTZ, *Parallel Imports, Demand Dispersion*, cit., p. 187-196.

⁷⁴¹ AHMADI and YANG, *Parallel Imports: Challenges from unauthorized distribution channels*, in *Marketing Science*, 2000, no. 19, p. 279-294.

⁷⁴² A fundamental assumption behind this result is that parallel traded products are different with respect to the original ones, or at least they are perceived as such by consumers.

Raff and Schmitt⁷⁴³ develop a model that shows that letting retailers trade unsold inventories may result in larger orders being placed with the manufacturers and higher profits and consumer gains. Raff and Schmitt show that this will be the case where distributors must place orders for the good before they know actual demand; the products have little value at the end of the demand period or inventories are costly to maintain. Demand differs across countries and the differing demand affects the quantity of the good demanded rather than the consumer's willingness to pay.

If, under these conditions, the manufacturer were to ban parallel trade, then distributors could become saddled with large inventories, which would depress prices. Distributors foresee such a loss and reduce their orders, thereby reducing also manufacturer's profits.

If the manufacturer allows parallel trade, then this stops the retail price falling dramatically since the distributors are able to sell to parallel traders if demand is unexpectedly lower. Thus, the distributor will place a larger order with the manufacturer than it would do without parallel trade. The manufacturer's incentive to allow parallel trade is stronger when the price elasticity of demand is similar across countries but country demand is uncertain. Conversely, when the price elasticity of demand differs across countries, then the manufacturer's inclination is toward banning parallel distribution so as to practice third degree price discrimination.

Three other papers model the relationship between parallel trade, profits and R&D incentives.

Valletti and Szymanski⁷⁴⁴ find that parallel distribution causes a reduction in investment in product R&D and quality. Consequently, consumers are supplied an inferior product which lowers their surplus *ex ante*. However, *ex post* there is a gain in consumer surplus since consumers who did not previously purchase the good now buy. The overall effect of parallel trade depends on whether the *ex ante* loss dominates the *ex post* gain in welfare. They show that when the monopolist can price discriminate based on differences in demand (willingness to pay) allowing parallel distribution will reduce their investment in R&D. However, if consumers in the low priced market have different

⁷⁴³ RAFF and SCHMITT, *Why Parallel Distribution may Raise Producers' Profits*, CESIFO Working Paper No. 1503, July 2005.

⁷⁴⁴ VALLETTI and SZYMANSKI, *Parallel distribution, International Exhaustion and Intellectual Property Rights: A welfare analysis*, in *Journal of International Economics*, 2006, no. 70, p. 314-324.

valuations depending on whether there has been investment in R&D which they value more after the investment has been made, then the marginal return on investment, together with the incentive to innovate, will be greater when parallel distribution is allowed.

Li and Robles⁷⁴⁵ also challenge the claim that parallel trade necessarily decreases the incentive to innovate by reducing profits and they show that this form of competition may also spur innovation.

They argue that innovation incentives depend not so much upon post-innovation profits, but upon the difference between post-innovation and pre-innovation profits. That is, if parallel trade reduces pre-innovation profits more than it reduces post-innovation profits, then it is not detrimental to innovation. The degree of this effect depends on the type of products involved. If goods are independent, parallel trade decreases post-innovation profits. If goods are complements, parallel trade reduces both pre-innovation and post-innovation profits. If goods are substitutes, parallel trade reduces more pre-innovation profits than it may reduce post-innovation profits, provided that the manufacturer has a competitive advantage (e.g. in transportation costs) in distributing the new good. In this latter case, parallel trade provides an incentive to innovate.

But the most important contribution to the literature on the subject comes from Grossman and Lai⁷⁴⁶. They also challenge the view that parallel trade necessarily reduces investment in R&D. This result stems from a specific assumption, which suits very much the case under examination: unlike other studies that treat the government as an exogenous actor, the authors incorporate government price controls in their analysis. The result is that where the level of prices set in negotiations with health authorities/governments is endogenous, it is not self evident that the pharmaceuticals companies' profits would necessarily fall. There may be a harder bargaining over price levels in the knowledge that prices set in different countries will encourage some re-

⁷⁴⁵ LI and ROBLES, *Product Innovation and Parallel Trade*, in *International Journal of Industrial Organization*, 2007, no. 25, p. 417-429.

⁷⁴⁶ GROSSMAN and LAI, *Parallel Imports and Price Controls*, cit., p. 378-402.

importation of drugs from lower to higher priced countries. This allows the firm to earn a larger profit, so that innovation is not undermined⁷⁴⁷.

This model shows that the relationship between parallel trade and prices, profits and R&D is more complex for pharmaceuticals, because of price regulation. Government regulation, pharmaceuticals companies' actions, prices and strategies, and the level of parallel trade are all simultaneously determined. However, the former has a fundamental impact on all the other variables considered: it affects gross profits directly, through price controls, but also indirectly, through the scope it leaves to parallel trade. For instance, the lower the price in the exporting country, the higher the level of parallel and exports. *Vice versa*, the higher the price in the exporting country, the tinier the scope for parallel trade and the smaller is the negative impact on pharmaceuticals (expected) profits.

In other words, the impact of parallel trade of pharmaceuticals on manufacturers' profits is not straightforward to determine, as it depends on several variables. It follows that in the analysis of efficiency claims such effect should concretely ascertained and not just presumed. Pharmaceutical companies should, thus, produce enough evidence that shows how specifically parallel trade has negatively affected their budget.

3.2. *Does more money always bring more innovation?*

The correlation between expected profits and the investment on innovation – supporting the second stage of pharmaceutical companies' efficiency claim – is largely underpinned by the literature mentioned in the previous Section, which investigated at length the issue and substantiated it.

However, it appears incorrect to interpret such literature as supporting the statement that *more money always brings more innovation*.

From an *ex ante* perspective, an R&D project is going to be undertaken provided that the expected return is enough to cover costs and give a sufficient profit. If this expected profit is going to be jeopardized, then there may be discouragement to invest in the project. If competition dissipates only what is in addition to this profit, there should not be any disincentive to innovation.

⁷⁴⁷ GROSSMAN and LAI, *Parallel Imports and Price Controls*, cit., p. 398.

That is why, beyond a certain point, more financial incentives in the form of a broader exclusive right do not necessarily lead to an increased innovation activity. That is, additional future profits to those necessary to sufficiently reward the inventive effort do not necessarily spur more innovation *ex ante*⁷⁴⁸.

This means that the appropriation of *all* possible return from an innovation is not necessary to induce companies' innovative effort⁷⁴⁹. In fact, as some legal commentators exemplified, the economic return per invention, which is attributable to patent protection, i.e. the 'patent premium', and the production innovation curve '*are not indefinitely parallel, as at some point, the innovation curve diverges*'⁷⁵⁰.

The innovation pattern that has been characterising the pharmaceutical industry in the last twenty years seems to substantiate these objections.

The virtuous rent-seeking model appears to experience a crisis and the major pharmaceutical companies are mostly producing 'me-too drugs'⁷⁵¹. In 2002 the FDA approved 78 new drugs. Of these, only 17 contained new active substances. Among the latter, only 7 were classified as improvements with respect to the existing products⁷⁵². The other 61 were just 'me-too drugs'⁷⁵³. From these figures, it clearly appears the difficulty for companies to refill the product pipeline and to increase the number of novel medicines reaching the market.

The reason behind the proliferation of me-too drugs is that discovering new

⁷⁴⁸ Similarly see KAPLOW, *The Patent-Antitrust Intersection*, cit., p. 1824 and 1825, who affirms that prolonging patent life in order to induce further inventive activity increases the period of monopolistic exploitation for those inventions that would have been created even without lengthening the patent life. In these cases, a stretching patent life would only result in a social cost that is not offset by any social benefit.

⁷⁴⁹ See LEMLEY, *Property, Intellectual Property and Free Riding*, *Texas Law Review*, 2005, no. 83, p. 1057, who says that "*Sufficient incentive ... is something less than perfect control*"; LESSIG, *Intellectual Property and Code*, *Saint John's Journal of Legal Commentary*, 1996, no. 11, p. 635; BRUNNELL, *Appropriability in Antitrust: How much is enough?*, *Antitrust Law Journal*, 2001, no. 69, p. 1; LANDES and POSNER, *An Economic Analysis of Copyright Law*, *Journal of Legal Studies*, 1989, no. 18, p. 325.

⁷⁵⁰ See HUMPE and RITTER, *Refusal to Deal*, in *GCLC Research Papers on Article 82 EC*, cit., p. 151.

⁷⁵¹ For instance, in 2005 there were 6 statins in the world market: Mevacor, Lipitor, Zocor, Pravachol, Lescor and Crestor, all variations of the first one. Cf. the Table 2 in Chapter I.

⁷⁵² The FDA classifies drugs in two ways. First it examines the chemical compound, in order to ascertain whether this is new or it exists already in the market. In the former case, the compound is classified as drug number 1; in the latter, it is classified as a compound derived from another one or combined with an old one. Secondly, the FDA looks at the therapeutic effect, to check whether the drug offers any superior therapeutic benefit with respect to existing products. In the affirmative case, the FDA classifies it as 'P' (privileged) and accelerates the approval procedure. Technically speaking, only a drug whose compound is new and adds new therapeutic benefits is a new drug, i.e. an innovation. The other are just improvements to previous innovations.

⁷⁵³ See www.fda.gov/cder/rdmt/pstable.htm to check the number and the type of drugs approved every year. Note that the 7 drugs that were considered really new products were not produced by US companies.

drugs has become more complex and more expensive, and pharmaceutical companies have become risk averse. This, besides triggering a wave of mergers during the nineties, generated a substantial flow of investments directed towards 'easier products'. In terms of profitability, in fact, it is financially safer to make a small improvement on an existing drug, patent it and re-direct patients to that one, instead of investing a large amount of resources in R&D projects for entirely new products whose commercial success is highly unknown⁷⁵⁴.

This loss of 'creative vein' is happening notwithstanding the increased investment in R&D, but most importantly, despite the extraordinary earnings that the sale of some blockbusters has been entailing to them⁷⁵⁵. In 2002, for instance, big pharma together were earning 200 billions dollars of sales in US and 400 billions worldwide; in average, their profits amounted to 17% of sales, while 14% went into R&D, and 31% in marketing and administration.

It is evident, thus, that more money may not necessarily lead to increased innovation. It rather seems more appropriate to affirm that pharmaceutical companies invest in innovation that percentage of their profits that allows them to stay competitive in the market.

In determining such amount, the shape of the innovation production function is fundamental. With decreasing marginal returns to scale from investment in innovation, there is a certain point where an extra dollar invested in R&D entails less than a unit of innovative output. In other words, beyond the point where the marginal cost and the marginal benefit of investing in innovation balance each other, any further penny in R&D is not worthwhile.

The form of the innovation function over the research and development cost levels is essential to understand also the impact that price competition can have on innovation. Assuming diminishing returns to scale from investment on innovation, there will be cost levels at which the marginal productivity is high and at which the effect of reduced research and development costs, due to lower profits, on innovation will be

⁷⁵⁴ Cf. the interview to Sharon Levine, doctor and director of the Kaiser Permanente Medical Group, in FamiliesUSA, *Out-of-Bounds: Rising Prescription Drug Prices for Seniors*, July 2003.

⁷⁵⁵ Similarly see the interview to Silvio Garattini, founder and director of the Istituto di Ricerche Farmacologiche Mario Negri in Italy, in *Il Messaggero* on October 30th, 2005, where he declares that out of 8500 drugs available in Italy, only 100 are really effective.

substantial. At the same time, there will also be cost levels at which marginal productivity is low and where this effect is moderate or negligible.

In addition, the effect of competition on innovation depends on the type of projects that the company is running.

For instance, R&D projects that lead to the introduction of me-too drugs do not entail the extraordinary costs that are generally attributed to the discovery and the development of an entirely new compound with new therapeutic effects. At the same time, me-too drugs are blockbuster products in terms of per year earnings for pharmaceutical companies⁷⁵⁶. On the contrary, new drugs that treat diseases for which there is not an adequate cure often cover a smaller part of the worldwide population and entail much lower earnings compared to the huge costs needed to develop them.

If, within a company's R&D portfolio, the number of low-risk projects, i.e. projects that require lower R&D investment and entail high expected profits, prevails over the number of high-risk projects, i.e. projects that require higher R&D investments and entail lower expected profits, a given profits loss is overall less detrimental than in the case when the company is running a larger number of high-risk projects compared to low-risk projects.

From these considerations follows that the same profit loss does not have the same effect on each pharmaceutical company's incentive to invest in innovation, and that a certain reduction in the profitability of patents cannot be expected to discourage firms' innovation activity that would not take place anyway. Differently stated, some limitation on an IPR owner's right to exclude competitors may have only a marginal effect on investment decisions or not have it at all⁷⁵⁷.

⁷⁵⁶ AstraZeneca's Prilosec was per-year 6 billion dollars drug for the treatment of conditions caused by excess stomach acid. At the expiry of the patent, the company isolated the active part of Prilosec's molecule and patented with the name of Nexium. With a massive campaign (cost: 500 millions dollars) and a temporary reduction of price, the company managed to convince doctors to move to Nexium and prescribe it also when the price rose. See HARRIS, *As a Patent Expires, Drug Firms Lines Up Pricey Alternative*, in *Wall Street Journal*, 6 June 2002, p. A1 and SWIDEY, *The Costly Case of the Purple Pill*, in *Boston Globe Magazine*, 17 November 2002, p. 11. Similarly, Schering-Plough substituted its per-year 2.7 billion dollars Claritin with Clarinex, which is just the active metabolite, i.e. the molecule in which the human body converts the former. A similar story happened for Prozac and its weekly version.

⁷⁵⁷ Similarly see AYRES and KLEMPERER, *Limiting Patentee's Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, in *Mich. Law Rev.* no. 97, 1999, p. 987-990, who affirmed that 'unconstrained monopoly pricing is not a cost-justified means of rewarding patentees because the last bit of monopoly pricing produces large amounts of deadweight loss for a relatively small amount of patentee profit. [...] Restricting the patentee's monopoly of a small amount is likely to increase social welfare because

That is why it appears more appropriate to say that parallel trade may curtail incentives to innovate, but the magnitude of that risk varies from case to case, depending on the impact it has on profits.

3.3. *Interim conclusions*

From the analysis above it appears that the impact of antitrust intervention in the market, in the form of a policy encouraging parallel trade, on dynamic efficiency is not clear. Parallel trade may or may not decrease profits, depending on circumstances. Even when it has a negative impact on companies' budget, its harm on innovation is not straightforward.

Observing a decline in profits of a certain percentage is of limited value from a policy perspective. While it may decline as a consequence of price competition, it is necessary to measure what would be exactly the consequence on R&D intensity and, in turn, on innovation, if any.

This means that *it is not possible to rely on a presumption of existence of positive effects* in terms of increased innovation coming from the extra-money earned through the restrictions of parallel trade.

This has an important twofold implication, for the policy on parallel trade and for antitrust in general.

The analysis conducted has shown that it is possible to presume that restrictions to parallel trade have negative effects on consumers in the short run. Unfortunately, there are no economic grounds to support the existence of an equivalent presumption with regards to the efficiencies coming from such restrictions in the long run. It follows that pharmaceutical companies have to specifically demonstrate through convincing evidence that their strategies against parallel trade are going to generate gains for consumers.

In fact, economic theory does not support a standard of proof of efficiencies coming from anticompetitive practices that leaves *carte blanche* to innovators. On the contrary, it requires to concretely demonstrating the existence and the magnitude of positive effects from business practices in order to escape the application of competition law rules.

the benefit of reducing the deadweight loss of supra-competitive pricing is likely to outweigh the cost of a slightly lower incentive to innovate.'

And this leads me to the more general implication: although efficiency gains are relevant in the assessment of anticompetitive corporate conducts, they cannot represent a goal in themselves under EU competition law. Hence, the preservation of innovation incentives cannot be considered a redeeming virtue *per se* to anticompetitive corporate conducts.

4. A test for efficiencies under Article 102 TFEU

The considerations expressed in the previous Sections help shedding some light on one of the most interesting aspects of the debate over the modernization of Article 102 TFEU.

It is largely discussed whether dynamic efficiencies should be actually proved, also in their magnitude, and compared to the static inefficiency created by an abusive conduct, or whether their mere assertion, absent quantification, would be sufficient to escape the application of Article 102 TFEU.

The Commission, supported by prominent scholars⁷⁵⁸, opted for the former choice⁷⁵⁹. However, other scholars, inspired by recent developments in the US case law⁷⁶⁰, criticize it and privilege the latter⁷⁶¹.

Those scholars who support the former option, also discussed whether the proportionality test for efficiencies under Article 102 TFEU should be crafted according to a 'softer' version of the test or according to a 'stricter' one: the former would consist only of the balancing exercise between the efficiencies and the anticompetitive effects, whereas the latter require that the dominant undertaking proves that it can do no business without the alleged restriction of competition⁷⁶².

I personally envisage four possibilities, which I am going to name as following:

- 1) the 'legitimate business conduct *à la Syfait I'*;

⁷⁵⁸ See GYSELEN, *Rebates: Competition on the Merits*, cit., p. 291; TEMPLE LANG and O'DONOGHUE, in *The Concept of an Exclusionary Abuse under Article 82 EC*, in *GCLC Research Papers on Article 82 EC*, cit.

⁷⁵⁹ See the Guidance on Art. 82 EC, where at para. 30 *et seq.* See better *infra* this Section.

⁷⁶⁰ See *Verizon Communications Inc v Law Offices of Curtis V Trinko, LLP*, 540 US, 2004 (Case No 02-682).

⁷⁶¹ See EVANS and PADILLA, *Designing Antitrust Rules for Assessing Unilateral Practices: A Neo-Chicago Approach*, in *University of Chicago Law Review*, 2005, no. 72; AILBORN, DENICOLÒ, GERADIN, and PADILLA, *DG Comp's Discussion Paper on Article 82: Implications of the Proposed Framework and Antitrust Rules for Dynamically Competitive Industries*, 2006.

⁷⁶² The latter option was supported by AG Cosmas in his opinion in the case C- 344/98 *Masterfoods Ltd v. HB ICE Cream Ltd*.

- 2) the 'legitimate business conduct à la Syfait II';
- 3) the 'strict approach';
- 4) the 'efficiency defence'.

In this subsection I am going to analyse all of them in the presented sequence, in order to pick the one that better suits the structure of Article 102 TFUE and that is in line with economic theory.

4.1 *The 'legitimate business conduct à la Syfait I'*

By this name I identify the efficiency arguments put forward by the pharmaceutical companies, which I discussed at length in the previous Section from an economic perspective.

The similarity of this test with the type of analysis employed in the United States in relation to Section 2 of the Sherman Act, where the concept of 'competition in the merits' is already inclusive of efficiency gains⁷⁶³, is evident.

Indeed, it recalls the innovation-centred rebuttable presumption proposed by one US scholar⁷⁶⁴: a company's patent-based action would be lawful as long as there is a plausible justification based on efficiency, rather than on injuring competitors. Being substantially based on the *presumption* that any action that defend the IPR owner profits stimulates innovation, this test supports the recognition of efficiencies also when their existence is not concretely proved and, most of all, even if it is not demonstrated that they benefit consumers.

Such test is claimed to have three nice properties: first, it avoids the prohibition of efficient conducts; second, it prevents costly and lengthy forward-looking inquiry that may not provide any useful insight; third, it offers clarity and predictability for Courts and parties.

The question is, thus, whether an American approach to Article 102 TFUE is envisageable.

Despite its easy manageableness, the test has two main drawbacks. First, it overlooks the fact that this presumption does not hold and that a case-by-case analysis is needed, in order to account for the actual materialisation of efficiency gains. Secondly,

⁷⁶³ See *United States v. Grinnel Corp.*, 348 US 563 (1966), where the Court defined the actual monopolisation as 'the wilful acquisition or maintenance of [monopoly] power as distinguished from growth or development as a consequence of superior product', i.e. based on efficiency.

⁷⁶⁴ CARRIER, *Unraveling the Patent-Antitrust Paradox*, cit., p. 816.

the test does not require a balance between pro-competitive effects and anticompetitive effects of the conduct. Nor does it require the conduct to be the least restrictive alternative that will achieve the goal.

This approach can be hardly reconciled with Article 102 TFEU's policy objective.

It is largely recognised that the main goal of this provision is to protect the competitive process⁷⁶⁵, as the method of interfirm rivalry that better serves the interest of consumers according to economic theory. This objective, which to a certain extent also protects the freedom of competitors to compete on the merits, is not, however, a policy goal in itself. Case law, in fact, indicates that before a finding of material adverse effect on consumer welfare can be made, the competitive assessment must focus on the consequences of a practice on the marketplace. It follows that the substantive test for the application of this provision should be based on the effect of the company's conduct on consumer welfare⁷⁶⁶. The latter paradigm represents, thus, the rationale of the provision.

In line with an effect-based approach, the substantive test underpinning the application of Article 102 TFEU should look at the consequences the conduct has for consumers⁷⁶⁷.

This approach, claimed by a large number of legal and economic scholars⁷⁶⁸, has been recently and more explicitly endorsed by the European Commission in the *Discussion Paper on Art. 82*, which at § 55 states that '*Article 82 prohibits exclusionary*

⁷⁶⁵ See GYSELEN, *Rebates: Competition on the Merits*, cit., p. 297; FOX, *Abuse of Dominance and Monopolisation: How to protect Competition without Protecting Competitors*, in *World Competition*, 2003, no. 26, p. 149.

⁷⁶⁶ See among others, *BPB*, cit., para. 65 and 66, which held that promotional payments made by a dominant supplier to a customer in return for an exclusive purchasing commitment are "a standard practice forming part of commercial cooperation between a supplier and its distributors" that "cannot, as a matter of principle, be prohibited," but rather must be assessed in the light of their effects on the market in the specific circumstances.

⁷⁶⁷ See for example, *BPB*, para. 65-66, which held that promotional payments made by a dominant supplier to a customer in return for an exclusive purchasing commitment are "a standard practice forming part of commercial cooperation between a supplier and its distributors" that "cannot, as a matter of principle, be prohibited," but rather must be assessed in the light of their effects on the market in the specific circumstances.

⁷⁶⁸ See BISHOP, *Price Discrimination under Article 86: Political Economy in the European Court*, in *MLR*, 1981, no. 44, p. 282; LORENTZ, LUBBIG and RUSSEL, *Price Discrimination: a Tender Story*, in *ECLR*, 2005, no. 26, p. 355; SINCLAIR, *Abuse of Dominance at a Cross-roads: Potential Effect, Object and Appreciability under Article 82 EC*, *ECLR*, 2004, no. 25, p. 491; TEMPLE LANG and O'DONOUGHUE, *Defining Legitimate Competition: how to clarify abuses under Article 82 EC*, in *Fordham Int'l L. J.*, 2002-2003, no. 26, p. 83-84, at 108-111, and at 158-162; AHLBORN and PADILLA, *From fairness to welfare: implications for the assessment of unilateral conduct under EC Competition Law*, 2006; EILMANSBERGER, *How to distinguish good from bad competition under Article 82 EC: in search of clearer and more coherent standards for anti-competition buses*, in *CMLR*, 2005, no. 42, p. 129; GLYNN, *Article 82 and price discrimination in patented pharmaceuticals: the Economics*, in *ECLR*, 2005, no. 3, p. 135; EHRLMANN and ATANASIU, *European Competition Law Annual 2003*, cit.; *GCLC Research Papers on Article 82 EC*, cit.

conduct which produces actual or likely anticompetitive effects in the market and which can harm consumers in a direct or indirect way’.

Mutatis mutandis, this reasoning also applies to efficiencies in my opinion. Given that the paradigm of consumer welfare is the rationale of Article 102 TFEU, it is not appropriate that efficiency gains are accounted for irrespective of the identity of the ultimate beneficiary. It is correct, on the contrary, that their admission to antitrust analysis of abusive conducts is subject to the passing on requirement. Differently stated, as much as the proof that a reduction of consumer welfare has actually materialised as a result of the exclusionary conduct is necessary, proof that consumers benefit from the efficiency gains entailed by the conduct should be also required⁷⁶⁹.

Differently from what is required under Section 2 of the Sherman Act, the analysis of potentially anticompetitive unilateral conducts under Article 102 TFEU presupposes that the existence and the magnitude of the efficiency gains are actually proved and that simply putting forward their future *possibility* is not sufficient. That is why a test similar to the one applied under the former provision is not applicable to the latter⁷⁷⁰.

4.2. The ‘legitimate business conduct à la Syfait II’

The second option is the ‘legitimate business conduct à la Syfait II’.

In the ruling rendered by the ECJ in that case, the Court acknowledged that it is legitimate under EU competition law for a dominant company to honour only part of the received orders when these are out of the ordinary, so as to protect its commercial interests. This necessarily implies that the Court recognised that an unlimited amount of parallel trade may have a negative impact on such interests. The ECJ, thus, implicitly acknowledged that parallel trade might threaten companies’ profits.

For this reason, the Court left open the possibility for a pharmaceutical manufacturer to justify its refusal to supply where the orders are ‘out of the ordinary’.

This ‘rule of thumb’ indicates that the ECJ was aware of the fact that, on the one hand, parallel trade is capable of entailing short-term savings for consumers, but that, on the other hand, parallel trade may have an impact on manufacturers’ profits and, on the

⁷⁶⁹ Cf. GYSELEN, *Rebates: Competition on the Merits*, cit., p. 287.

⁷⁷⁰ Cf. ROUSSEVA, *Abuse of Dominant Position Defences. Objective Justification and Article 82 EC in the Era of Modernization*, in *European Community law of competition*, 2008, p. 406.

basis of the magnitude of this impact, potentially also on R&D investments, thereby harming consumers in the long term.

In order to strike a balance between these two effects, the ECJ maintained that the protection of commercial interests could justify only a limitation of quantity supplied, but never a total refusal to supply⁷⁷¹. The Court clearly said that there is no way to escape from the application of competition law when a company puts in place conducts aimed at avoiding all parallel exports⁷⁷². In other words, the EU Treaty cannot be interpreted as to allow companies to drop markets in order to protect their commercial interests⁷⁷³.

On the contrary, following the principle of proportionality in evaluating the anticompetitiveness of a dominant company that refuses to supply wholesalers to defend itself from parallel trade, it appears that honouring only those requests that are not out of the ordinary constitutes a balanced way for dominant companies to respond to the threat that parallel trade may pose to their commercial interests. A supply quota, contrary to a total refusal to deliver goods, in fact, does not eliminate all competition but it leaves some room to it.

This suggests that the proportionality test should look at whether the response of a pharmaceutical company that refuses to supply wholesalers that engage in export activities is appropriate and proportionate to protect the company's profits, and, indirectly, its incentive to innovate.

One may argue against the criterion identified by the ECJ in *Syfait II* that the 'out of ordinary rule' is not an adequate tool to carry out an analysis of dominant companies conducts according to an effect-based approach, because it lacks the flexibility to account for the fact that innovation is not a one size-fits-all concept and that the same level of parallel trade may have a different impact on the R&D expenditures of two different pharmaceutical companies.

It seems, however, that this objection overlooks that fact that the reference to previous commercial relationships between manufacturer and distributor, in relation to the size of the domestic market, for single products, may give a good measure of the

⁷⁷¹ See para. 71 of the decision on *Syfait II*

⁷⁷² See para. 66 of the decision on *Syfait II*.

⁷⁷³ See para. 69 of the decision on *Syfait II*.

amount of parallel trade that the manufacturer believes to be sustainable for its R&D activity⁷⁷⁴.

In my view, the shortcoming lies somewhere else: being an application of the 'legitimate business conduct' doctrine, this criterion does not mandate the measurement of the efficiency gains to perform the balancing exercise, whose outcome should be decisive to permit (or prohibit) the conduct⁷⁷⁵. Therefore, the test elaborated by the ECJ in the *Syfait II* case is incomplete, as it does not allow for an exhaustive analysis of the effects of a supply quota on consumer welfare. In sum, it also seems inappropriate to match Article 102 TFUE's rationale.

4.3 The 'strict approach'

The two tests that have been analysed so far appear to be too lenient with respect to the objective of ascertaining the existence and the magnitude of efficiency gains accompanying an anticompetitive conduct of a dominant company.

An analogy with the proportionality test applied under Article 106(2) TFEU to the supply of universal services, thus, may help providing an interesting paradigm to craft a stricter approach⁷⁷⁶.

The jurisprudence on Article 106 TFUE experienced a development. At an earlier stage the jurisprudence affirmed that the grant of an exclusive right that restricts competition was not indispensable to ensure the existence of a universal service whenever the State could support the company entrusted with the provision of this service with subsidies. At a later stage, the European Courts held that the legitimacy of the exclusive right under Article 106 TFUE should be checked in light of a thought

⁷⁷⁴ This does not mean I am not aware of the fact that the 'out of ordinary' criterion poses several interpretative problems that render more difficult its practical application. For instance, when it comes to a new product or to a new customer of the producing company, there are no previous commercial relationships on which the ordinarity of the supply requested can be evaluated.

⁷⁷⁵ Cf. supra fn. 685 and accompanying text, where it is recalled that in the context of the *Microsoft* case before the GC, the latter indicated that there is no balance test within the legitimate business conduct.

⁷⁷⁶ Art. 106 TFEU disciplines state measures, like the granting of an exclusive right to private undertakings to carry out activities in the public interest, which may restrict competition. For a general comment on the provision see BUENDÍA SIERRA, *Article 86 – Exclusive Rights and Other Anti-competitive State Measures*, in FAULL and NIKPAY, *The EC Law of Competition*, cit., p. 593-646; ID., *Exclusive Rights and State Monopolies Under EC Law*, 1999. The provision applies, *inter alia*, to those exclusive rights conferred to private undertakings to provide universal services, i.e. services to which all citizens have the right to access. The right to every individual to have access to medicines and the corresponding duty of the State to provide them to protect public health clearly in this sense fall within the scope of the notion of 'universal service'. Note that the ECJ excluded patents and other IPRs from the notion of 'exclusive right'. See ECJ, 16 November 1977, in case C-13/77 *Inno v. ATAB*, para. 41.

experiment that looks at whether the elimination of such right would render the provision of the service more difficult.

In *Corbeau*, the ECJ for the first time held that the grant of an exclusive right to an undertaking does not contrary to Article 106 TFUE if this is necessary to offer a universal service that is rendered under acceptable economic conditions⁷⁷⁷.

The Court followed this reasoning: in many cases where a universal service is at stake, the State requires the entrusted company to set a uniform tariff for the whole territory, no matter the ability to pay of consumers in the different areas composing it. In this situation, the more densely populated areas paying also for the (fixed) cost of serving those areas where few people live and the price they pay does not cover the cost of guarantee the service there. If competition is introduced, competitors would enter the densely populated area where prices are higher than costs and undercut the undertaking, which would be left with the unprofitable area. This is known as '*écrémage*', or 'cherry picking'.

Pharmaceutical companies charge (in this case, different!) prices to consumers in different geographic areas, depending on their ability to pay. Wealthier consumers pay medicines a much higher price than the cost of producing them, because they are somewhat called to 'subsidize' the R&D activity, which poorer consumers cannot pay for. The introduction of parallel trade in this setting may have the same effect of the *écrémage*: traders would enter the more profitable market and undercut the company there. Exporters could even gain the whole market share for a given portfolio of products in the importing country and consequently endanger the profits of a pharmaceutical company, together with its investment in R&D.

Under these conditions, it appears reasonable to assume that the company cannot run its activity in a situation of economic equilibrium that allows it to offset those unprofitable markets with profitable ones and to cover its R&D costs any longer. Therefore, a conduct restrictive of parallel trade would be justified.

It should be noted, however, that for parallel trade to be capable of endangering the economic equilibrium of a pharmaceutical company, the volume of exported products should be unlimited. This would require two conditions: (i) wholesalers should

⁷⁷⁷ See ECJ, 19 May 1993, in case C-320/91 *Criminal proceedings against Paul Corbeau*, para. 15-18.

be entitled to receive all quantities they have ordered, i.e. they should have an unlimited right to be supplied; (ii) no public service obligations should oblige them to serve the domestic market first⁷⁷⁸.

However, none of these conditions appear realistic. The first one cannot be supported, because it would call for the imposition on undertakings of a permanent duty to supply their rivals, which – as already recalled – is not recognized in any legal system. The second assumes a violation of the provision of the Human Use Directive.

Also, such a crafting of the proportionality test may indeed be too strict or just miss the innovation issue behind the efficiency claims. R&D investments are very much likely to be endangered when the volume of parallel trade is unlimited. Nevertheless, even under a more limited but substantial amount of parallel trade, traders may achieve very high percentages of market penetration for a large range of products in the importing country. This may represent a considerable threat for pharmaceutical companies' profits that may urge them to downsize their investment in R&D.

Stated differently, profit losses may force the firm to drop one or more investment projects, determining the erosion of the optimal amount of resources devoted to R&D that allows the firm to be competitive in the market, without that the firm is driven out of the market.

Such efficiency losses represent harm for consumers and competition law should prevent them. That is why it appears that the proportionality test should be shaped differently, in order to capture the mentioned inefficiencies.

4.4 The 'efficiency defence'

The considerations previously expressed about the need to prove efficiency gains in the same way that foreclosure is demonstrated implicitly suggests that the inquiry on efficiencies under Article 102 TFEU should be the mirror image of the '*bilan économique*' under Article 101(3) TFEU⁷⁷⁹.

⁷⁷⁸ These assumptions are fictitious, given that they do not comply with European law. As with regards to the public service obligation, I have already explained in Chapter III that the Human Use Directive provides for this obligation both on manufacturers and wholesalers, thereby obliging them to serve the domestic market first. Although this provision is mirrored everywhere in European countries, most of them have it. With regards to refusal to supply practices and the right of wholesalers to be given all the goods they have ordered I will show *infra* that this right does not have citizenship within European competition law.

⁷⁷⁹ Note that this interpretation implicitly requires that it is up defendant companies to prove the existence of efficiencies. However, this issue is going to be dealt with in the next Chapter.

This is precisely the approach of the *Guidance on Art. 82 EC*, where the Commission established that for the ‘efficiency defence’ to be admitted it must demonstrated that the following conditions are fulfilled: (i) that efficiencies are realised or likely to be realised as a result of the conduct concerned; (ii) that the conduct concerned is indispensable to realise these efficiencies; (iii) that the efficiencies benefit consumers; (iv) that competition in respect of a substantial part of the products concerned is not eliminated⁷⁸⁰.

This choice has an important policy implication: it guarantess a uniform enforcement of both Articles 101 and 102 TFEU required by the EU jurisprudence⁷⁸¹, and it creates consistency with merger analysis.

With regards to Article 101 TFEU, as I already recalled, the jurisprudence requires that profitability and innovation must be proven and must concretely contribute to consumer welfare, in order to take them into consideration in the balancing exercise between the anticompetitive and the procompetitive effects of a corporate conduct.

With regards to merger analysis, under EU competition law, when the merger both causes a reduction in allocative efficiency and produces pro-competitive benefits, only if the latter outweigh the former, the merger is permitted by the Commission⁷⁸². Efficiencies must be merger-specific and likely to be passed on to consumers, in order to be considered in the competitive analysis of the merger⁷⁸³.

⁷⁸⁰ Cf. the opinion of the AG Colomer in the *Syfait II* case at para. 70 and 118.

⁷⁸¹ See ECJ, 21 March 1972, in case C-6/72 *Continental Can v. Commission*, para. 25, where the Court affirmed that the provision pursue the same objective, albeit at a different level. Cf. on this TEMPLE LANG and O'DONOGHUE, in *The Concept of an Exclusionary Abuse under Article 82 EC*, in *GCLC Research Papers on Article 82 EC*, cit., who observe that, given that the purpose of Articles 101 and 102 TFEU should be consistent then, as Article 101(3) TFEU incorporates an analysis of consumer interests, so too should Article 82, even in the absence of an express exemption clause.

⁷⁸² See Recital 29 of the Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (hereinafter the ‘EC Merger Regulation’), where it affirmed that “in order to determine the impact of a concentration on competition in the common market, it is appropriate to take account of any substantiated and likely efficiencies put forward by the undertakings concerned. It is possible that the efficiencies brought about by the concentration counteract the effects on competition, and in particular the potential harm to consumers, that it might otherwise have and that, as a consequence, the concentration would not significantly impede effective competition, in the common market or in a substantial part of it, in particular as a result of the creation or strengthening of a dominant position. The Commission should publish guidance on the conditions under which it may take efficiencies into account in the assessment of a concentration.”

⁷⁸³ See US Guidelines state that merging firms ‘must substantiate efficiency claims so that the Agency can verify by reasonable means the likelihood of magnitude of each asserted efficiency, how and when each would be achieved, how each would enhance the merged firm’s ability and incentive to compete, and why each would be merger-specific’. This policy orientation is usually referred to as an effect-based analysis. This approach for merger controls resulted in the switch from a dominance test to a significant-restriction-of-competition test in EC Regulation

Similarly, also under Article 102 TFEU, efficiencies must be properly substantiated and balanced with the foreclosure effect, in order to enter the anticompetitive assessment.

The case law underpins this view. Both in *British Airways*⁷⁸⁴ and *Michelin II*⁷⁸⁵, the GC affirmed that if the efficiency justifications put forward by defendants would have been based on countervailing advantages that outweighed the foreclosure caused by their conducts, their argument would have likely to be accepted.

In light of the above, the choice of the Commission appears to be the most appropriate.

The following proportionality test⁷⁸⁶ should thus be applied when abusive dominant conducts are analysed in their pro-competitive facets: firstly, efficiencies must be conduct-specific, i.e. there must be a link between the latter and the gains, and the conduct must be indispensable to achieve them; secondly, they must outweigh the anticompetitive effects⁷⁸⁷.

Whilst this test appears to be the only one that complies with both economic theory and the *acquis communautaire*, it is also affected by a weakness.

This test overall is quite demanding, because it includes a suitability test, a necessity test, a test of proportionality *strictu sensu*, and a 'multi-variable' proportionality test, because the anticompetitive effects have to be balanced with the pro-competitive effects⁷⁸⁸. Not surprisingly, thus, this test may rarely be found to apply.

The whole case law on Article 102 TFEU and, in particular, the opinion of AG Colomer in the *Syfait II* case confirms this prediction. The AG Colomer, in fact,

no. 139/2004. Also according to the Guidelines on the assessment of mergers, para. 86, efficiencies and the resulting benefits for consumers should be quantified.

⁷⁸⁴ See *British Airways*, para. 244 *et seq.*

⁷⁸⁵ See *Michelin II*, para. 74.

⁷⁸⁶ See DE BÜRCA, *The Principle of Proportionality and its Application in EC Law*, in YEL, 1993, p. 103-150, at 113; STEENBERGEN, *Proportionality in Competition Law and Policy*, in LIEL, 2008, no. 35(3), p. 259-268, at 265; TRIDIMAS, *Proportionality in Community law: Searching for the appropriate standard of scrutiny*, in ELLIS, *The principle of proportionality in the laws of Europe*, p. 84.

⁷⁸⁷ Cf. DOLMANS, *Efficiency Defences Under Article 82 EC Seeking Profits Or Proportionality? The EC 2004 Microsoft case in context of Trinko*, 24th Annual Antitrust and Trade Regulation Seminar, NERA, Santa Fe, New Mexico July 8, 2004, who suggested a four-stage analysis: (1) there should be an efficiency or another legitimate objective other than exclusion of competitors; (2) the conduct should be 'suitable', i.e. capable of achieving the legitimate goal; (3) the conduct should be 'necessary', in the sense that there is no alternative that is equally effective in achieving the legitimate goal; (4) the conduct should be "proportionate", in the sense that the legitimate objective pursued by the firm should not be outweighed by the exclusionary effect.

⁷⁸⁸ STEENBERGEN, *Proportionality in Competition Law and Policy*, cit., p. 266.

dismissed the defendant's claim because the latter did not succeed in demonstrating the existence of a causal link between parallel trade and GSK's reduced incentive to invest in R&D, or the diminished value of GSK's patents caused by parallel trade⁷⁸⁹. On the contrary, AG Colomer felt that GSK's claim only showed the company's expectation of being in a position to recoup lost profit, without actually proving that such extra-profit would have spurred innovation and promoted efficiency to the benefit of consumers⁷⁹⁰.

Also, with regard to the necessity test, AG Colomer observed that European law provides different policy instruments aimed at spurring innovation and revitalize the European pharmaceutical sector such as the tax credit, the block exemption for technology transfer agreements and of R&D agreements⁷⁹¹. For this reason, he considered GSK's conduct as disproportionate to the threat posed by parallel trade and inappropriate to pursue the object of protecting the competitiveness of the company⁷⁹².

This outcome is likely to be replicated whenever efficiencies are at stake in abusive conducts cases, because not only the assessment is more complex, but also it also takes a perspective that clashes with the traditional approach generally taken by antitrust agencies to conduct market analysis.

In fact, dynamic efficiencies are at odd with static efficiency considerations in competition enforcement. This is because they take place from different perspectives (*ex post* v. *ex ante*).

This creates an asymmetry: whilst the legal assessment of anticompetitive agreements and abusive conducts typically takes place from an historical standpoint, efficiencies require a prognosis. Thus, anticompetitive effects would be analysed from an *ex post* perspective, whereas efficiencies would be assessed from an *ex ante* point of view. This clearly creates disparity in the burden of proof that parties bear in relation to the existence of the facts they allege.

In particular, this discrepancy creates severe problems both for convicted undertakings and for antitrust authorities, or judges: the former may not be able to

⁷⁸⁹ See AG Colomer opinion at para. 109.

⁷⁹⁰ See AG Colomer opinion at para. 116-118.

⁷⁹¹ See the Reg. EC of the 29 November 2000 n. 2659, applying Article 101(3) TFEU to agreements on R&D. In particular see Recital 10 of the Regulation.

⁷⁹² See AG Colomer's opinion at para. 113-114.

provide a certain proof of the existence of efficiencies, and consequently the latter may not be in the position to evaluate such allegations and ascertain the alleged existence.

It follows that the test for efficiency should be structured in a more flexible way.

5. Conclusions

The Chapter analysed the claim put forward by pharmaceutical companies about the efficiency gains obtainable from restrictions to parallel trade of pharmaceuticals. Based on the positive correlation between the expected return from drug innovation and the level of investment in R&D, they argue that the strong enforcement of patents against parallel trade puts the right incentives to innovate on privates. The extra money recouped from the restriction to competition, in fact, would be invested in innovation to the benefit of consumers. From this it should follow that actions against it are justified under efficiency grounds and thus permitted.

This reasoning would underpin a minimalist vision of antitrust intervention, which should not interfere with the market when incentives to innovate are at stake.

However, under competition law this approach leads to give *carte blanche* to innovators and entails the paradoxical conclusion that any restriction to competition that allows the diversion of monetary resources from non-innovative subjects to innovative ones should be considered legal.

Also, a deeper analysis of economic theory shows that evidence is largely inconclusive about the relationship between parallel trade, profitability and R&D incentives: traditionally it was believed that this was a negative one; however, recent economic investigation suggested opposite findings under certain conditions.

In addition, even assuming that parallel trade has a negative impact on profits, the magnitude of such impact is unknown at a general level. It depends on the innovation skills of the firm, on where it stands in the innovation production function, on the type of product and on the characteristics of the market for that product.

This uncertainty appears stronger when applied to the pharmaceutical sector, given that the inquiry involves an analysis of future outcomes that leads to an antitrust scrutiny based on an empirical investigation.

From this it follows that it is not possible to rely on the presumption that the extra money earned through the elimination of competition will generate a higher level of innovation. On the contrary, a case-by-case analysis is necessary to ascertain the existence and the magnitude of efficiencies.

These considerations have important implications in the process of modernisation of Article 102 TFEU, as they provide an answer to the question of how efficiency gains should enter the antitrust analysis of potentially anticompetitive unilateral conducts.

For the purpose of answering this question, four options are analysed.

The arguments put forward by the pharmaceutical companies resemble very much the application of the Section 2 of the Sherman Act, where efficiencies are included in the concept of ‘competition in the merit’. According to this approach, defendants may just put forward a justification to their conduct based on efficiency, without the concrete proof of the existence and magnitude of such gains, in order to escape the application of competition rules.

However, this method contrasts the fundamental principles of European competition law, which requires that efficiencies contribute to the improvement of consumer welfare. This, in turn, calls for a test that looks into the link between the abusive conduct and the procompetitive effects and allows a balancing between the latter and the anticompetitive effects.

In view of these considerations, both the ‘out of ordinary criterion’ elaborated by the ECJ in the *Syfait II* case, and the strict approach provided by the case law on Article 106 TFUE on universal service, do not appear appropriate either. The first one provides a good rule of thumb that account for innovation considerations, but does not allow for any concrete inquiry into the materialisation of efficiencies. It is, thus, too lenient. The second one is, in the contrary, too strict, as it requires the jeopardization of the economic equilibrium of the company, in order for a corporate conduct to be justified.

Therefore, it appears that the choice of envisaging a *bilan économique* of the sort of Article 101(3) within the provision prohibiting the abuse of dominant position is preferable. The existence of a link between their conduct and the efficiencies should be

proven; the former should be indispensable to achieve the latter; and such gains should outweigh the detriment caused by foreclosure.

This choice, however, leaves us with two open questions.

The first one relates to who bears the burden of such proof, although the preference for an analysis similar to the one performed under Article 101 TFUE necessarily leads to one answer only: the defendant.

The second one relates to the practical feasibility of this case-by-case approach. Interpreting the provision that prohibits the abuse of dominant positions in light of the *rule of reason* certainly looks more appropriate both from a legal and economic standpoint, because it is in line with the effect-based rationale of the provision. However, the uncertainty linked to a full-blown market analysis can severely increase the administrative costs of the rule.

Such costs appear enormous when efficiency considerations are involved, as they require a prognosis that may not perfectly fit the legal analysis as traditionally structured.

It follows that it is necessary to determine a standard of proof that capitalizes on economic teaching and is workable at the same time. A proposal at this regard will be put forward and examined in the next Chapter.

CHAPTER V

The welfare effects of parallel trade: a workable rule of reason

Introduction

Rules can be of two types: *per se* rules and *rule of reason*⁷⁹³. The former embody a presumption of lawfulness or unlawfulness⁷⁹⁴ of certain corporate conducts that does not admit rebuttal and is not accompanied by market analysis. The latter, instead, consists of a full-blown analysis and admits the prohibition of business practices only if their negative effects in the market are demonstrated⁷⁹⁵.

The choice between the two should solve a tripartite trade off. Legal rules should provide clear principles to facilitate compliance and enforcement, prevent the retroactive imposition of liability and minimize error costs. Errors can be of three types: type I errors, which identify the problem of over-inclusiveness of the legal rules; type II errors, which concern the opposite problem, the under-inclusiveness of the legal rules; and type III errors, which look into the administrative costs of a rule, including the costs of diminished legal certainty⁷⁹⁶.

⁷⁹³ For an articulated analysis of *per se* rules and the rule of reason, see BLACK, *Per se Rules and Rules of Reason: What are They?*, in ECLR, 1997, no. 3, p. 145 *et seq.*, where it demonstrates that there is not a single rule of reason, nor one *per se* rule, but there are several rules of reason and numerous *per se* rules.

⁷⁹⁴ With reference to US competition law, *per se* rules originally pertain to ‘unreasonableness of the restraint of trade’.

⁷⁹⁵ The dichotomy *per se* versus *rule of reason* taken from US competition law appears to be *à la mode* in the recent literature. However, it should be recalled that under EU competition law it might be more appropriate to talk of restrictions by object and by effect for bilateral agreements and of burden of proof of the objective justification of abusive conducts from dominant companies. Similarly see WHISH, *Competition Law*, cit., p. 112-113.

⁷⁹⁶ In 1928, two statisticians, Jerzy Neyman and Egon Pearson, discussed the problems associated with ‘deciding whether or not a particular sample may be judged as likely to have been randomly drawn from a

Neither of the mentioned rules is capable of optimally striking this trade off.

Per se rules increase legal certainty but are rigid and bring the risk of incurring in type I or type II errors.

For instance, *per se illegality* of anticompetitive corporate conducts may lead to prohibit overall efficient corporate practices (type I errors).

Per se legality, on the other hand, may entail the permission of overall anticompetitive business practices (type II errors).

A *rule of reason* minimizes both risks through a case-by-case analysis that serves the purpose of prohibiting only those business practices that harm consumers. Still, it requires a full-blown market analysis that may increase the administrative costs of its implementation (type III error).

In the choice of the policy to be adopted with respect to parallel trade, the design of competition law rules plays an important role.

The consideration of agreements impeding cross border exports as hardcore restrictions to competition that cannot be exempted, and the substantial application of the prohibition for companies in a dominant position to refuse to supply as a *per se* rule, have practically given full citizenship to a potentially unlimited parallel trade under European law.

It is claimed that this formalistic approach to the enforcement of competition law rules does not take into account the trade off that parallel trade may create.

On the one hand, a significant amount of parallel trade is capable of exerting pressure on prices of original products and of entailing short-term savings for consumers. On the other hand, it may have an impact on manufacturers' profits and potentially also on R&D investments. In this way, it may harm consumers in the long term.

certain population' and identified 'two sources of error': Type I error, also known as an 'error of the first kind', or a 'false positive', in statistics is the error of rejecting a null hypothesis when it is actually true. Plainly speaking, it occurs when we are observing a difference when in truth there is none. Type I error can be viewed as the error of excessive credulity. Type II error, also known as an 'error of the second kind', or a 'false negative', is the error of failing to reject a null hypothesis when it is in fact not true. In other words, this is the error of failing to observe a difference when in truth there is one. Type II error can be viewed as the error of excessive scepticism.

This makes clear that a *per se* prohibition of restrictions to parallel trade that does not take into account this trade off may risk prohibiting corporate practices that on the whole are efficient.

Similarly, *per se* legitimacy of restrictions to parallel trade based on efficiency grounds does not seem to be appropriate either, given that the stimulus to innovation provided by the increased resources devoted to R&D may be negligible, with respect to the anticompetitive effects entailed in the market.

That is why a *rule of reason* should be favoured to identify the circumstances where restrictions to parallel trade should be prohibited and those where they could be permitted.

The implementation of the rule of reason and its workability has been debated for long time among US scholars.

At the beginning of the 20th century, the *Standard Oil* case, first, and the *Chicago Board of Trade* case, later, established the 'rule of reason' as the legal standard pursuant which Section I of the Sherman Act should be enforced. Still, many US judges feared the 'sea of doubt' entailed by a test established by some Courts that required the consideration of any reasonable argument for a restraint, and rejected it as unsuitable for judicial decision-making.

The opacity of the boundaries of the rule of reason impeded lower Courts to fully apply the standard and urged them to replace it with a net of *per se* rules applying to all restraints having 'pernicious effect on competition and lack of redeeming value'. Between 1940 and 1970s, the scepticism for the rule of reason grew until the standard was defined '*an euphemism for an endless economic inquiry resulting in a defence verdict*'⁷⁹⁷. Theoretically judges were free to approve any restraint that looked reasonable. *De facto*, however, *per se* rules dominated for over three decades and almost eclipsed the rule of reason.

From the '70s, the Supreme Court backed away from the prevalence of *per se* rules and, starting with *Sylvania*, expanded again the scope of the rule of reason. This step-back was favoured by the progress of economic thinking over the functioning of markets and firms. As a result, *per se* rules and the rule of reason were considered

⁷⁹⁷ See BLECHER, *The Schwinn Case. An Example of a Genuine Commitment to Antitrust Law*, in *AJL*, 1975, no. 44, p. 550, at 553.

complementary categories of antitrust analysis designed to form a judgement about the competitive significance of a corporate conduct.

From then on, the rule of reason little by little expanded its coverage and became the default standard for decision making in antitrust cases. The recent *Leegin* case, where the Supreme Court re-examined the *per se* rule against resale price maintenance witnesses this expansion.

Its scope and application, however, still does not assume clear-cut contours. Some *per se* rules have been sometimes subjected to exceptions. At the same time, some Courts developed an 'abbreviated' rule of reason, or 'quick look', in order to avoid a full-blown market analysis. Such shortcut have been applied differently though: sometimes the defendant is required to establish a pro-competitive justification and if he succeeds the Court reverts to a full-blown market analysis; some other times the plaintiff must make some showing of actual anticompetitive effects, without a full-blown market analysis.

Also, whilst most judicial statements establish that in the application of the rule of reason Courts must balance pro-competitive and anti-competitive effects, prominent commentators admit that this standard is not practical and, as a matter of fact, Courts avoid it by shifting burdens of proof on parties (Hovenkamp, 1998).

For this reason, even after such long history of theoretical refinement and practical application, commentators feel that some unanswered issues still remain, especially with regards to how the burden of proof is shared between parties (as it appears from the issue no. 68 of the *Antitrust Law Journal* entirely devoted to this topic in 2000-2001).

Indeed, the analysis of the case law shows that the outcome of court cases is definitely a matter of proof. As it has been affirmed: "[...] *the outcome-determinative event is not the precise measurement itself but the judgement-call that determined where the ball was placed.*"⁷⁹⁸ The same goes with the examination of the effects of a business practice: the outcome of a case depends on the ability of parties to convince the judge.

It follows that the way the burden of proof is shared between parties and what is the standard of proof is crucial in this context.

⁷⁹⁸ See LEARY, *Efficiencies and Antitrust: A Story of Ongoing Evolution*, Address delivered at the ABA Antitrust Section 2002 Fall Forum in Washington D.C. (Nov. 8, 2002), reporting the words of Don Baker.

To my knowledge, very little has been said about how facts are proven and evidence presented before ECJ. The literature on the burden of proof is quite dated (Weber, 1967; Andre, 1967; Lasok, 1982; Brealey, 1985), and recently only Nazzini (2006) examined this issue in the context of the modernisation of European competition law.

The aim of this Chapter is to formulate a proposal about how parties may discharge their burden of proof in relation to their claims in parallel trade cases. This should help European Courts in applying an effect-based approach to business practices restrictive of parallel trade, in order to form learned judgments that avoid type I and type II errors, as well as a costly full-blown analysis.

Section 1 examines what is the scope for a full-blown welfare analysis under Articles 101 and 102 TFEU respectively. It reviews the old theoretical debate about the existence of a rule of reason under Article 101(1) TFEU through the analysis of the literature on the issue and of the related case law. A similar analysis is performed under Article 102 TFEU, especially in light of the recent debate about the modernization of this provision.

Section 2 implements a theoretical welfare analysis of the impact of parallel trade on consumers, by weighing anticompetitive against pro-competitive aspects in the scrutiny of restrictions to parallel trade under competition law rules. The main theoretical references used are the Williamsonian trade off analysis and the Kaplow test.

These methods of analysis are analysed in their practical feasibility, particularly in view of the prognostic analysis entailed by the integration of efficiency considerations into the antitrust analysis.

The acknowledged difficulty related to the balancing of anticompetitive effects and efficiencies provides ground to formulate in Section 3 a proposal about how these difficulties can be overcome. The answer to the question is found in the instruments of the law of evidence: the Section analyses how the burden of proof can be allocated between parties, in order to help judges perform the balancing between the anticompetitive and the pro-competitive effects of restrictions to parallel trade, and what is the standard of proof to be fulfilled in this discharging.

Section 4 concludes.

1. The rule of reason

The term ‘rule of reason’ was not developed in the area of EU competition law, but it was imported from US antitrust jurisprudence.

Already in the first years of application of the Section I of Sherman Act, US judges felt that applying literally the wording of the provision prohibiting ‘*every restraint on trade*’ would have not been appropriate, as all business practices have a restrictive effect on trade and other parties’ economic freedom⁷⁹⁹.

The first refinement of the rule came with the judgment in *U.S. v. Addyston Pipe & Steel Co.*, where Justice Taft stated that restrictive clauses that are ancillary to a lawful agreement should not be prohibited⁸⁰⁰.

In *Standard Oil Co. of New Jersey v. U.S.*, the US Supreme Court asserted that the Section I of the Sherman Act does not prohibit *tout court* any agreement restrictive of trade but only those that entail *unreasonable* restraints of competition. What still remained unclear was what ‘unreasonable’ meant, though.

In *Chicago Board of Trade*, the Court clarified that a restraint of trade was unreasonable when capable of producing monopolistic effects in the market, i.e. when it would yield higher prices and lower output⁸⁰¹.

Accordingly, an economic analysis was necessary to understand the possible effects of an agreement in the market. Only when such agreement was found to be overall anti-competitive it would fall within the scope of the provision. Otherwise, it would have not been caught by the prohibition⁸⁰².

This way of applying Section I of the Sherman act was termed the ‘rule of reason’.

⁷⁹⁹ The most eloquent objection to a strict application of Section I of the Sherman Act came with the well-known statement from Justice Brandeis in the case *Board of Trade of the City of Chicago v. United States*, 1918, 246 U.S. para. 231, at para. 238: “[E]very agreement concerning trade, every regulation of trade, restraints. To bind, to restrain, is of their essence”. Compare Bork’s point that an agreement to eliminate competition is basic to almost every productive unit consisting of more than one person: BORK, *The Rule of Reason and the Per Se Concept: Price Fixing and Market Division*, in *Yale Law Journal*, 1966, II, no. 75, p. 377.

⁸⁰⁰ *U.S. v. Addyston Pipe & Steel Co.*, 1898, 85 F. 271.

⁸⁰¹ See *Chicago Board of Trade*, cit., where Justice Brandeis stated that “the true test of legality is whether the restraint imposed is such that as merely regulates and perhaps thereby promotes competition or whether is such that it may suppress or even destroy competition”.

⁸⁰² See *National Society of Professional Engineers v U.S.*, 1978, 435 US 679, 691-2, where the Court said that “[T]he inquiry mandated by the Rule of reason is whether the challenged agreement is one that promotes competition or one that suppresses competition... [T]he purpose of the analysis is to form a judgement about the competitive significance of the restraint”.

This approach showed immediately its virtues and its drawbacks, though. While it crafted a very flexible application of the provision that allowed to perform an assessment that took into account the reality of markets, it also required an ‘*incredibly complicated and prolonged economic investigation into the entire history of the industry involved*’⁸⁰³.

In order to lighten the excess of work, the Supreme Court developed a series of *per se* rules. The latter establish that certain business practices, like price fixing or market sharing, are presumed to be restrictive of trade and, for this reason, are automatically prohibited, without that further economic analysis is needed. It may well be that also those practices have positive effects on competition, but economic theory is generally unanimous in affirming that the chances that this happens are so limited that concerns on judicial economy and certainty of law justify a strict approach.

Accordingly, US Courts make a distinction between hardcore restrictions and all other restrictions. The former are presumed *iuris et de iure* to harm competition, and rebuttal is not admitted.

But also these rules were subject to refinement, because practice showed that the risk of catching pro-competitive agreement within the scope of the prohibition was high.

In the past two decades, Courts restricted the scope of *per se* rules and expanded that of the rule of reason, as the improved understanding of economics of competition gave the possibility to Courts to better perform economic analysis in a wider range of cases⁸⁰⁴.

Following this trend, in *Continental TV Inc v. GTE Sylvania* the Supreme Court reversed its previous orientation towards the *per se* prohibition of non-price vertical restraints and called for a case-by-case evaluation of all the circumstances that may determine the likely effect of these agreements in the market⁸⁰⁵. On this view, only

⁸⁰³ See *Northern Pacific Railway Co. v. United States*, 1958, 356 U.S. 1.

⁸⁰⁴ WHISH and SUFRIN, *Article 85 and the Rule of Reason*, cit., pp. 7 and 9 affirms that the influence of the Chicago School has spurred a drift away from the *per se* illegality, while the rule of reason is playing a larger role.

⁸⁰⁵ See *Continental TV Inc v. GTE Sylvania*, 1977, 433 US 36, where the Court accepted that a location clause in a distribution agreement should no longer be subjected to a *per se* rule, but rather should be analysed under the rule of reason. See also *Broadcast Music v. CSB*, 1979, 441 U.S. 1, 99, S. Ct. 1551, where the Court said that one has first to look into efficiency rationales before condemning an agreement as *per se* illegal. Among the economists who spurred this view, see TELSER, *Why Should Manufacturers Want Fair Trade?*, in *Journal of Law and Economy*, 1960, no. 3, p. 86. Among the legal scholars see AREEDA and TURNER, *Antitrust Law*, 2003, Vol.

agreements that have a “*pernicious effect on competition and lack [...] any redeeming virtue*” are caught by the prohibition⁸⁰⁶.

The distinction between *per* rules and rule of reason was further elaborated in *Polygram (The Three Tenors)*⁸⁰⁷, where the Court distinguished between agreements that appear harmful, and therefore are ‘inherently suspect’, and those that are not obviously harmful. In order to assess the effect of the latter in the market, according to the Court it is necessary to conduct a full market analysis to see whether there are anti-competitive effects resulting from the agreement and whether these are outweighed by pro-competitive effects.

As of the ‘70s, the rule of reason little by little expanded its coverage and became the default standard for decision making in antitrust cases, as the recent decision in *Leegin*, where the Supreme Court re-examined the *per se* rule against resale price maintenance, shows⁸⁰⁸.

The appealing of the effect-based approach captured the attention of EU competition law scholars, who, as of the ‘80s, engaged in an intense debate about the application of the rule of reason to the assessment under Articles 101 and 102 TFEU.

1.1 Is there a ‘European rule of reason’?

In Europe, the term ‘rule of reason’ has been somewhat confusingly used to indicate both the netting of positive and negative effects deriving from a business practice, as applied by the described US jurisprudence, and the consideration of non-competition objectives in the antitrust assessment.

Typically, the latter are generally identified with integration and completion of the internal market, economic and social cohesion, regional development and environmental protection.

These policy objectives generally play an important role under EU law and often enter the legal assessment of alleged anti-competitive practices or agreements. As a

VII, ch. 15; HOVENKAMP, *Federal Antitrust Policy: the Law of Competition and its Practice*, 2000, paras. 6.4, 11.1, 11.2 and 11.6, supporting the approach of the Court.

⁸⁰⁶ See *Northern pacific Railway v. US*, 1958, 356 US 1, 5.

⁸⁰⁷ See *In the Matter of Polygram Holding Inc. v. FTC*, 2005, 426 F. 3d 29.

⁸⁰⁸ See, for instance, the recent case *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, decided in 2007, where the U.S. Supreme Court overruled its 1911 precedent declaring vertical minimum resale price maintenance to be *per se* illegal. The Court held that the practice should instead be examined on a case-by-case basis under the rule of reason.

result, the freedom of movement principle and, more recently also competition law rules, are usually enforced so that appropriate room is left to national policies that deserve particular protection under the ‘philosophy’ of the EU⁸⁰⁹.

This ‘balancing’ may sometimes reduce the scope of antitrust enforcement actions.

For instance, in the field of free movement of goods, starting with *Dassonville* and *Cassis de Dijon*, the ECJ established that certain national measures aimed at protecting national public policy are shielded from the application of the rules of the internal market. This principle has been recently applied to competition law rules in *Wouters*⁸¹⁰, where the consideration of policy objectives other than the welfare of consumers led the Court to favour a more limited application of competition law, with the purpose of accommodating other policy concerns.

In other cases, the consideration of these additional goals may expand the scope of competition law rules beyond the traditional purpose of protecting the competitive process and promoting allocative and productive efficiency⁸¹¹. The achievement of the internal market is, for instance, the reason why distribution agreements that entail absolute territorial protection are prohibited no matter if there are pro-competitive effects⁸¹².

⁸⁰⁹ See MONTI, *Article 81 and Public Policy*, cit., p. 1057, for an analysis of how public policy considerations could play a role under Art. 101(3) TFEU.

⁸¹⁰ See ECJ, 19 February 2002, in case C-309/99 *JCJ Wouters, JW Savelbergh and Price Waterhouse Belastingadviseurs BV v. Algemene van de Nederlandse Orde van Advocaten*, where the ECJ held that the Dutch regulation of the Bar Council of the Netherlands prohibiting lawyers from entering into partnerships with accountants did not infringe Art. 101(1) TFEU. In doing so, it adopted a test whereby it balanced anti-competitive effects of collusive behaviour against both pro-competitive effects and non-economic/regulatory objectives. See NAZZINI, *Article 81 between time present and time past*, cit., p. 521 *et seq.*, where he supports the view that the Court applied a bi-dimensional test: it balanced the anti-competitive effects of the practice against both the pro-competitive effects and mandatory requirements of national public policy. He rejected both views that *Wouters* incorporates the *Cassis de Dijon* test, thereby rendering consistent the application of Articles 34 and 101 TFEU (as proposed by MONTI, *Article 81 and Public Policy*, cit., p. 1087), and that the Court carried out an assessment of the anticompetitive effects of the regulations in the legal and economic context (See MANZINI, *The European Rule of Reason Crossing the Sea of Doubt*, in *ECLR*, 2002, no. 23(8), p. 396-7).

⁸¹¹ See WHISH and SUFRIN, *Article 85 and the Rule of Reason*, cit., p. 13, where he states that Treaty itself, through the backdrop of the former Articles 2 and 3(g) EC (now replaced in substance by Article 3 TEU and Article 3(1)(b) TFEU) against which competition rules have been developed, envisages an expansive role for competition rules and that there is potential for growth in several directions.

⁸¹² And in fact, WHISH and SUFRIN, *Article 85 and the Rule of Reason*, cit., p. 14, suggests that the integration function attributed to EU competition law justifies the centralized enforcement of competition rules, instead of leaving this task to single Member States.

It is widely acknowledged among legal scholars that the rule of reason, intended in the last mentioned sense, under EU competition law exists and it is a legal principle⁸¹³.

The question, however, remains whether there exists under European competition law the balancing between anti-competitive effects and pro-competitive effects of a business practice as it is applied by US jurisprudence.

1.1.1 The rule of reason under Article 101 TFEU: the old doctrinal debate

This issue has been highly debated among European scholars. In particular, the academic debate focused on Article 101 TFEU and the excessive formalistic application of this provision from the Commission.

Generally the conditions set forth by Article 101(1) TFEU are met when a) a restriction of competition exists, b) it is appreciable and c) affects trade between Member States. As already mentioned in Chapter III, before the beginning of the modernisation process of Article 101 TFEU, the Commission had considered a restraint to commercial freedom as a restraint to competition. This enlarged very much the scope of Article 101(1) TFEU and triggered the criticism of a large part of the legal scholars⁸¹⁴.

In particular, many scholars claimed that Article 101(1) TFEU should have been applied in a more flexible way and that a rule of reason should be foreseen within the first paragraph of the provision⁸¹⁵.

This triggered a long interpretative debate among scholars about the scope of the first paragraph of the provision under discussion. The choice was between a narrow and a broad scope: according to the former, only agreements that on net are anticompetitive should fall within the scope of Article 101(1) TFEU; according to the latter, the presence of anticompetitive effects, without the consideration of pro-competitive effects, is sufficient to catch the agreement under the mentioned provision.

The procedural pendant of a substantive interpretation of Article 101(1) TFEU as a narrow provision is that the Commission bears the burden of proving that, taken as a

⁸¹³ See SCHRAUWEN, *In Defence of Public Interest: The Rule of Reason*, in *The Rule of Reason*, cit., p. 1; GORMLEY, *The Genesis of the Rule of Reason in the Free Movement of Goods*, in *The Rule of Reason*, cit., p. 21.

⁸¹⁴ Cf. *supra* fn 593 in Chapter III.

⁸¹⁵ See JOLIET, *The Rule of Reason in Antitrust Law: American, German and Common Market Laws in Comparative Perspective*, 1966; KORAH, *The Rise and Fall of Provisional Validity*, cit., p. 320; SCHECHTER, *The rule of Reason in European Competition Law*, in *Legal Issues of Economics Integration*, 1982, p. 11; FORRESTER and NORALL, *The laicization of Community Law*, cit., p. 11; STEINDORF, *Article 85 and the Rule of Reason*, in *CMLR*, 1984, p. 621; KON, *Article 85, para. 3: a Case for application by National Courts*, in *CMLR*, 1982, p. 541.

whole, the agreement is anti-competitive. In other words, not only does it have to show that competition is restricted, but also that there are no pro-competitive effects arising from the agreement capable of justifying it.

In this case, the Commission's burden of proof is much harder, because it has to prove that no pro-competitive effects that outweigh the anticompetitive ones are produced by the agreement. Symmetrically, defendants do not bear any burden of proof in relation to the existence of efficiency gains, if not disproving what their counterpart put forward.

If, on the contrary, Article 101(1) TFEU is considered to be broad, i.e. to catch all agreements that have anticompetitive effects no matter the existence of efficiencies, it is easier for the antitrust authority to make the case and allege the anticompetitiveness of the practice. And once the Commission has affirmed the anticompetitiveness of the agreement, it is up to the defendant to prove that the agreement has pro-competitive effects that outweigh the negative effects. It follows that the procedural pendant of such interpretation of the provision is that defendants have the burden of proof of the existence of pro-competitive effects.

Supporting the existence of a rule of reason within Article 101(1) TFEU was obviously leading to opt for the allocation of the burden of proof of both anticompetitive and pro-competitive effects on the Commission.

Scholars endorsing this view adduced that this interpretation avoided the procedural paradox generated by the division of competences in the application of Article 101 TFEU. Whilst the first paragraph of the provision had (and has) a direct effect and could (and can) be enforced directly by national Courts, the Commission kept an exclusive role in applying the third paragraph. The result was that national Courts were subject to the obligation of applying Article 101(1) TFEU, but they were unable to apply Article 101(3) TFEU, because the Commission had the 'monopoly' over it⁸¹⁶. Therefore, companies were basically denied the possibility of exemptions domestically.

The procedural need of having a rule of reason within Article 101(1) TFEU ceased when the EC Regulation no. 1/2003 came into force. The Regulation, besides

⁸¹⁶ See the First Regulation Implementing Articles 81 and 82 of the Treaty, 1962, OJ Special Edition 204/62.

establishing that defendant have to prove the existence of efficiencies⁸¹⁷, also turned the centralised system based on *ex ante* authorisation of anticompetitive agreements into a decentralised system based on the legal exemption provided for by Article 101(3) TFEU. Thus the latter is now applicable also by national Courts⁸¹⁸.

But the view that Article 101(1) TFEU contains a rule of reason was backed also by substantive arguments. The ECJ in the case *Société Technique Minière* refused a formalistic application of the provision contained in Article 101(1) TFEU and affirmed that in the legal assessment of an agreement account of the economic and the legal context should be taken, by comparing the effects of the agreement on existing and potential competition with a situation in the absence of the agreement⁸¹⁹. More specifically, under the framework of a counterfactual analysis, parties' market power, and consequently the relevant market, the market structure, *interbrand* competition, and opportunities for the parties to launch a new product should be analysed.

The Commission has later on adopted this approach. In the *Guidelines on Art. 81(3) EC*, it indicated that the anticompetitiveness of an agreement arises from the damaging effects of the latter in terms of output, prices, innovation and the variety or quality of goods and services⁸²⁰.

This approach has some commonalities with the analysis under the Section I of the Sherman Act. However, there are several reasons that may cast doubts about the *tout court* application of the US rule of reason to Article 101(1) TFEU⁸²¹.

⁸¹⁷ See Article 2 of EC Reg. 1/2003 reads as following: "In any national or Community proceedings for the application of Articles 81 and 82 of the Treaty, the burden of proving an infringement of Article 81(1) or of Article 82 of the Treaty shall rest on the party or the authority alleging the infringement. The undertaking or association of undertakings claiming the benefit of Article 81(3) of the Treaty shall bear the burden of proving that the conditions of that paragraph are fulfilled".

⁸¹⁸ The rationale of this change rests on the need to reduce the administrative workload to which the Commission was subject and to share the burden of the application of competition rules among the Commission and the national authorities, in order to grant an effective enforcement. Also, it affirmed that, while a centralised system was needed in the first phase of the application of the system of competition rules, in order to ensure an adequate learning process and uniformity in the practice. See the White Paper on Modernisation of the Rules Implementing Articles 85 and 86 of the EC Treaty Commission Programme No. 99/027, 1999, OJ C 132/1, of the Commission (hereinafter the 'White Paper').

⁸¹⁹ See *Société Technique Minière*, para. 71.

⁸²⁰ See the Guidelines on Art. 81(3), para. 16 and 24.

⁸²¹ See WHISH, *Competition Law*, cit., p. 125, where he says that calling for reasonable judgements from EU Courts does not equal to implement the US rule of reason under EU competition law. In his opinion such claim is misplaced because the structure of Art. 101 TFEU and the additional goal of market integration, for instance, render EU law materially different in many respects from US law; see WILS, *Rule of Reason: une règle raisonnable en droit communautaire?*, in *Cahiers de Droit Européen*, 1990, p. 27, who affirms that "La règle de raison est une invitation aux tribunaux fédéraux américains d'utiliser leur méthodes traditionnelles de common law

First of all, Article 101 TFEU, differently from Section 1 of the Sherman Act, has a bifurcate structure⁸²².

The first paragraph contains a list of agreements, hardcore restrictions that are considered anticompetitive by object, which are automatically caught under Article 101(1) TFEU and declared void pursuant Article 101(2) TFEU. Such declaration of anticompetitiveness comes notwithstanding the existence of any effect in the market⁸²³.

For instance, the Commission is aware of the fact that the effect of vertical restraints on consumer welfare is ambiguous: in fact, it is not obvious that consumer surplus is diminished when *intra*brand competition is reduced through vertical restraints, because supra-competitive profits may be already dissipated by *inter*brand competition. Actually, the implementation of an exclusivity contract may help a new competitor penetrating the relevant market and thus increase *inter*brand competition⁸²⁴.

Still, a legal assessment of vertical restraints solely based on economic considerations does not bear market integration overtones. On the contrary, the Treaty imposes that whenever this principle is violated, agreements are immediately considered void. That is why these types of agreement may look similar to the

pour développer le droit en l'appliquant". This, together with the fact that European competition law - differently from US - does not have a unique objective, would pose a substantial obstacle in importing the rule of reason under EU law.

⁸²² See WHISH and SUFRIN, *Article 85 and the Rule of Reason*, cit., p. 1; similarly MANZINI, *The European Rule of Reason Crossing the Sea of Doubt*, cit., p. 392; GYSELEN, *The Substantive Test*, cit., p. 189, affirms that the dual structure of Article 101 TFEU provides two filters for the assessment of agreements.

⁸²³ By this expression it is not in any way meant that agreements whose object is anticompetitive are not analysed in their economic and legal context. The latter, on the contrary, serves the purpose of ascertaining the anticompetitiveness of the object. However, recall that anticompetitiveness by object embodies a presumption of anticompetitive effects that renders futile any concrete ascertainment of the effects of the agreement in the market.

⁸²⁴ This was the argument of the Chicago School to claim that vertical restraints should be considered *per se* legal. See BORK, *The Rule of Reason and the Per Se Concept*, cit., p. 375; COMANOR, *Vertical Territorial and Customer Restrictions: White Motor and its Aftermath*, *Harv. L. Rev.*, 1968, no. 81, p. 1419; ID., *Vertical Price Fixing, Vertical Market Restrictions, and the New Antitrust Policy*, *Harv. L. Rev.*, 1985, no. 98, p. 983, at 986-90. Other strand of the literature argued for presumptive illegality: see LOUIS, *Vertical Distributional Restraints Under Schwin and Sylvania: An Argument for the Continuing Use of a Partial Per Se Approach*, *Mich. L. Rev.*, 1976, no. 75, p. 275; POSNER, *The Rule of Reason and the Economic Approach: Reflections on the Sylvania Decision*, in *University of Chicago Law Review*, 1977, no. 45, p. 1; ID., *The Next Step in the Antitrust Treatment of Restricted Distribution: Per Se Legality*, in *University of Chicago Law Review*, 1981, no. 48, p. 6; PTOFSKY, *The Sylvania Case: Antitrust Analysis of Non-Price Vertical Restrictions*, in *Colum. L. Rev.*, 1978, no. 78, p. 1; ID., *In Defense of Discounters: The No-Frills Case for a Per Se Rule Against Vertical Price Fixing*, in *Geo. L.J.*, 1983, no. 71, p. 1487. A third strand proposed the presumptive legality of vertical restraints: see MEEHAN and LARNER, *A Proposed Rule of Reason for Vertical Restraints on Competition*, 26 *Antitrust Bulletin*, 1981, p. 185.

‘inherently suspect’ business practices that are prohibited *per se* under US antitrust law⁸²⁵.

However, there is an important difference between the EU and the US competition law: practices prohibited *per se* do not have the possibility to be exempted under the latter system. On the contrary, European Courts – as already said⁸²⁶ – expressly rejected the *per se* approach and established that any agreement that is anticompetitive can be exempted if it meets the criteria established in Article 101(3) TFEU⁸²⁷.

1.1.2 The rule of reason under Article 101 TFEU: the case law

But what differentiates the most the European provision from its American equivalent is the presence of the third paragraph itself. This was, in fact, the main objection of the ECJ in *Métropole Télévision* to the view that Article 101(1) TFEU incorporates a rule of reason⁸²⁸.

In that occasion the ECJ dispelled all doubts that emerged in the literature about the substantive interpretation of Article 101(1) TFEU⁸²⁹. The Court, confronted with the question of whether there exists a rule of reason under Article 101(1) TFEU, held that there is no such balancing under this provision⁸³⁰. Also, it affirmed that any pro-competitive effect and its balancing with the anticompetitive effect brought about by an agreement should be taken into account in the application of the third paragraph of the provision under examination, otherwise that provision would be useless.

⁸²⁵ See MANZINI, *The European Rule of Reason*, cit., p. 395, but see *contra* ROBERTSON, *What is a Restriction of Competition? The implications of the CFI's Judgement in O2 Germany and the Rule of Reason*, in ECLR, 2007, no. 4, p. 261, who says that the fact that these types of agreements are immediately caught under the provision does not derive from the wording but rather from their nature. In this sense he sees a parallelism with the *per se* rules under US antitrust law.

⁸²⁶ Cf. fn 632 *supra*.

⁸²⁷ It should be noted that this difference may be sometimes more theoretical than practical. The overview of the Commission practice has shown, in fact, that hardcore restrictions are unlikely to pass the individual exemption because they lack the indispensability criterion and they do not fall within the block exemption. See the Guidelines on Art. 81(3) EC, para. 46.

⁸²⁸ See *Métropole Télévision*, para. 73 *et seq.*

⁸²⁹ However, ROBERTSON, *What is a Restriction of Competition?*, cit., p. 257, affirms that from some sentences of the decision it appears that the Court is pre-supposing the net effect of the agreement without balancing.

⁸³⁰ See *Métropole*, para. 72 *et seq.*, at para. 74-76. The defendants had argued that the EU Commission should have applied the rule of reason, according to which an anti-competitive practice falls outside the Article 101(1) TFEU if it has more positive effects than negative effects on competition on a given market (See para. 68 of the GC ruling). Such approach has been confirmed in *O2 Germany*, where the Court at para. 69 said taking into account the competitive situation existing in the absence of the agreement “*did not amount to carrying out an assessment of pro-competitive and anti-competitive effects of the agreement and this applying a rule of reason, which the Community judicature has not deemed to have its place under Article 81(1) EC*”.

The ECJ clarified that *Société Technique Minière* did not intend to incorporate a rule of reason in EU competition law, and it explicitly said that calling ‘rule of reason’ that trend in the case law that affirmed that not each and every agreement restricting the freedom of action of one or more parties is necessarily caught by the prohibition under Article 101(1) TFEU, is a mistake. The consideration of the economic context is functional to understand what are the negative and the positive effects entailed by a business practice to competition. But it is not the balancing exercise itself.

In *Metro*⁸³¹, the Court affirmed that qualitative conditions of selective distribution networks might in some cases fall outside the scope of the provision. Such conclusion was driven by the fact that the structure of the market did not preclude the existence of various channels of distribution capable of satisfying consumers’ needs, despite the absence of price competition among distributors. In other words, price rigidity (absence of intra-brand competition) was balanced against high quality and technology products and adequate distribution system (promotion of inter-brand competition)⁸³². However, the language of the judgement does not allow drawing a clear distinction of where such balancing was taking place⁸³³. It follows that, while a balancing of anti-competitive and pro-competitive facets of an agreement is possible, the question is rather *where* it takes place⁸³⁴.

In *Pronuptia*, the Court said explicitly that the effect on competition deriving from a franchise agreement has to be based on the economic context where the latter takes place and made a list of ancillary restraints that do not violate Article 101(1) TFEU because of their objective necessity with respect to the attainment of a lawful agreement. The Court considered that market sharing may be necessitated by the willingness to penetrate a new market. In that case, the agreement may qualify for the exception under the third paragraph of the provision⁸³⁵. Accordingly, it follows that this is where the balancing should take place.

⁸³¹ See ECJ, 25 October 1977, in case C-26/76 *Metro SB-Großmärkte v Commission*.

⁸³² However, the Court also evaluated the existence of a justification by weighing the price rigidity created by the selective distribution system against the other improvements, like the maintenance of standards of service. This is by definition an economic evaluation.

⁸³³ See para. 20-22 of the *Metro* ruling.

⁸³⁴ Cf. HILDEBRAND, *The Role of Economic Analysis in the EC Competition Rules*, 2002, p. 218; ID., *Economic Analyses of Vertical Agreements: a Self-Assessment*, 2005, p. 220.

⁸³⁵ See *Pronuptia*, para. 24.

In *Nungesser*⁸³⁶, the Court held that an exclusive licence of maize seeds to plant breeders in the form of an open licence, whereby the owner merely undertakes not to grant other licences in the same territory and not compete himself there, does not violate Article 101(1) TFEU. In fact, such licences do not affect third parties' rights, such as parallel traders or licensees for other territories. In addition, the Court considered that the protection of plant breeders' rights was important in view of the nature of the product, whose development requires substantial investments, and in view of the dissemination of new technology and of the promotion of competition in the EU through new products. Therefore, it appears that this judgement contains a hint of a partial rule of reason within the first paragraph of the provision⁸³⁷.

The same goes for the *Gøttrup-Klim* case⁸³⁸: in the analysis under the first paragraph of the provision under examination the Court explicitly weighed beneficial effects against the adverse effects on competition of a provision in the statute of a cooperative purchasing association prohibiting members from joining other association in direct competition with it⁸³⁹.

In *Delimitis* the Court was confronted again with an exclusivity agreement that, however, had an impact only on *interbrand* competition. *Intrabrand* competition was not an issue there. On the contrary, what was discussed was the possible foreclosure effect towards potential entrants of a beer supply contract between a brewer and a publican whereby the latter agreed to buy a minimum quantity of beer and soft drinks from the brewer or a company nominated by it.

In that case, the ECJ established a two-parts test: first the assessment focuses on the relevant market where undertakings operate, in order to ascertain whether entry is difficult or not, and then it is checked to which extent the agreement contributes to render entry difficult⁸⁴⁰. If the latter is significant, the agreement is caught by the

⁸³⁶ See ECJ, 8 June 1982, in case C-258/78 *Nungesser v Commission*, para. 54-58, where the Court said that a total prohibition of an open exclusive licence was contrary to the interest of the Community, because this would hamper the dissemination of new technology; but the Court also reaffirmed the prohibition of exclusive licences that confer absolute territorial protection against parallel imports, because they partition the common market.

⁸³⁷ See *Nungesser*, para. 56-57.

⁸³⁸ See ECJ, 5 December 1994, in case C-250/92 *Gøttrup-Klim e.a. Grovvarforeninger v Dansk Landbrugs Grovvarsekskab AmbA*.

⁸³⁹ See *Gøttrup-Klim*, para. 34 and 35.

⁸⁴⁰ See *Delimitis*, para. 27.

prohibition. The Court applied a kind of rule of reason that led to analyse the relevant market, parties' market position, the number and the size of producers, the degree of saturation, customer fidelity, and consumption trends⁸⁴¹.

The test has been further refined in *Mars/Langnese* and it became a tripartite test: the Commission checks whether the agreement has an appreciable negative effect on competition or trade between Member States, whether other agreements entered by the undertaking have this effect, and whether other agreements existing in the relevant market have this effect. If one of the questions is answered in the affirmative, then the agreement falls within the scope of Article 101(1) TFEU. In the specific case the agreement was an exclusive purchase obligation and was found to have an indirect effect on competition between suppliers of goods throughout the relevant market, because it made more difficult to set up an independent distribution system for new entrants that wanted to access the market⁸⁴².

In the *O2 Germany* case the GC reaffirmed the approach of *Métropole* and said that pro-competitive and anti-competitive effects are not to be balanced under Article 101(1) TFEU. Nevertheless, the Court *de facto* conducted a balancing, because it performed an analysis of the conditions of actual and potential competition in the absence of the agreement⁸⁴³.

1.1.3 Recent contributions to the academic debate

In the interpretation of the jurisprudential strand initiated by *Société Technique Minière* scholars are still divided. Prominent commentators did not see in that case law a

⁸⁴¹ See *Delimitis*, para. 15-26.

⁸⁴² See para. 72 of the *Mars/Langnese* judgement.

⁸⁴³ See para. 78-79 of the *O2 Germany* ruling: "[...] it was unlikely that O2 would have been able, individually, without the agreement, to ensure from the outset better coverage, quality and transmission rates for 3G services, to roll out a network and launch 3G services rapidly, to penetrate the relevant wholesale and retail markets and therefore be an effective competitor [...] Such considerations, which imply some uncertainty concerning the competitive situation and, in particular, as regards O2's position in the absence of the agreement, show that the presence of O2 on the 3G communications market could not be taken for granted, as the Commission had assumed, and that an examination in this respect was necessary not only for the purposes of granting an exemption but, prior to that, for the purposes of the economic analysis of the effects of the agreement on the competitive situation determining the applicability of Article 81 EC". In the view of MARQUIS, *O2 (Germany) v Commission and the Exotic Mysteries of Article 81(1) EC*, in *E.L. Rev.*, 2007, no. 2, p. 29-47, this is equal to weigh positive and negative effects on competition, i.e. to apply a rule of reason.

rule of reason in a US sense⁸⁴⁴; others saw an application of the rule of reason limited to the concept of ‘ancillary restraints’⁸⁴⁵; others saw the hint of a balancing exercise⁸⁴⁶.

From the above-described case law, it appears that European Courts sometimes have been applying some balancing in the context of the first paragraph of Article 101(1) TFEU. However, to equate this analysis to the US-style rule of reason appears excessive. The term indicates a much broader analysis under US law: it comprised the identification of the relevant market, the assessment of entry barriers, of buyer power and of general market circumstances, etc. and it involves a multitude of factors used to analyse whether a restraint adversely affects competition in the *interbrand* market and the justifications establishing a legitimate objective and the necessity of the restraint to achieve that objective. In Europe, the assessment done by European Courts so far involved the identification of the relevant product market, but, for instance, the assessment of market power needs more refinement. The analysis of *interbrand* competition, of justifications establishing a legitimate objective and the necessity of restraints can be found in some judgments only⁸⁴⁷.

This does not mean that there is no balancing under Article 101(1) TFEU.

The Court in *Métropole* said that not *all* the economic analysis should take place under the first paragraph of the provision. This still leaves us with the question of whether there is *some* economic analysis to be performed there⁸⁴⁸.

Some legal scholars put forward the hypothesis that certain types of efficiencies are relevant under Article 101(1) TFEU and others are considered under Article 101(3) TFEU⁸⁴⁹. But which ones?

⁸⁴⁴ WHISH and SUFRIN, *Article 85 and the Rule of Reason*, cit., p. 28, affirm that those restrictions were permitted in application of the doctrine of objective necessity. As a confirmation, see the para. 26-28 of the *Metro* judgement: “Provided that the obligations undertaken in connection with such safeguards do not exceed the objective in view they do not in themselves constitute a restriction on competition but are the corollary of the principal obligation and contribute to its fulfilment. [...] Since such obligations concerning verification do not exceed what is necessary for the attainment of their objective and in so far as they are designed to ensure respect for the conditions of appointment regarding the criteria as to technical qualifications, they fall outside the scope of Article 85(1) whereas, in so far as they guarantee the fulfilment of more stringent obligations, they will fall within the terms of the prohibition contained in Article 85(1), unless they together with the principal obligation to which they are related are exempted where appropriate pursuant to Article 85(3).”

⁸⁴⁵ WILS, *Rule of Reason*, cit., p. 59, affirms that the case law on ancillary restraints can be seen as very limited application of the rule of reason.

⁸⁴⁶ NICOLAIDES, *The Balancing Myth*, cit., p. 123; NAZZINI, *Article 81 EC between Time Present and Time Past*, cit; ROBERTSON, *What is a Restriction of Competition?*, cit.; MARQUES, *O2 Germany v. Commission and the exotic mysteries of Article 81(1) EC*, in *E.L. Rev.* 2007, no. 32, p. 29.

⁸⁴⁷ See HILDEBRAND, *Economic Analyses of Vertical Agreements*, cit., p. 220.

⁸⁴⁸ ODUDU, *A New Economic Approach To Article 81(1)?*, in *European Law Review*, 2002, no. 27, p. 104.

As underlined in the literature, there are two categories of pro-competitive effects that may be considered⁸⁵⁰: welfare-enhancing effects, which impact on output and price, namely *interbrand* competition and market power, and agreement-specific efficiencies, like cost reduction and incentive to innovate⁸⁵¹.

The first category should be part of the analysis performed under the first paragraph of the provision under examination, in order to detect those elements in the agreement that are capable of influencing consumer welfare, both in a positive and in a negative way. The second category is represented by dynamic efficiencies and should be assessed under the third paragraph⁸⁵².

So, for instance, it has been suggested that the analysis under Article 101(1) TFEU aims at looking whether the agreement has the effect of bringing about (*interbrand*) competition that benefits consumers and that would have not emerged otherwise (namely, without restricting *intra*brand competition)⁸⁵³.

Instead, under Article 101(3) TFEU agreement-specific efficiencies are considered. Such analysis takes place once it is verified that the agreement is detrimental to consumer welfare and it is performed in order to ascertain that such efficiencies compensate the deadweight loss caused to consumers. It follows that the ultimate effects

⁸⁴⁹ See ODUDU, *A New Economic Approach To Article 81(1)?*, cit., p. 104, who says that the first paragraph is concerned with allocative efficiency, while the third is about productive efficiency. In his opinion, restriction to competition and allocative inefficiency are synonymous.

⁸⁵⁰ See NAZZINI, *Article 81 EC between time present and time past*, cit., p. 519.

⁸⁵¹ See MARQUIS, *O2 Germany v. Commission*, cit., p. 38, who says that the third paragraph does not refer to the elements of price and output. He also adds that this approach appears to be confirmed by the new approach taken by the Commission towards the enforcement of Art. 102 TFEU: in the Discussion Paper, for instance, the Commission consider foreclosure as taking place if the maintenance of the degree of competition still existing in the market or the growth of that competition is likely to be hindered. In the view of the author, only if this analysis reveals market distortive effects, the efficiency defence would come into consideration. Similarly see NICOLAIDES, *The Balancing Myth*, cit., p. 142, affirms that the third paragraph of the provision provides for a series of filters rather than for a balancing test.

⁸⁵² However, such approach seems to be circular to ROBERTSON, *What is a Restriction to Competition?*, cit., p. 262, because under Art. 101(3) TFEU efficiencies are relevant as long as they benefit consumers, i.e. they entail lower prices, larger output, better variety and quality, criteria that should guide the analysis under Art. 101(1) TFEU instead. For this reason, he suggested that all the effects of an agreement should be taken into account under the first paragraph of the provision under examination and that the analysis under third paragraph should be devoted to the consideration of non-competition goals, i.e. public policy objectives.

⁸⁵³ See NICOLAIDES, *The Balancing Myth*, cit., p. 133-134, who says that the first paragraph of Art. 101 TFEU checks whether there is an increase of competition through joint action against potential competition. Note that this interpretation is only partially supported by EU case law. For instance, in *Pronuptia* the Court said at para. 24 that "It is of course possible that a prospective franchisee would not take the risk of becoming part of the chain, investing his own money, paying a relatively high entry fee and undertaking to pay a substantial annual royalty, unless he could hope, thanks to a degree of protection against competition on the part of the franchisor and other franchisees, that his business would be profitable. That consideration, however, is relevant only to an examination of the agreement in the light of the conditions laid down in Article 85(3)."

on consumers of a restriction to competition, if any, are established in the third paragraph of the provision.

In light of this, it can be affirmed that a sort of ‘European structured rule of reason’ can be envisaged in Article 101 TFEU *as a whole*⁸⁵⁴.

1.1.4 The rule of reason under Article 102 TFEU

Drawing on the well-known concept of ‘*competition in the merits*’, Article 102 TFEU case law indicates that a dominant undertaking, having a “*special responsibility not to allow its conduct to impair undistorted competition on the common market*”⁸⁵⁵, must refrain from any action that would lead to an increase in its market power and harm competitors⁸⁵⁶.

The special responsibility principle, however, cannot be interpreted as imposing a general positive obligation on the dominant undertaking not to distort the competitive process, because it would impair firms’ incentive to compete in the market to win customers with better products or through improved production process, i.e. through methods of ‘normal competition’⁸⁵⁷.

As the ECJ affirmed in *Hoffmann-La Roche*, the essence of abuse of dominant position lies in the weakening of the competitive process through recourse of methods different from those which condition normal competition in products or services⁸⁵⁸.

⁸⁵⁴ See MARQUIS, *O2 Germany v Commission*, cit. p. 46, who says that the real difference between EU and US competition law is that consumer welfare test and productive/dynamic efficiencies are weighed all together in the latter system, while under the former Art. 101(3) TFEU takes care of efficiencies.

⁸⁵⁵ See *Michelin I*, at para. 57. The origin of the ‘*special responsibility*’ traces back to the ordoliberal principle according to which firms which are price makers, i.e. which possess (significant) market power, do not only have a negative obligation (i.e. not to commit certain harmful acts), but also a positive obligation (i.e. to behave as if they do not have any market power).

⁸⁵⁶ The concept of ‘*normal competition*’ was mentioned for the first time in *Hoffmann-La Roche*, para. 120 and then referred to as ‘*competition on quality*’ by the ECJ, V ch., 3 July 1991, in case C-62/86, *AKZO Chemie BV v Commission of the European Communities*, para. 70 and 81, and as ‘*competition in the merits*’ by the GC, 7 October 1999, in case T-228/97, *Irish Sugar v Commission*, para. 111. As it was affirmed by the ECJ, 13 February 1979, in case C-85/76, *Hoffmann-La Roche & Co. AG v Commission of the European Communities*, para. 91, a dominant firm does not compete on the merits when “*through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition*”. An abuse is therefore a commercial practice that cannot be regarded as normal competition based on quality and price and which has the effect of restricting competition. Or, according to the formulation put forward by the GC in *Michelin II*, para. 107 and 110, any conduct that lacks objective economic justification.

⁸⁵⁷ See JONES and SUFRIN, *EC Competition Law. Text, Cases and Materials*, 2007, p. 280.

⁸⁵⁸ See *Hoffmann-La Roche*, para. 91.

This definition generated what it is known as a 'two-tier analysis': for a conduct to amount to an abuse it must a) affect the economic opportunities of rivals in the market, and b) not be performance-based competition⁸⁵⁹.

The first part of the two-tier analysis is directed at ascertaining the likelihood of foreclosure; the second part looks at the existence of objective justifications or objective necessity to the anticompetitive conduct.

As previously indicated⁸⁶⁰, the Commission and the European Courts have seldom found a dominant company's conduct that had the effect of hindering competition to be proportionate and justified. As a result, the prohibition of abuse of dominant position has been almost always applied as a *per se* provision. This has generated the criticisms of large part of legal and economic scholars, who claimed that the provision should have been also applied according to a *rule of reason*, and triggered the second wave of the process of modernization of European competition law⁸⁶¹.

In the wake of this process, the AG Colomer in *Syfait II*, as well as AG Jacobs previously in *Syfait I*, claimed that the legal analysis under Article 102 TFEU cannot be discharged by simply limiting the analysis to the first tier, i.e. to the likelihood of foreclosure⁸⁶².

According to the AG Colomer, a careful reading of Article 102 TFEU does not support such an interpretation. First of all, the wording of Article 102 TFEU, as already

⁸⁵⁹ The identification of a two-tier analysis in the context of Article 102 TFEU can be traced back to Prof. Ulmer who acknowledged the necessary existence of two features in order for a conduct to be considered abusive: the significant impairment of the opportunities of rivals on the market, and the absence of a performance-based competition. It should be noted that this analysis is very much similar to examination of monopolisation practices under Section 2 of the Sherman Act: according to *United States v. Grinnel* (see 384 US 563, 570-1, 1966), it should be distinguished between the wilful acquisition or maintenance of monopoly power and its development as a consequence of a superior product. See LOEWENTHAL, *The defence of 'Objective Justification' in the Application of Article 82 EC*, cit., p. 458.

⁸⁶⁰ See *infra* Section 1.2 in this Chapter.

⁸⁶¹ See KORAH, *An Introductory Guide to EC Competition Law and Practice*, 2000; GYSELEN, *Vertical restraints in the distribution process: Strength and weakness of the free rider rationale under EEC competition law*, in CML Rev., 1984, no. 21, p. 647; HAWK, *System failure: Vertical restraints and EC competition law*, in CML Rev., 1995, no. 32, p. 973; EHLERMANN AND ATANASIU, *European Competition Law Annual 2000: The Modernisation of EC Antitrust Policy*, 2001; WESSELING, *The Modernisation of EC Antitrust Law*, 2000; WHISH AND SUFRIN, *Community competition law: Notification and individual exemption – Goodbye to all that*, in HAYTON, *Law's Future(s)*, 2000, p. 150; EHLERMANN, *The modernization of EC antitrust policy: A legal and cultural revolution*, in CML Rev., 2000, no. 37, p. 537; EHLERMANN AND ATANASIU, *European Competition Law Annual 2003: What is an Abuse of Dominant Position?*, 2005; GCLC *Research Papers on Article 82 EC*, 2005; O'DONOGHUE, *Verbalizing a General Test for Exclusionary Conduct under Article 82 EC*, in EHLERMANN and MARQUIS, *European Competition Law Annual 2007: A Reformed Approach to Article 82 EC*, 2008, p. 15.

⁸⁶² See para. 54-62 of AG Colomer's opinion.

pointed, clearly suggests that the conduct of a dominant undertaking amounts to an abuse when two cumulative conditions are present, namely (a) existence of the exclusionary effect in the downstream market, *and* (b) the absence of any valid and proportionate objective justification for the refusal⁸⁶³.

The reasoning goes that, if the conduct of the dominant undertaking was presumed to be abusive *iuris et de iure*, without looking into the existence of possible objective justifications, such undertaking would be deprived of its right of defence. The examples of abusive conducts listed in Article 102 TFEU, no. 2, lett. a)-d) should be regarded as presumptions *iuris tantum*, which admit rebuttal⁸⁶⁴.

Indeed, a *per se* approach would run counter to the principle under the EU jurisprudence that requires a careful assessment of the legal and economic context in which the infringement was put in place.

Also, it would also conflict with the rationale of Article 102 TFEU, whose objective is to preserve the competitive process, as a means to protect consumer welfare⁸⁶⁵.

Therefore, when applying the consumer welfare test, the assessment of dominant undertakings' conduct should consider whether such a conduct, besides harming consumers, also yields benefits to them. To this purpose, a potential reduction of consumer welfare should be weighed also against the possible efficiency gains resulting from that conduct.

Accordingly, as both AG Colomer and AG Jacobs recognized⁸⁶⁶, a dominant pharmaceutical company does not necessarily abuse its dominant position by refusing to supply in full the orders placed with it by wholesalers, even when such a refusal has an anticompetitive effect, i.e. when this hinders parallel trade. It should still be assessed whether such a conduct that looks *prima facie* anticompetitive can be objectively justified, among other things, by the existence of efficiency gains for consumers⁸⁶⁷.

⁸⁶³ See *Télémarketing*, para. 26.

⁸⁶⁴ See para. 69 of AG Colomer's opinion.

⁸⁶⁵ Cf. the analysis performed in Section 4.1 in Chapter IV.

⁸⁶⁶ See para. 69 of AG Jacobs' opinion and para. 76 of AG Colomer's opinion.

⁸⁶⁷ While previous jurisprudence was reticent in admitting economic justifications to dominant companies' behaviours – see *Tetra Pack* and *General Motors* – more recently the Courts are relaxing such approach. For instance, as AG Colomer recalled, the GC, Ch. II, extended composition, 25 June 1998, in case T-219/99, *British Airways v Commission*, did not consider a system of rebates connected to the achievement of sales targets from travel agencies as *per se* abusive and conceded the company to economically justify the practice.

It follows that either a dominant firm's conduct is abusive, or it is not. And the presence of an objective justification or of efficiencies must be taken into account when assessing such conduct, following a dialectic process.

On this basis it appears correct to infer that Article 102 TFEU does not contain *per se* prohibitions of abusive conducts from dominant undertakings and that its seeming unitary structure does not preclude the balancing of anticompetitive and pro-competitive effects.

The above interpretative analysis supports the conclusion that the structure of Articles 101 and 102 TFEU abstractly permits the application of an effect-based examination of competition law rules to anticompetitive business practices. The question of how such examination should take place is going to be examined in the following Sections.

2. The impact of parallel trade on welfare

As it emerges from the analysis previously conducted, a rule of reason cannot consist of the mere acknowledgement of dynamic efficiencies deriving from an anticompetitive business practice. This would be of a limited significance from a consumer welfare perspective. In considering the welfare implications of a conduct restricting parallel trade, for instance, it is necessary to consider two dimensions: the short-term harm to consumers (or losses in static efficiency) and the long-term benefits to consumers (or gains in dynamic efficiency)⁸⁶⁸. It follows that after having acknowledged and measured the effect of price competition on dynamic efficiency, it is necessary to weight it against the dead weight loss created by impeding such competition⁸⁶⁹.

⁸⁶⁸ On this point see VERNON, *Examining the link*, cit., p. 10; BRUNNELL, *Appropriability in Antitrust: How Much is Enough?*, cit., p. 20, who affirmed that '[a]cknowledging that the long-term welfare effects of dynamic efficiency gains are far more significant than short-term allocative efficiency gains does not mean that any possible diminution in incentives, no matter how remote, ought to trump significant and certain short-term gains'.

⁸⁶⁹ See the opinion of the AG Trstenjac in the *Glaxo* appeal, at para. 295: "It must first be borne in mind in this context that, in the present case, the disadvantages in terms of efficiency resulting from the limitation of parallel trade constitute the 'debit side' of the overall assessment in terms of competition to be carried out under Article 81(3) EC, whereas the 'credit side' includes, in particular, the advantages in terms of efficiency which may result from promoting technical progress." The AG supported the GC on this issue and affirmed that the Commission did not carry out a balancing exercise in respect of the assumed gains and losses in efficiency.

For instance, a dominant undertaking's conduct preventing parallel trade, like the refusal to supply wholesalers who engage in exporting activities, would involve some static efficiency loss and some dynamic efficiency gain. *Ex post* static efficiency gains, which can be maximised by an obligation to deal, should be weighed against the *ex ante* dynamic efficiency gains, which could be preserved by not imposing such a duty⁸⁷⁰. On this view, a refusal to supply would fall within the scope of Article 102 TFEU where static losses prevail over dynamic gains.

Symmetrically, as suggested by the GC in the *Glaxo* case, the analysis of the legal and economic context in which an agreement restrictive of parallel trade on pharmaceuticals takes place should have taken into account the loss in efficiency associated with parallel trade and a gain in efficiency associated with the agreement. Secondly, the disadvantages in terms of efficiency resulting from the limitation of parallel trade should be weighed against the advantages in terms of efficiency that may result from promoting technical progress⁸⁷¹.

2.1 Balancing the anti- and pro-competitive effects of a business practice

Two important theoretical tools have been developed in the economic literature to perform this balance: the Williamson's trade off⁸⁷² and the Kaplow test⁸⁷³.

The first one assesses both the anticompetitive and the pro-competitive effects of a business practice and weigh the latter against the former. When the harm caused to competition is likely to be offset by the efficiencies produced by the conduct, a corporate practice that produces anticompetitive effects in the market is considered legitimate.

The second test looks at the proportion between the profits earned by the defendant through its anticompetitive practice and the harm caused. The first term of

⁸⁷⁰ See the Guidance on Art. 82 at para. 89 *et seq.* where the Commission shows to be aware of the possible adverse effect on the incentive to innovate from companies if they are imposed a pervasive duty to supply. The Commission, in fact, affirms that careful attention should be placed when imposing a duty to deal on companies: this should happen always by taking into account that it is necessary to allow the dominant undertaking to realise an adequate return on the investment required to develop its business, thus generating incentives to continue to invest in the future, taking into account the risk of failed projects into account. For this reason, defendants should demonstrate the negative impact that the obligation to supply would have on its level of innovation.

⁸⁷¹ See para. 267-301 of the *Glaxo* ruling. Furthermore, see para. 294-295 of the opinion of the AG Trstenjac in the appeal to that ruling, where she affirms that in the overall assessment in terms of competition to be carried out under Article 101(3) TFEU, the anticompetitive effects constitute the 'debit side' of such assessment, whereas efficiencies are the 'credit side'. She also adds that such a balancing might be performed also on the assumption that efficiencies were achieved.

⁸⁷² WILLIAMSON, *Economies as an antitrust defence: The welfare Tradeoffs*, in *Am. Econ. Rev.*, 1968, no. 58, p. 18.

⁸⁷³ See KAPLOW, *The Patent-Antitrust Intersection*, cit., p. 1829 *et seq.*

comparison considered under antitrust law only represents just part of the total costs society has to bear by permitting the anticompetitive behaviour from the company⁸⁷⁴. However, when also patent law is considered, the profits of the company serve as the reward, and therefore the incentive, for the innovative activity conducted by the company.

Inventive activity should take place at the least cost possible for society. To this purpose, the reward the patentee receives from the practice should be balanced against the resulting monopoly dead weight loss:

$$K\Pi_m/DWL^{875}$$

In a competition policy that aims at maximising consumer welfare, this second test appears more appropriate, because it allows corporate practices that overall sacrifice the lower social cost in the short run.

So, to determine whether a policy encouraging parallel trade on pharmaceuticals is, on net, good or bad for social welfare, it is necessary to know what is the effect on the reward (*read*: profits) of the innovator, namely in terms of dynamic efficiency, and on consumer welfare, namely in terms of static efficiency.

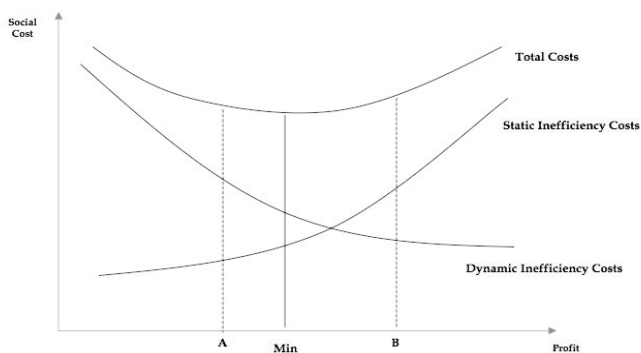
To this purpose, let us consider the graph below: the level of the industry's average pharmaceutical profit margin (in the horizontal axis) is fundamental. If the current position is point B, then it is possible that parallel trade will be welfare enhancing, as long as industry profit margins are not pushed below the level associated with minimum total social cost. If instead the company's profits are currently at this minimum point, or to the left of it (e.g., point A), then parallel trade will have a negative effect on social welfare⁸⁷⁶.

⁸⁷⁴ See POSNER, *The Social Costs of Monopoly*, cit., p. 807.

⁸⁷⁵ The nominator represents the patentee incremental reward. K reflects the fact that not all the monopoly profits are invested in innovation but just a percentage, which in the pharmaceutical market is around 15% of gross profits. The denominator represents the incremental loss for society deriving from the anticompetitive practice.

⁸⁷⁶ See VERNON, *Examining the Link*, cit., p. 11, where he affirms also that the policy could move industry margins below the minimum point and still be welfare enhancing: so long as margins were not displaced too far below the minimum point, and the sum of static and dynamic efficiency costs still declined relative to their pre-policy level.

Graph 9: The net effect of parallel trade on welfare



Source: Vernon, *Examining the link between price regulation and pharmaceutical R&D investment*, in *Health Economics*, 2008, no. 14, p. 11.

In the former case, restrictions to parallel trade from the company should not be allowed. In the latter, they may be allowed.

This approach is in line with the process of abandonment of the *per se* competition law rules in favour of a *rule of reason*, through the use of economic analysis, where Courts are called to apply a case-by-case standard that weighs the extent to which the anticompetitive practices contribute to innovation incentives against the allocative inefficiency created⁸⁷⁷.

Notwithstanding the theoretical appealing of this test, especially in the academic world, Courts have never applied it so far. The reason is that the application of the test rests on a full-blown market analysis that Courts often avoid to perform.

⁸⁷⁷ Note, however, that Kaplow himself admitted that a pure case-by-case approach may not be the most appropriate approach to solve the patent-antitrust paradox. In fact, outcomes of different cases are not necessarily autonomous. On the contrary, they can be interdependent. In other words, the same amount of reward that is considered appropriate for the innovator can be given both by permitting a series of practices that were prohibited or by prohibiting others that were previously allowed. See KAPLOW, *The Patent-Antitrust Intersection*, cit., p. 1844-1845.

2.2 The workability of the rule of reason

It is often claimed that Courts are not able to perform the balancing exercise required by the rule of reason, given that it involves a measurement that so far has never been performed⁸⁷⁸.

For instance, the feasibility of the Williamsonian trade off has been questioned several times as '*enormously complex and impossible to implement*'⁸⁷⁹ for two concurrent reasons: the difficulty of the concrete assessment of efficiencies, which often involve obscure predictions about the future, and the weight of the latter with the anticompetitive effects, which requires the comparison between two differently measured objects.

The Williamsonian trade off, in fact, requires an arbitrage between elements that cannot be compared in similar terms: the analysis of the anticompetitive effects is necessarily *ex post*, while dynamic efficiencies are about *ex ante* incentive to invest in innovation and thus necessarily have not materialised yet. Thus, whilst dynamic efficiencies are praised as providing the greatest potential enhancement of social welfare, still they are the least measurable⁸⁸⁰. For this reason, their quantification may be problematic and may trigger the scepticism of Courts and the legal community⁸⁸¹.

In fact, Courts may not be skilled enough to appreciate the dynamic efficiency facets of a business practice, especially in absence of any theoretical framework that shows how much appropriability is necessary to spur innovation, and of any empirical evidence that establishes a clear correlation between profits, R&D intensity and innovative output⁸⁸².

⁸⁷⁸ See HOVENKAMP, *Antitrust Law*, 1998, p. 302, where he affirms that the "*set of rough judgements we make in antitrust litigation does not even come close to this 'balancing' metaphor. Indeed, most courts do not define a unit of measurement in which the quantities to be balanced can be measured*".

⁸⁷⁹ See FISHER and LANDE, *Efficiency Considerations in Merger Enforcement*, in *Calif. L. Rev.*, 1983, no. 71, p. 1582.

⁸⁸⁰ See BORK, *The Antitrust Paradox*, cit., p. 123, 124, 126-127, where he affirms that the consideration of efficiency in a trade-off analysis may promote some uncertainty, because the related quantification is likely to become an intractable subject for litigation; CARLTON and GERTNER, *Intellectual Property, Antitrust and Strategic Behaviour*, in *Innovation Pol. & Econ.*, 2003, no. 9, p. 42, where it is affirmed that innovation is intangible, uncertain, immeasurable and often even unobservable, except *ex post*.

⁸⁸¹ Legal scholars expressed their scepticism about the feasibility of this quantification exercise, as production efficiencies are too complex to be contemplated and measured. See RAPP, *The Misapplication of the Innovation Market Approach to Merger Analysis*, in *Antitrust L.J.*, 1995, no. 64, p. 19, at 27. The difficulties of performing an entire full-blown analysis are discussed in Chapter V.

⁸⁸² See BOURGEOIS and BOCKEN, *Guidelines on the Application of Article 81(3) of the EC Treaty or How to Restrict a Restriction*, in *Legal issues of Economic Integration*, 2005, no. 32(2), p. 121, where it is affirmed that few courts are sufficiently proficient in economics to consider the evidence of efficiency gains submitted by companies

The Kaplow test suffers similar drawbacks, as the author himself acknowledged⁸⁸³.

These difficulties appear harder when the assessment involves parallel trade of pharmaceuticals. As pointed in the previous Chapter, proving the link between parallel trade and innovation, and performing a balancing exercise between anticompetitive effects and efficiencies, is very difficult, especially in the pharmaceutical market⁸⁸⁴.

The existence of savings can be reasonably presumed. However, their magnitude is not always entirely measurable, especially with regards to indirect savings. Moreover, whilst it is possible to envisage that a large amount of parallel trade may decrease the profits so much that investments in innovation may sharply decline, by how much this would decline and what would be impact on innovation is not easily measurable.

The empirical analysis necessary to determine the outcome of the inquiry under competition law rules is thus complex. The features of the market, the role of regulation and the significant time lag between the possible reason of the erosion of profits and the effect on innovation turn the identification of a robust causality link between parallel trade and rate of pharmaceutical innovation into a hard task⁸⁸⁵.

under Article 101(3) TFEU in order for them to seek the exemption; similarly ELHAUGE, *Defining Better Monopolisation Standards*, cit., p. 307; FLETCHER, 'The Reform of Article 82: Recommendations on Key Policy Objectives', Speech at the Competition Law Forum in Brussels, where he affirmed that the balancing exercise goes beyond the skills of antitrust agencies and creates uncertainty from the firms' side. See also PITOFISKY, *Policy objectives of competition law and enforcement*, in EHLERMANN and ATANASIU, *The European Competition Law Annual 2003: What is an Abuse of a Dominant Position?*, p. 127, who said that there are limits to what enforcement officials, judges can deal with in terms of economic complexity; MELAMED, *Exclusionary Conduct Under the Antitrust Laws: Balancing, Sacrifice, and Refusals to Deal*, in *Berkeley Technology Law Journal*, 2005, no. 20, p. 1249; O'DONOGHUE, *Verbalizing a General Test for Exclusionary Conduct under Article 82 EC*, cit., p. 15, who affirmed that 'A firm embarking on a course of unilateral conduct ex ante may be unsure as to where the balance between pro-competitive and anticompetitive aspects lies and when such effects will materialize. Much would depend on the effect of a practice on the dominant firm's rivals, which the dominant firm cannot generally be expected to know. Moreover, what a firm expects ex ante may of course turn out to be different from what occurs ex post'.

⁸⁸³ See KAPLOW, *The Patent-Antitrust Intersection*, cit., p. 1842-1845.

⁸⁸⁴ Technological opportunity determines the productivity of R&D, as WESLEY and COHEN, *Empirical Studies in Innovative Activity*, in *Handbook of the Economics of Innovation and Technological change*, p. 182, 197, show, while appropriability determines the fraction of the returns from R&D that the innovator is able to retain, as KLEVORIK ET AL., *On the Sources and Significance of Interindustry Differences in Technological Opportunities*, Cowles Foundation Discussion Paper no. 1052, 1993. The relationship between these two variables and innovation is complex, because they are endogenous to the market structure. That is, they affect innovation but are also affected by innovation. CARRIER, *Two puzzles resolved*, cit., p. 408, affirms that to the extent that the two variables affect market structure, they weaken the link between market structure and innovation.

⁸⁸⁵ SOAMES and LEBRUN, *Self-Assessment, a New Burden of Proof for Companies*, in *Lawyers Europe*, 2004, believe that it should not be too difficult for parties to show efficiency gains; however, see RBB ECONOMICS, *Art or Science? Assessing Efficiencies under the Commission's Article 81(3) Notice*, Brief 15, available at http://www.rbbecon.com/publications/downloads/rbb_brief15.pdf, who say that quantifiable savings are achieved with horizontal agreements, while vertical agreements tend to generate benefits in terms of

In other words, a rule of reason that bans or allows parallel trade depending on the effects of the latter on the market is certainly justified from the perspective of a competition law that looks at the maximisation of consumer welfare. But the uncertainty of the effects of parallel trade, especially in the long term, is such that the related inquiry may become too costly.

Courts generally avoid this *impasse* by attributing the burden of proof to parties. In particular, Courts distribute the burden of proof in relation to the facts that may help them ascertain the existence of the facts alleged by parties.

A correct allocation of the burden of proof, thus, rests crucial, as it determines the dialectic between the parties in the proof of facts: what evidence should be submitted by defendants and by the Commission in support of their arguments and what is the standard of review of such material from judges.

The success, or the failure, of a party in discharging the burden of proof determines the anticompetitiveness judgement over a business practice. The latter is going to be more adherent to market reality the more the parties adduce evidence that strengthens their allegations.

This procedural activity can be effectively stimulated by carefully formulated presumptions. As proposed by a prominent scholar, for instance, presumptions should be framed on the basis of the rationale of the involved provisions and on the accumulated experience about markets' functioning. And they should be rebuttable on the basis of empirical evidence showing the inapplicability of the general rule to the particular case⁸⁸⁶. In this way parties are called to overcome such presumptions by presenting sufficient evidence to rebut them. Such activity helps the judge form a learned judgement over the effects of the business practice in the market.

Otherwise stated, a proper division of the burden of proof between parties may serve the purpose of rendering the effect-based analysis truly operational. This could

enhanced investments and improved quality, which are difficult to quantify and to prove. Similarly VAN DEN BERGH and CAMESASCA, *European Competition Law*, cit., p. 31, also say that in case of dynamic efficiency, it must be shown that new and improved products create sufficient value for consumers. While in the case of productive efficiency it is possible to measure them, it seems very difficult to assign values to dynamic efficiencies.

⁸⁸⁶ See AREEDA, *Antitrust Law as Industrial Policy: Should Judges and Juries Make it?*, in TEECE, *Antitrust Competitiveness and Innovation*, 1992, p. 40.

facilitate the implementation of open-ended legal rules that provide the necessary clarity without sacrificing flexibility.

3. **Sharing the burden to lighten it: the law of evidence and the rule of reason**

This sub-section is going to analyse how the burden of proof works under EU law, and especially how this is shared between parties in competition cases. This overview on the principles of the law of evidence is aimed at identifying the tools that parties could use to discharge their burden of proof in parallel trade cases.

3.1 *The legal burden of proof and the evidential burden of proof*

The burden of proof is the burden borne by a party of persuading a Court of the truth of a fact alleged. If the party bearing this burden fails to do so, it will not be able to secure an outcome favourable to his interests in relation to the whole or part of the proceedings⁸⁸⁷.

In the law of evidence, there are two fundamental burdens: the legal burden of proof and the burden of adducing evidence. The latter encompasses the so-called 'evidential' burden and the 'tactical' burden.

The evidential burden of proof requires any proponent of a fact to adduce sufficient evidence to raise an issue as to the existence of such fact. Its discharging is very important, because the failure to raise an issue about the existence of the claimed fact determines the dismissal of the claim⁸⁸⁸.

The evidential burden is generally borne first by the claimant. Until then, the defendant may remain idle. But when the claimant has adduced the evidence that would entitle the judge to find the fact, the defendant is urged to adduce counterevidence in rebuttal. If the defendant succeeds in this task, the claimant is called again to produce new evidence to strengthen its case (so-called 'duty of going forward').

⁸⁸⁷ See GENIN-MERIC, *Droit de la Preuve: l'Exemple Français*, in LEBRE DE FREITAS, *The Law of Evidence in the European Union*, p. 159-160.

⁸⁸⁸ Different, but often identified with the evidential burden of proof, is the burden of making a definite allegation. The latter expresses the duty of setting out precise facts relied upon in support of his claim and of presenting his conclusions in an unequivocal manner. The difference with the evidential burden is that the failure to discharge the latter leads to the rejection of the claim, although admissible in principle, as unfounded. On the contrary, the failure to discharge the burden of making a definite allegation leads to the inadmissibility of the claim, because the Court risks giving judgement *ultra petita* and the defendant does not know precisely what he is charged of.

The evidential burden of proof has been developed in the Common Law system. However, also Civil Law systems recognised the existence of circumstances where one of the parties may rely on the evidential burden, although this generally assumes the characteristics of inferential reasoning based on presumptions⁸⁸⁹ or *prima facie* evidence. The inferential reasoning is based on the assumption that if certain facts are established, other facts can normally be presumed. The establishment of a *prima facie* case consists of the presentation of evidence that, if left uncontradicted and unexplained, could be accepted as a proof⁸⁹⁰.

The tactical burden is borne by the opponents after the proponent has discharged the evidential burden. The essential difference with the evidential burden is that the latter is imposed by law, whilst the tactical burden stems from procedural strategy. It is, in fact, up to the counterpart to produce counterevidence, if it does not want to incur in the risk of having the facts adduced by the other party accepted.

The evidential burden is different from the legal burden of proof, or burden of persuasion, where the party has not only to come forward with evidence that supports its claim, but also to actually prove it (*actori incumbit probatio*)⁸⁹¹.

Not only must the applicant adduce sufficient evidence to raise an issue as to the existence of facts essential to his claim, he also bear the legal burden of ultimately proving those facts to the satisfaction of the Court.

⁸⁸⁹ The term 'presumption' is generally used to indicate a presumption of law, i.e. inferences as to the existence of a fact on the basis of certain evidence that the tribunal is compelled to draw. However, the term also includes presumptions of fact. Under European competition law, the presumptions of law are quite rare, because judgements are not formally binding in subsequent cases. It follows that any 'presumption' established in EU jurisprudence is a presumption of fact.

⁸⁹⁰ In German law, according to the *Anscheinbeweis*, when a party has produced evidence of the facts in issue, the other party bears the burden of adducing counterevidence in rebuttal, if it does not want to bear the risk of having those facts established by the judge. Under administrative French law the evidential burden of proof is defined as the act of '*faire un commencement de preuve*' and '*faire naître le doute dans l'esprit du juge*' as to the substance of his allegations. Also, in civil law, judges can evaluate presented evidence through a '*raisonnement probatoire (tendant à cerner la vérité) érigé en mode de preuve*'. In Italy, courts can inferentially draw the existence of a fact at stake from the evidence adduced by a party according to the model of '*presunzioni giurisprudenziali*'. Symmetrically, the other party is urged to adduce counter evidence to avoid that the judge operates such inference.

⁸⁹¹ On the basis of this distinction, concerns about the definition of the burden of proof for efficiencies in the EU Commission Discussion Paper have been expressed at a public debate held on June 2006 in Brussels. There it was objected that an obligation for the undertaking to prove efficiency gains is contrary to Art. 2 of the Regulation 1/2003, which requires the authority to prove the alleged abuse. For theories supporting such interpretation see NAZZINI, *The wood began to move*, cit., p. 51. However, see ROUSSEVA, *Objective Justification and Article 82 EC in the Era of Modernisation*, in BELLAMY and CHILD, *European Community Law of Competition*, 2008, p. 427, where she affirms that this concern is unfounded because it does not match the principle of *negativa non sunt probanda*.

In sum, each party bears the legal burden of proof and the burden of adducing evidence as to his own allegations. The defendant also bears the burden of disproving of the applicant's claim. Such tactical burden can be shifted back to the applicant, once discharged by the defendant.

The distinction between the legal burden of proof and the evidential burden of proof has become part of the EU law of evidence. Article 38 of the Rules of Procedure before the ECJ establishes the evidential burden, by requiring the applicant to give the '*nature of any evidence founded upon*'. The case law confirms the existence of the evidential burden of proof: in *Italy v. Council*, the Court dismissed the applicant's action for the annulment of certain regulations because it has not been '*able to furnish any proof whatsoever in support of its allegations*'⁸⁹².

Also, European Courts consistently adopt a framework for the evaluation of evidence that relies on the establishment of a *prima facie* case and on the distinction between the burden of persuasion and the evidential burden of proof.

In sum, before the ECJ the burden of proof has three meanings: the legal burden, the evidential burden, and tactical burden, although the last two are not technically burdens of proof but just burdens of adducing evidence.

The same evidence may serve to discharge the three burdens. The applicant may put forward some evidence that satisfies the evidential burden and make the case *prima facie*. Such evidence, if strengthened by the passivity or the incapability of rebutting such evidence of the defendant, may lead to the discharging of the legal burden of proof for the applicant.

The burden of proof should be distinguished from the standard of proof. The latter is the level of proof required in a legal action to discharge the burden of proof, i.e. the quantity and quality of evidence that is necessary to convince the Court that the alleged fact is true.

These distinctions are very helpful to ascertain how the balancing between anticompetitive effects and pro-competitive effects may take place in competition cases.

⁸⁹² See ECJ, 28 August 1978, in case C-166/78 *Italy v. Council*, para. 16.

3.2 *The proof of restriction of competition*

In competition cases, the Commission must prove a breach of the Treaty. The standard of proof of such violation is high, as it is subject to the burden of persuasion of the Court and to the burden of adducing evidence in this respect.

The defendant does not bear the legal burden of disproving a breach of the Treaty, but of proving that the Commission was not correct in its findings.

If, for instance, the Commission draws conclusions as to the prevailing market conditions based on '*objectively justified evidence from stated sources, the undertaking concerned cannot refute the Commission's findings*' by simply disputing them. It falls on the undertaking to adduce arguments and evidence that show '*why the information used by the Commission is inaccurate, why it has not probative value, or why the conclusions drawn by the Commission are unsound*'.⁸⁹³ Such confutation does not entail a reversal of the burden of proof *strictu sensu*, but just the pressure on the defendant to adduce evidence in rebuttal.

For instance, in *United Brands* the Commission, *inter alia*, accused the firm of charging excessive prices. The firm challenged this allegation through documents in its possession. The Court considered these documents as unreliable and unsupported by any other evidence, but at the same time it affirmed that the Commission was not able to refute the applicant's arguments that proved '*beyond doubt that the basis for the calculation adopted by the Commission was open to criticism*'.⁸⁹⁴ The Court, therefore, annulled the decision in that part, concluding that '*the Commission has not adduced adequate legal proof of the facts and evaluation which formed the foundation of its findings that U.B.C. had infringed Article 86*'.⁸⁹⁵

3.2.1 *The burden of proof under Article 101(1) TFEU*

Let us apply these principles in the context of agreements restrictive of parallel trade⁸⁹⁵.

⁸⁹³ See the opinion of the AG Kokott in case C-105/04 P *Nederlandse Federatieve Vereniging voor de Groothandel op Elektrotechnisch Gebied v. Commission*, December 8, 2005, para. 73.

⁸⁹⁴ See *United Brands*, para. 265, where the Court referred to '*the normal operation of the respective burdens of adducing evidence*'.

⁸⁹⁵ I will not consider here the foreclosure analysis to be performed in the context of Art. 102 TFEU, as in the examined case law this point was not under discussion.

It has been already indicated that an agreement is considered to run against Article 101(1) TFEU when it a) restricts competition *and* b) hinders cross border trade, both in an appreciable way⁸⁹⁶.

In parallel trade cases, the requirement sub b) does not entail particular issues for the proof of its existence. It is, in fact, plain that any ban on export, also when indirectly provided by a dual pricing clause, displays its effect on trade covering the whole territory of the European Union.

The requirement sub a) represented the debated issue in the *Glaxo* case.

As discussed earlier, such debate focused on whether market mechanisms characterising the pharmaceutical sector allow to presume that parallel trade brings savings to consumers, and consequently, also that any obstacle to it constitute a restriction of competition 'by object'.

The analysis conducted in Chapter III showed that *in principle* there are all the economic and legal conditions for having savings from parallel trade. It follows that it is not unreasonable to adopt a presumption of effects also in the pharmaceutical sector and to consider a restriction to parallel trade anticompetitive in its object.

Still, being competition law provisions based on the paradigm of consumer welfare, the need of giving significance to the effects of an agreement remains, also when the restriction is by object.

In fact, in the application of Article 101 TFEU, it is always open to parties to argue that their agreement does not appreciably affect competition. This is conceptually different from affirming that the practice is not restrictive of competition. A restriction, in fact, can run against Article 101(1) TFEU in its object, but have little effects in the market. Put it differently, *qualitatively*, the agreement is anticompetitive, but *quantitatively*, it may not be.

Otherwise stated, defendants always have the possibility to demonstrate that, in a quantitative sense, a given agreement does not affect competition in a sensible manner, namely that actual anticompetitive effects are negligible. I believe that allowing the

⁸⁹⁶ See ECJ, 9 July 1969, in case C-5/69 *Franz Völk v S.P.R.L. Ets J. Vervaecke*.

rebuttal of the presumption embodied in the category of 'restriction by object' serves this purpose⁸⁹⁷.

Such approach resembles the *de minimis* doctrine⁸⁹⁸ and the above considerations may suggest its application to hardcore restrictions.

At present, part II, paragraph 11(3), of the *de minimis* Notice excludes hardcore restrictions, like those blacklisted in the EC Regulation no. 2790/99 on vertical agreements, from the scope of the Notice, and it specifically states that export bans cannot benefit from the 'safe harbour'.

This does not mean that the criterion of 'non appreciability' can never be applied to hardcore restrictions. The case law confirms that it is possible for an export ban to fall outside the scope of the provision because its effects on the market are negligible: the landmark case that initiated the *de minimis* doctrine did concern an export ban. Still, at present there is no assurance that the Commission would not proceed against a hardcore agreement where the market share of the parties is less than the indicated threshold.

Whilst these considerations may enrich the debate about the further improvement in the policy towards vertical restraints recently started by the Commission⁸⁹⁹, they do not seem to solve the issue at stake, i.e. the crafting of an appropriate effect-based approach to antitrust analysis of restrictions of competition.

Even if one believes that the *de minimis* doctrine should be applicable also to hardcore restraints such as restrictions to parallel trade, the related threshold is

⁸⁹⁷ Cf. AMATO and ELHERMANN, *EC Competition Law*, p. 164-165, who also suggest that this is a possible reading of the *Glaxo* ruling, where the Court envisages for the first time the possibility of rebutting such presumption through the analysis of the economic context.

⁸⁹⁸ The *de minimis* doctrine was first formulated by the ECJ in *Völk v. Vervaecke*. A German producer of washing-machines granted an exclusive distributorship to Vervaecke in Belgium and Luxembourg and guaranteed its absolute territorial protection against parallel import. Volk's market share was negligible and the ECJ held that 'an agreement falls outside the prohibition in Article 81(1) where it has only an insignificant effect on the market, taking into account the weak position which the persons concerned have on the market of the product in question'. The EU Commission has provided guidance on the *de minimis* doctrine in a series of Notices, the most recent of which was released in 2001 (*Notice of Minor Importance Commission's Policy Newsletter*, June 2001): there the EU Commission set out the aggregate market share threshold for determining when a restriction to competition is not appreciable (the 'safe harbour'): 10 per cent, where the agreement is made between undertakings which are actual or potential competitors in the relevant market; 15 per cent, where the agreement is made between undertakings which are not actual or potential competitors in the relevant market. Agreement above that threshold may have only a negligible effect on competition and for this reason they will not be caught.

⁸⁹⁹ See the ongoing review of the rules applicable to vertical agreements through a public consultation launched by the EU Commission. See http://ec.europa.eu/competition/consultations/2009_vertical_agreements/index.html.

generally grounded on the weak position of parties in the market, i.e. on the absence of market power. Parallel trade on pharmaceuticals generally involves products that are covered by patents: the exclusivity right conferred to pharmaceutical companies endows them with substantial market power. Therefore, any action undertaken is likely to have a potential significant impact on the market.

This does not mean that appreciability cannot be relevant to the application of Article 101(1) TFEU to restrictions to parallel trade in a different way. Judgements of the European Courts and decisions of the Commission can be found in which it was concluded that a restriction of competition was not appreciable, not because the parties to an agreement lacked market power, but because the restriction itself was insignificant⁹⁰⁰.

I believe that the principles expressed in these cases provide a useful paradigm of how the concrete effects of the restriction of parallel trade in the market may acquire significance.

In order to discharge its evidential burden of proof in relation to the anticompetitiveness of the agreement, the Commission may adduce evidence about the analysis of the legal and economic context showing that the latter allows it to reasonably presume a potential restriction of competition, and the consequent violation of Article 101(1) TFEU, without going into the concrete analysis of the effects of the examined agreement on consumers.

⁹⁰⁰ See ECJ, 12 September 2000, in case C-180/98 *v. Stichting Pensioenfonds Medische Specialisten*, para. 90-97, where the ECJ concluded that a decision by medical specialists to set up a pension fund entrusted with the management of a supplementary pension scheme did not appreciably affect competition within the common market: the cost of the scheme has only a marginal and indirect influence on the final cost of the services that they offered. In *Irish Banks' Standing Committee* (see the EU Commission decision no. 86/507/EEC of 30 September 1986 relating to the case IV/31.362 - *Irish Banks' Standing Committee*), the Commission decided that an agreement on the opening hours of Irish banks did not appreciably restrict competition. Similarly, in the mentioned *Visa International* case, the Commission considered that one of rules of the Visa card system, which required a bank to issue a certain number of Visa cards before contracting with retailers for processing credit card payments, did not appreciably restrict competition since it improved the utility of the card system for traders and did not create significant barriers to entry. In its decision no. 2001/478/EC of 19 April 2001 relating to the case 37.576 — *UEFA's broadcasting regulations*, the Commission concluded that regulations preventing the live transmission of football matches at, did not result in an appreciable restriction of competition. Finally, in the decision no. 2001/696/EC of 31 July 2001 relating to the case No. COMP/37.462 — *Identrus*, the Commission decided that a prohibition on the members of Identrus selling their equity interest in it to third parties without first offering to sell the interest to Identrus itself or its other members did not amount to an appreciable restriction of competition.

By producing such evidence, the Commission is making a *prima facie* case of anticompetitiveness. This does not mean that it discharged its legal burden of proof, because the firm has always the possibility of disproving the Commission's allegations.

In other words, once the Commission has discharged the evidential burden, the defendant acquires the tactical burden (not the legal burden, which rests on the Commission) of rebutting the facts affirmed by the Commission.

Three scenarios are then available.

If the defendant does not challenge the evidence adduced by the Commission, through convincing counterevidence, the judge may use the *prima facie* evidence provided by the latter to infer that the agreement runs contrary to Article 101(1) TFEU.

If the evidence produced by the defendant is capable of casting doubt about the *prima facie* case established by the Commission, the burden is shift back to the latter. It is then up to the Commission to make a definite allegation of precise facts in support of his claim to present his conclusions in an unequivocal manner.

If the Commission manages to challenge the evidence provided by the defendant and the Court considers this new evidence apt to strengthen the likelihood of the anticompetitive story, the Court will be likely to believe that the agreement falls within the scope of Article 101(1) TFEU.

If the Commission does not succeed in providing the definite proof of the facts supporting the anticompetitive story, the Court may be more prone to believe that agreement is out of the scope of Article 101(1) TFEU.

Applied to parallel trade cases concerning pharmaceuticals, the Commission can show that there exists regulation encouraging parallel trade and pressure on prices of original products, and on this basis claim that the economic and legal context suggest that any restriction to this form of trade will most likely impede national health care systems to benefit of savings from price competition. If left uncontradicted, this evidence represents the indicia on which the judge can consider, through inferential reasoning, the Commission's allegation of violation proven.

Pharmaceutical firms have two options to rebut the evidence put forward by the Commission: they may either provide evidence that the legal and economic context is different from what the Commission presented, or they may agree on the economics

presented by the Commission but allege that the restriction does not have an appreciable effect in the market.

Thus, for instance, a pharmaceutical company may adduce evidence of the absence of any negative effect from the restriction to parallel trade by showing that savings accruing to consumers were negligible. It is then up to the Commission to provide its own assessment of the effects of the restriction on consumers.

In sum, the consideration of agreements restricting parallel trade as anticompetitive in their object is not at odd with an effect-based approach to European competition law. By interpreting the category of restriction of competition 'by object' as a rebuttable presumption of anticompetitiveness, it is possible to construe a rule that has two positive properties. As a general rule, which has been set in light of the accumulated knowledge on the effect of certain business practice in the market, it avoids costly market inquiry and save transaction costs. At the same time, the rebuttal allows to account for the concrete effect of the specific practice and to eventually call for the non-application of the general rule to the particular case.

3.3 *The proof of efficiencies*

As indicated earlier, the application of competition law rules that looks at the effect of business practices in the market necessarily includes also the accounting of their long-term facets. The previous Chapter has been devoted to the crafting of a test that allows for the consideration of efficiencies under Article 102 TFEU. However the choice of the 'efficiency defense' left two questions unanswered.

A first question concerns the identification of the party who bears the burden of proof in relation to the existence of efficiencies.

The second question regards the standard of proof that has to be adopted in order to discharge such burden of proof⁹⁰¹.

The two issues are going to be discussed in the indicated sequence.

3.3.1. *Who has to prove efficiencies under Article 102 TFEU?*

It is now clearly established that defendants bear the legal burden of proof with respect to the existence of efficiencies under Article 101 TFEU.

⁹⁰¹ Note that this issue remains open also in the context of Art. 101 TFEU. Therefore, the analysis will be applied also to this provision.

As mentioned earlier, this interpretative question has, in fact, been solved by the EC Regulation no. 1/2003. The Regulation provides guidance about the burden of proof of parties under Article 101 TFEU, specifies that the legal, as well as the evidential, burden of proof in relation to the breach of Article 101(1) TFEU is on the antitrust authority/plaintiff, who has to prove that the practice has an appreciable (actual or potential) negative effect on competition and influences the trade flow among Member States. Symmetrically, it is up to the defendant to give proof of the existence, of the magnitude of efficiency defence, and to show that consumers benefit from them under Article 101(3) TFEU ⁹⁰².

Whilst the bifurcate structure of Article 101 TFEU renders somewhat easier this interpretative task, Article 102 TFEU is more of a problem from this point of view. The issue of how to allocate the burden of proof under the latter provision is still under discussion among scholars.

Two options are available: either efficiency considerations come into the assessment in the form of a defence, or as a factor within the overall assessment of a corporate conduct.

While the latter choice requires the Commission to bear the burden of proof in relation to efficiencies, the former interpretation implicitly entails the shifting of the burden of proving their existence and magnitude, compared to the static inefficiency created with the conduct, on the company alleging them.

One main argument may lead to exclude the second option: the wording of the examined provision does not support the existence of an 'Article 102(3) TFEU'. In fact, unlike Article 101 TFEU, Article 102 TFEU does not contain a paragraph where exemption is granted to abusive conducts⁹⁰³.

⁹⁰² This provision reads as follows: 'In any national or Community proceedings for the application of Articles 81 and 82 of the Treaty, the burden of proving an infringement of Article 81(1) or of Article 82 of the Treaty shall rest on the party or the authority alleging the infringement. The undertaking or association of undertakings claiming the benefit of Article 81(3) of the Treaty shall bear the burden of proving that the conditions of that paragraph are fulfilled.'

⁹⁰³ AG Jacobs in his opinion in *Syfait I* at para. 72 said that 'the two stage analysis suggested by the distinction between an abuse and its objective is to my mind somewhat artificial. Article 82 EC, by contrast with Article 81 EC, does not contain any explicit provision for the exemption of conduct otherwise falling within it. Indeed, the very fact that conduct is characterised as an 'abuse' suggests that a negative conclusion has been already reached... It is more accurate to say that certain types of conduct on the part of a dominant undertaking do not fall within the category of abuse at all.' See also ALBORS-LLORENS, *The Role of Objective Justification and Efficiencies in the Application of Article 82 EC*, in CMLR, 2007, no. 44, p. 1747; NAZZINI, *The wood began to move: an essay on consumer welfare*, cit., p. 518, especially makes the following argument: Reg. 1/2003 does not support this interpretation, as

The ECJ confirmed this by saying that ‘no exemption may be given, in any manner whatsoever, in respect of abuse of a dominant position; such abuse is simply prohibited by the Treaty and it is for the competent national authorities or the Commission, as the case may be, to act on that prohibition on that prohibition within the limits of their powers’⁹⁰⁴.

Similarly, the AG Kirschner in his opinion in *Tetra Pack* in reply to Tetrapack’s arguments that Article 102 TFEU should be examined in two stages, namely whether the conduct was *prima facie* an abuse and whether it was objectively justified, affirmed that ‘it is not possible to read into Article [82] a set of criteria for dispensation’⁹⁰⁵.

Alternatively, if the second option purported above is chosen, efficiency gains are considered merely as a factor to be accounted for when deciding whether the dominant company’s conduct is abusive or not, the burden of proof rests with the Commission, which should demonstrate that the conduct falls within the scope of Article 102 TFEU, because there are no efficiencies stemming from the conduct⁹⁰⁶. The company would only have to show that there is evidence of potential efficiency gains and not the full burden of proving their existence and magnitude.

Again, if interpreted in this way, the analysis under Article 102 TFEU could resemble the appraisal performed under Section 2 of the Sherman Act.

The Supreme Court recently developed a ‘structured rule of reason’ under this provision, where the burden of proof has been clearly attributed to each party: the Court established that if the defendant puts forward a pro-competitive justification that stands unrebutted, then the plaintiff must demonstrate that the anticompetitive harm caused by the defendant’s conduct outweighs the pro-competitive benefit⁹⁰⁷.

Article 2 provides for distribution of the burden of proof between the authority and the defendant only in relation to Article 101 TFEU. Moreover, Recital 5 of the same Regulation states only in the context of Article 101(3) TFEU that it is for the undertaking invoking the benefit of a defence to demonstrate to the required legal standard that the condition for applying such defence are satisfied.

⁹⁰⁴ See ECJ, 11 April 1989, in case C-62/86, *Ahmed Saeed Flugreisen and Silver Line Reisebüro GmbH v. Zentrale Bekämpfung Unlauteren Wettbewerbs eV*, para. 32.

⁹⁰⁵ See AG Kirschner’s opinion at para. 21.

⁹⁰⁶ Notice that it is a consolidate principle of law that *negativa non sunt probanda* and it is, therefore, obvious that the authority cannot bear the burden of proving the absence of efficiencies. Cf. AG Colomer at para. 68.

⁹⁰⁷ See *U.S. v. Microsoft*, cit., at para. 95-97, where the Supreme Court established that ‘First, to be condemned as exclusionary, a monopolist’s act must have an ‘anticompetitive effect.’ That is, it must harm the competitive process and thereby harm consumers. In contrast, harm to one or more competitors will not suffice. Second, the plaintiff, on whom the burden of proof of course rests, must demonstrate that the monopolist’s conduct indeed has the requisite anticompetitive effect. Third, if a plaintiff successfully establishes a *prima facie* case ... by demonstrating anticompetitive effect, then the monopolist may proffer a ‘pro-competitive justification’ for its conduct. If the monopolist asserts a pro-competitive justification—a non-pretexual claim that its conduct is indeed a form of

However, the same reasons that led to exclude the establishment of a US-like test for efficiencies within Article 102 TFEU also apply here. It clearly appears that if defendants were not required to show the existence of efficiencies, the burden of proof for defendants would be lighter, with respect to what is generally required under EU competition law. In particular, it would be unbalanced compared to what is called for in the context of Article 101(3) TFEU. This may represent a problem within the *acquis communautaire*.

In fact, it is established case law that the analysis under Article 102 TFEU should not differ from that in Article 101 TFEU, otherwise the enforcement of the two provisions would be lop-sided⁹⁰⁸. Thus, proposing that the burden of proof, also for efficiency gains, rests entirely on the Commission would render the test under Article 102 TFEU more lenient with respect to what Article 101(3) TFEU provides. The coherence of the EU competition law system thus would not admit this solution.

Hence, as much as the analysis of efficiency gains should be performed both under Article 101 TFEU and Article 102 TFEU, such gains should enter the antitrust assessment under Article 102 TFEU in the same way they do under Article 101 TFEU, despite the absence of an explicit paragraph providing an exemption.

Another reason supports the view that the burden of proving the efficiency defence rests on the undertaking.

Calling the 'objective justification' an exception or a factor that enters the antitrust scrutiny does not change the practical means that are going to be used by parties to prove the existence of the efficiency gains⁹⁰⁹.

Under Article 101 TFEU, the agreements that prevent, restrict or distort competition are caught by the prohibition set forth in the first paragraph of the provision. It is then necessary to check whether such agreement can be exempted, notwithstanding the fact that competition remains restricted. Similarly, under Article 102 TFEU, only

competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal – then the burden shifts back to the plaintiff to rebut that claim. Fourth, if the monopolist's pro-competitive justification stands un rebutted, then the plaintiff must demonstrate that the anticompetitive harm of the conduct outweighs the pro-competitive benefit'.

⁹⁰⁸ Cf. fn 781 *supra*.

⁹⁰⁹ See LOEWENTHAL, *The defence of 'Objective Justification'*, cit., p. 463, who says that the difference between the two provisions lies more in their wording than in their application. Also he welcomes the adoption of a two-tier structure under Art. 102 TFEU, similar to Art. 101 TFEU, in order to give a greater degree of structure to the application of the provision, otherwise vague in its wording.

conducts that have the effect of hindering competition will be subject to the second tier of analysis, to check whether they are objectively justified. If the conduct passes this test, it is not abusive, but that does not mean that competition is not hindered any longer.

In fact, especially when efficiency gains are considered, i.e. when the foreclosure of rivals is claimed to aim at increasing the resources devoted to R&D activities, the anticompetitive effect in the market does not cease and eventually cause harm to consumers in the short-term. However, they may be ‘tolerated’ to provide companies with the incentive to invest in innovation and benefit consumers in the long-term.

The law of evidence confirms this.

It is a well-established principle of procedural law that *incumbit probatio qui dicit, non qui negat*. It follows that, besides the fact that undertakings are better placed to discharge this burden of proof, it is up to the party who asserts the existence of a fact to prove it, and not to the counterpart to prove its absence.

Therefore, also under Article 102 TFEU it is up to the plaintiff to make the case and demonstrate the anticompetitiveness of the conduct, at least *prima facie*. Then the defendant may allege justifications to its conduct.

If this happens through a an affirmative defence, or through a negative one, i.e. by putting forward enough evidence that casts doubt about the findings of the plaintiff, it appears largely immaterial.

In fact, even if the plaintiff bears all the burden of proof, it will discharge it by proving that the efficiency gains do not exist, or are insufficient, or are not passed on to consumers. It follows that it remains up to the defendant to overcome this allegation and affirm their existence. *De facto*, the burden of proving the efficiency gains rests on the defendant, through convincing evidence⁹¹⁰.

The case law again comes in support of this statement. Even if European Courts have never addressed the issue of how the burden of proof is shared between parties in Article 102 TFEU cases, in those cases where defendants put forward economic arguments to justify the foreclosure caused by their conducts, judges always asked them to substantiate their allegations with evidence.

⁹¹⁰ ROUSSEVA, *Objective Justification and Article 82 EC*, cit., p. 427, affirms that given that the objective justification is formulated as a negative fact, i.e. the conduct is abusive if not justified, the undertaking has to prove the corresponding positive fact.

For instance, in *Michelin II*, the Court affirmed whether the dominant undertaking has established that the quantity rebate system was based on objective economic reasons⁹¹¹. Similarly, in *British Airways*, the Court affirmed that the defendant did not appear to have demonstrated that the fidelity-building character of its performance reward scheme was based on economically justifiable considerations⁹¹². In *Atlantic Container*, the Court stated that the company failed to show that its conduct was necessary to bring about these advantages⁹¹³.

On this basis, I believe that, no matter whether in the discharging of its legal burden of proof or of its tactical burden of proof, a defendant undertaking charged of abusive conduct restrictive of parallel trade must adduce evidence that shows that such conduct is likely to have a positive impact on the market in terms of innovation.

One last reason to support this view is that the sharing of the burden of proof between parties should be designed so that administrative costs are minimized. It follows that it should up to the party in the best position to gather the relevant information that provides the proof at the cheapest cost⁹¹⁴. And clearly, while an antitrust agency might suffer from information asymmetry with respect to the existence of efficiencies, the undertaking is better placed to collect and provide evidence at this regard⁹¹⁵. For the same reasons, agencies should bear the burden of demonstrating the violation of the competition provisions.

This division thus appears optimal, because the burden of demonstrating effects is on the parties that are 'closer to the proof', in terms of ability to acquire the necessary information to adduce the required evidence.

This does not mean that the Commission does not have any role in ascertaining the existence of efficiencies. As much as defendants cannot just dispute the

⁹¹¹ See *Michelin II*, para. 107.

⁹¹² See *British Airways*, para. 281.

⁹¹³ See *Atlantic Container*, para. 1117.

⁹¹⁴ Also case law confirms this approach: see *Michelin II*, where the Court said it was necessary to examine 'whether the dominant undertaking has established that the quantity rebates ... were based on objective economic reasons'; see *British Airways*, where the Court held that the defendant 'does not appear to have demonstrated that the fidelity-building character of its performance reward scheme was based on an economically justified consideration'; see finally *Atlantic Container*, where the GC said that 'the applicants fail to show how the practices in question are necessary to bring about the alleged advantages'.

⁹¹⁵ The Guidance on Art. 82 EC at para. 31 affirm that, after that the defendant has proven the efficiency, is then up the Commission to make the ultimate assessment of whether the conduct is necessary and whether it causes consumer harm.

Commission's findings, if they want to be successful in casting doubts about the existence of a violation of the Treaty, also the Commission cannot disprove the efficiencies claimed by defendants by simply disagreeing on their existence.

This issue has been subject to an intense debate in the context of the *Glaxo* case and, thus, specifically in relation to the analysis under Article 101(3) TFEU. However, the adoption of an 'efficiency defense' under Article 102 TFEU implies that the analysis of the considerations expressed in that context apply also to the latter provision.

Both the GC and ECJ believed that the Commission did not properly examine GSK's request for an exemption to the dual pricing clause through a thorough analysis of the factual evidence provided by the undertaking⁹¹⁶. This conclusion was driven by the fact that the Commission did not follow the *modus procedendi* that the Court considered more appropriate to examine the existence of efficiencies.

The Court suggested a four-pronged test: the Commission should first examine the factual arguments and evidence to check that there is an appreciable objective advantage. Secondly, it should consider whether there is a loss in efficiency associated with parallel trade. Thirdly, it should measure the extent of that loss in efficiency. Lastly, the gain in efficiency associated the restriction should be analysed. This four-stage analysis should precede the balancing⁹¹⁷.

Both Courts found that the Commission had examined whether parallel trade would give rise to a loss in efficiency for competition, but not whether dual pricing would entail a gain in efficiency for competition. They therefore held that the examination carried out by the Commission had not been sufficient.

Stated differently, the Commission bears the tactical burden of proof in relation to the evidence provided by undertakings about the existence of efficiencies. If the Commission want to convince the judge that such efficiencies do not exist, it should adduce countervailing evidence that casts doubt on the pro-competitive story put forward by the defendant: by showing why the defendant did not sufficiently prove that efficiency gains are likely to be realized, or by arguing that, even if their manifestation is highly probable, the defendant did not prove that they are likely to offset the anticompetitive effects.

⁹¹⁶ See para. 261-262 of the *Glaxo* ruling.

⁹¹⁷ See para. 128-129 of the ECJ ruling in the *Glaxo* appeal.

3.3.2 *The standard of proof for efficiencies*

The analysis conducted in Chapter IV and in the previous Sections has already introduced the reader to the main difficulty concerning the considerations of efficiencies in the antitrust assessment: the impossibility to affirm their certain existence and ascertain their magnitude at that time when the analysis is performed. That is, efficiency considerations require a prognostic analysis that renders their effect on consumer welfare hardly verifiable.

The forward-looking feature of dynamic efficiencies, in fact, does not perfectly fit the traditional antitrust scrutiny. The provision fails to provide an appropriate legal framework for the accounting of *ex ante* standpoints, being the analysis based on verifiable and quantifiable elements.

Still, whilst it is neither legally possible nor economically justified to base the assessment exclusively on the situation *ex ante*, it does not mean that this perspective is totally irrelevant⁹¹⁸. Both the *ex post* and the *ex ante* perspectives should be taken into account when analysing the innovation process, in order to ascertain the several factors that inform efficiency gains.

The question of how to give significance and appropriate weight to efficiencies in the antitrust assessment, thus, remains. In procedural parlance, the standard of proof, with which the evidence supporting the existence of efficiency gains from restrictions to parallel trade should be reviewed, is controversial.

The rationale of both provisions, as previously analysed, validates the adoption of a standard of proof that requires the full substantiation of the efficiency gains is in line with the teaching of economic analysis. However, it seems to be destined to fail before European Courts and antitrust agencies. The speculative nature inherent to dynamic efficiencies, in fact, is likely to render very difficult the discharging of this onus for defendants.

From an *ex post* perspective, in fact, the judge is unlikely to observe the effect of competition on innovation. Nor is the effect of price competition on R&D investments always apparent.

⁹¹⁸ See FAULL and NIKPAY, *The EC Law of Competition*, cit., p. 297-298.

For instance, in the *Glaxo* case the defendant declared that it had abandoned nine R&D projects due to the lack of financial resources⁹¹⁹. However, by looking at the percentage of the company's turnover devoted to R&D in the last twelve years, it appears clearly that the latter steadily increased along time: it was 13.9% in 1996, 15% in 1999, 16.7% in 2006, 16.2% in 2007⁹²⁰. The immediate conclusion from this analysis is that parallel trade has not affected the company's R&D budget and, therefore, that it did not have any negative impact on innovation.

However, parallel trade expanded in a significant manner only at the beginning of this decade⁹²¹. Therefore, any possible impact on R&D intensity might show up only in a considerable time lag, because of the long period needed for a new molecule to be developed and brought into the market.

In sum, even if parallel trade *did* not affect innovation *in the past*, it *may* do it *in the future*. However, such conclusion remains only theoretical. And hardly any tangible evidence can *now* provide the full proof of something that may happen in the *future*.

Judges can only guess that the impact that parallel trade has today on profits, in the future may also turn into a further impact on the investments in innovation. Still, the only thing measurable at the moment when the legal assessment is performed is the profit loss. Unfortunately, as explained in the previous Chapter, the latter is not always an adequate proxy for a reduction in innovation, though.

Stated differently, the examination of efficiency gains necessarily requires a projection of market analysis in the future. The full substantiation of efficiency gains, as generally intended in the law of evidence, in these cases appears difficult. It is necessary thus to envisage a more appropriate tool to allow companies to discharge their burden of proof when the prediction of future outcomes is involved.

Evidential inference seems to me the more appropriate standard. The company should be allowed to present evidence that provides concrete indicia supporting the probability of a future materialization of the efficiency gains. That is, the defendant should produce sufficiently proved facts that allow the judge to infer the reasonable

⁹¹⁹ See para. 98 of the decision of the European Commission on the *Glaxo Wellcome* case.

⁹²⁰ See GSK's annual reports for data. There it is also indicated that the 3% decrease that took place between 2006 and 2007 was due to winding-down of restructuring activities.

⁹²¹ See data provided in Section 5 in Chapter I.

conclusion that the realization of efficiency gains from the agreement is *more probable than not*, following a standard of proof based on the preponderance of evidence⁹²².

Such forward-looking analysis is not entirely unknown to the Commission, which can build on previous cases decided under Article 101 TFEU, where it exempted anticompetitive agreements also when related benefits were just highly likely⁹²³.

True, this approach is entirely new in the analysis under Article 102 TFEU, but it is certainly in line with the criteria chosen by the Commission in the *Guidance on Art. 82 EC* to perform the analysis of foreclosure⁹²⁴.

It has been previously indicated that Article 102 TFEU's baseline is consumer welfare. However, this does not mean that direct consumers harm should be considered as the necessary requirement to find an abuse, as the standard of proof would be too demanding. Article 102 TFEU applies also to conducts that do not have any direct effect on consumers but just on the effective competitive structure of the market⁹²⁵. It follows that the test in Article 102 TFEU looks at whether the conduct under examination has *potential* anticompetitive effects for consumers.

As much as it is possible for the Commission to prove foreclosure in terms of likelihood, it should be possible for defendants to show that efficiencies are probably

⁹²² The preponderance of the evidence, also known as balance of probabilities, is the standard of proof required in most civil cases in US. The standard is met if the proposition is more likely to be true than not true. Effectively, the standard is satisfied if there is greater than 50 percent chance that the proposition is true. In *Lord Denning, in Miller v. Minister of Pensions*, [1947] 2 All ER 372 it was affirmed that the standard is satisfied where a proposition is 'more probable than not'.

⁹²³ See Commission decision 2004/841/EC of 7 April 2004 in case COMP/A.38284/D2 - *Société Air France/Alitalia Linee Aeree Italiane SpA*; Commission decision 2004/207/EC of 16 July 2003 in case COMP/38.369 - *T-Mobile Deutschland/O2 Germany: Network Sharing Rahmenvertrag*, where the Commission affirmed that the agreement 'may have' efficiency gains; Commission decision 2003/778/EC of 23 July 2003 in case COMP/C.2-37.398 - *Joint selling of the commercial rights of the UEFA Champions League*, where the Commission affirmed that 'the benefits are ... evident'.

⁹²⁴ See para. 16 of the *Guidance on Art. 82 EC*, where the concept of 'tendency to foreclosure' has been replaced with the 'likelihood of foreclosure'. The reference to the 'likelihood of effects' of conducts distances the definition of exclusionary abuse adopted in *Michelin II*, where it was affirmed that the anticompetitive object or potential restrictive effects are sufficient to prove an abuse and it is unnecessary to prove that there was an actual or concrete effect. Among critics of the Commission's approach, see NAZZINI, *The wood began to move: an essay on consumer welfare, evidence and burden of proof in Article 82 cases*, in *Eur. L. Rev.*, 2006, no. 31, p. 518, at 520. Among supporters see LOEWENTHAL, *The defence of 'Objective Justification'*, cit., p. 468; EILMANSBERGER, *How to Distinguish Good from bad Competition Under Article 82 EC: In Search of Clearer and More Coherent Standards for Anti-competitive Abuses*, in *CMLR*, 2005, no. 42, p. 136.

⁹²⁵ Note that this interpretation sprang from the wording of the former Art. 3(1)(g) EC, which has been excised from the Treaty after the amendments of the Lisbon Treaty. For cases underpinning this view, see *Continental Can*, para. 36; *Hoffmann-La Roche*, para. 89 et seq.; *Michelin I*, para. 71; *Irish Sugar*, para. 232. Also cf. NAZZINI, *The wood began to move*, cit., p. 522, who acknowledges that the full proof of a reduction of consumer welfare would risk rendering difficult the public and private enforcement of Article 82 EC.

going to materialise. The choice of a similar test for efficiencies creates symmetry within the provision that is capable of eliminating that imbalance between *ex ante* and *ex post* analysis.

Thus, prognostic analysis is suitable to guide the application of the test for efficiencies under both Articles 101 and 102 TFEU. Such test should be crafted as following.

First comes the proof of the existence of efficiencies.

The existence of an appreciable objective advantage, which is a necessary requirement to grant the exemption, might require a prospective analysis regarding the occurrence of the advantages associated with the restriction of parallel trade. Thus, it contains a prognostic element. And a prognosis can ultimately never be made with 100% certainty⁹²⁶. It follows that it should be considered sufficient for a finding of an appreciable objective advantage to arrive, on the basis of the arguments and evidence submitted, at the conviction that the occurrence of such appreciable objective advantage is likely in the light of actual experience⁹²⁷. In parallel trade cases, pharmaceutical companies should show that additional financial resources are going to be used in the completion of pending or planned R&D projects that aim at developing new and better drugs.

Secondly, defendants should prove the link between the anticompetitive behaviour and the efficiencies.

To this purpose, defendants should provide evidence of the effects that parallel trade has on their activity by disclosing relevant information, *inter alia*, in relation to (i) the amount of resources that price competition has dissipated as compared with the whole budget of the company, (ii) the amount of money that is invested in innovation at present and that is going to be invested in the future, (iii) the ongoing and the upcoming R&D projects, and (iv) the way these projects are going to be affected by the profit losses.

⁹²⁶ Cf. para. 247-249 of the *Glaxo* ruling. These premises are certainly correct. Hence, the fact that the Courts spoke of the 'possibility' that profits are translated into investments in innovation comes as a surprise.

⁹²⁷ Cf. para. 193-194 of the opinion of AG Trstenjac in the *Glaxo* appeal, where she affirmed that the fact that the Court of First Instance took as its basis whether the occurrence of the advantage is likely is not wrong in law *per se*.

So, for instance, a large impact of parallel trade on a company's profit could lead the judge to reasonably infer that, lacking enough resources, the company may drop some important planned high-risk projects that require substantial financial resources.

If the losses from parallel trade appear negligible compared to the budget of the company, no concern should rise about the company's R&D projects, even when this is going to involve a considerable investment.

Thirdly, defendants should prove that the restriction is indispensable for the attainment of the efficiencies.

This requirement is the more difficult one to be fulfilled. It is, in fact, very difficult to show that restrictions to parallel trade are the only available means to increase the rate of innovation and foster the competitiveness of a pharmaceutical firm. One may, in fact, object that, being R&D the key for the company's competitiveness, it should be the last part of the budget to be cut and that resources to conduct R&D can be drawn from other parts of the company's budget. For instance, marketing and administration expenses can be easily reduced without endangering the pace of innovation.

However, reference to the test applied in the *Guidelines on Art. 81(3) EC* helps overcome this hurdle. There the indispensability test is one of 'reasonable necessity' and not of 'strict necessity'⁹²⁸. This assessment is made by reference to the actual context in which the agreement operates and must take into account the structure of the market, the risk to which the economic activity is subject and the incentive for the parties. That means that also the concept of indispensability can be evaluated in a forward-looking perspective: not according to a criterion of perfect certainty, but scaled to the standard of likelihood⁹²⁹. And this should also apply in the context of Art. 102 TFEU.

Let us imagine, for instance, that the amount of resources devoted to R&D is not sufficient any longer for a company to be competitive in the market and it wishes to increase the R&D budget. Clearly, additional monetary resources would be very useful to this purpose.

Investments' growth may take place also if profits overall do not increase (for instance, by diminishing other parts of the budget). However, it may not occur to the same extent and with the same degree of certainty, as if it was supported by larger

⁹²⁸ See the *Guidelines on Art. 81(3) EC* at para. 73.

⁹²⁹ Cf. para. 220 of the opinion of AG Trstenjac in the *Glaxo* appeal.

profits. It follows that a corporate conduct that aims at achieving some efficiencies should be considered indispensable not only when the advantages pursued cannot be attained in any other way at all, but also when they cannot be brought about to the same extent, within the same period of time or with the same degree of certainty⁹³⁰.

Fourthly, the defendant should also demonstrate that competition in the market is unlikely to be entirely eliminated.

This requirement can be quite controversial too, as parallel trade is the only form of competition during patent validity. Therefore, the defendant should prove the likelihood that the completion of additional R&D projects leads to the highly probable introduction in the market of new products, which in turn is likely to increase *interbrand* competition and to outweigh the elimination of *intra-brand* competition.

Finally, defendants should demonstrate that the efficiencies that the restriction of parallel trade is expected to bring are likely to outweigh the negative effects on consumers in the market.

Altogether, it appears that the policy on parallel trade, whilst on the whole it remains well founded and deserves to be upheld, does need some refinement. The belief that parallel trade exerts competitive pressure on prices of original products has economic grounds also in the pharmaceutical market. The judgement of anticompetitiveness generally attributed to obstacles to parallel trade of pharmaceuticals should be thus upheld. More careful consideration of efficiencies eventually deriving from such restrictions is required, though. This statement cannot be interpreted as if the protection of innovation should legitimize any corporate strategy against parallel trade *per se*, as this would entail the paradoxical conclusion that innovation is a policy goal that is pursued irrespectively from the benefit that consumers can get from it. Pharmaceutical companies should, instead, prove the likelihood of such efficiencies from the restrictions through appropriate evidence showing that the recouped profits are going to finance R&D projects that would otherwise be abandoned; also, they should demonstrate that restrictions are indispensable, in the sense that those projects could not be retrieved through other means with the same degree of probability; they should finally prove such projects are going to lead to products that are highly beneficial for

⁹³⁰ Cf. para. 267-268 of the opinion of AG Trstenjac in the *Glaxo* appeal.

consumers and, thus, compensate the detriment they suffered for having paid prices higher than those they would have otherwise paid under parallel trade.

These considerations apply also at a more general level and provide useful insights in the context of the modernization of European competition law. In particular, with regards to Article 102 TFEU, I believe that the modernization process cannot lead to craft a test for efficiencies that transplants the American approach to monopolization into the provision sanctioning the abuse of dominant position. The theoretical baseline that shapes antitrust analysis in US is very different from the one adopted in the European system, as the former does not consider the protection of consumer welfare as a *condicio sine qua non*. The test for efficiencies under Art. 102 TFEU must be, on the contrary, necessarily in line with this 'philosophy': i) efficiencies must be substantiated and not just claimed; ii) efficiencies must be proved by the party that asserts their existence.

However, in order to take into account the forward-looking perspective that is inevitably inherent to this proof, the test cannot require the full substantiation of efficiencies. On the contrary, the Commission should be considered the test fulfilled when the proof is provided with a high degree of credibility.

4. Conclusions

This Chapter examined the procedural mechanisms that may facilitate the application of the balancing between the anticompetitive effects and the efficiencies in the antitrust assessment of corporate practices aimed at impeding parallel trade both under Article 101 and 102 TFEU.

The conducted analysis starts from the apparent inability of the Commission and the ECJ to integrate efficiency considerations in the antitrust assessment of corporate conducts restrictive of parallel trade and to balance them with the related anticompetitive effects under Article 102 TFEU. Such failure, which has triggered the criticism of a large part of the literature that calls for the adoption of the *rule of reason* in EU competition law, is partially linked to the formalism that to a certain extent still characterises the application of EU competition rules.

However, it is very much likely that judges feel uneasy about the prognostic analysis related to efficiency considerations. Such perspective clashes with the *ex post* categories that generally characterise the antitrust assessment. Thus, judges may find themselves with inappropriate instruments to perform an assessment of the efficiency claims purported by the defendant undertakings.

The examination of US case law shows that, even in a legal environment where the use of economic analysis in antitrust scrutiny has a longer tradition, the uncertain boundaries of the *rule of reason* - i.e. the difficulties entailed by a full-blown market analysis, and the elusiveness of efficiencies' measurement - are still putting obstacles to a clear-cut application of the rule. Transposed into our system, these findings, together with the little acquaintance of judges to this institution, may explain why European Courts have shown even more hostility towards the *rule of reason*.

The analysis of the relevant case law has also shown that, even when willing to look into efficiency arguments, European Courts were sceptical about them because the evidence presented by defendants was insufficient to perform a comprehensive analysis of the overall effects of their practices in the market.

In fact, especially when they are unfamiliar with economic concepts, Courts rather base their decision on presumptions built on legal analysis and on their accumulated experience.

It follows that the judgment of anticompetitiveness depends on the ability of each party to overcome these presumptions, or the *prima facie* evidence, and cast doubt on the facts alleged by their counterpart.

For instance, the Commission may adduce the anticompetitiveness of a restriction of parallel trade, based on the presumption that this has negative effects for consumers. The judge may use this *prima facie* evidence to infer the existence of a restriction to competition, unless defendants adduce contradicting evidence to show that the claimants' findings do not correspond to market reality. In particular, in this Chapter it has been envisaged the possibility for defendants to demonstrate, through appropriate evidence, that, even though the existence of a restriction cannot be disputed, as it is for restrictions by object, the effects of the impediment to parallel trade on the market are negligible.

These considerations led me to affirm the existence, within the first paragraph of Article 101 TFEU, of rebuttable presumption of anticompetitiveness. Such rebuttal also appears to be the most appropriate legal instrument that allows applying an effect-based approach to the EU provision sanctioning agreements restrictive of competition.

Two important issues were then analysed: the identification of the party that bears the burden of proof under Article 102 TFEU and the standard of proof that should be fulfilled, in order to discharge such burden, both under Articles 101 and 102 TFEU.

Attributing the burden of proof to parties according to their 'proximity' to the evidence and facts that constitute the object of the proof seems to be more appropriate on several grounds: claimants should prove the anticompetitive effects of a corporate practice and the defendant should provide the proof of the existence of efficiencies that outweigh the consumer harm.

This approach should guide also antitrust litigation in parallel trade cases: antitrust agencies should bear the burden of proving the anticompetitive effects of restrictions to parallel trade; symmetrically, defendants should prove that such restriction is outweighed by the derived efficiency gains. To this purpose, defendants, not only they have to prove the existence of efficiencies, but also they should provide evidence of their magnitude.

The law of evidence provides a useful instrument, inferential reasoning, which may be very useful to overcome the difficulty surrounding the proof of efficiency gains and their balancing with anticompetitive effects.

Efficiency considerations are necessarily based on a prognostic analysis. Thus, defendants should be allowed to discharge their burden of proof in relation to their existence on the basis of sufficient evidence that shows that such efficiencies are going to materialise with a very high degree of probability, according to the rule of preponderance of evidence.

This criterion should apply to the four filters contained in Article 101(3) TFEU and to the proportionality test under Article 102 TFEU. That means that the analysis of an anticompetitive agreement should be subject to a prognostic form of the notion of indispensability, as much as a flexible forward-looking proportionality test should apply

to abusive conducts from dominant companies, followed by balancing exercise between the efficiencies and the anticompetitive effects.

Should defendants fulfil this standard of proof and succeed in making their case about the increase in R&D activity to the benefit of consumers, the Commission bear the tactical burden of proof of disproving such evidence if they do not want to incur the risk that the judge infers the existence of efficiency gains.

The main contribution of this Chapter is the identification of procedural rules that are capable of solving the imbalance between *ex post* analysis of anticompetitive effects and *ex ante* examination of pro-competitive effects created by the integration of efficiency considerations into the antitrust analysis.

Given the practical difficulties related to a balancing between differently measured objects – the present reduction of savings against the future increased pharmaceutical innovation – and the risk of losing procedural economy, the conducted analysis envisaged the procedural mechanisms that should help judges overcome these hurdles and form a learned judgement that reflects market reality and is workable at the same time.

This proposal has important reflections also at a wider level, as it provides a paramount of integration of economic reasoning into antitrust analysis that is valid also outside the field of parallel trade. It ultimately attempted to answer the question of how to actually modernise EU competition law and be consistent with the *acquis communautaire*. In other words, it sought to provide European Courts with the appropriate legal tools to implement flexible, but clear-cut, rules that allow for an effect-based analysis of anticompetitive business practices. The proposed procedural rules are, in fact, simple and clear, so that compliance and enforcement is facilitated, and can be adapted to market reality, without that procedural economy is excessively sacrificed.

Conclusions and future research

This work analysed the current policy applied at a European level towards parallel trade of pharmaceuticals, with the view of responding the question of whether the enforcement of EU competition law rules against restrictions to this form of cross border trade in this sector should change to embrace a new policy.

Traditionally, restrictions to parallel trade were regarded negatively because they hampered *intra-brand* competition and impeded cross border trade. However, in recent judgments, Courts doubted that in a highly regulated environment parallel trade could bring lower prices for consumers and even feared that parallel trade could undermine pharmaceutical companies' incentives to innovate due to the erosion of their profits.

Such jurisprudential reversal has been certainly influenced by the so-called 'process of modernization of European competition law'. It is, in fact, apparent that EU competition law is currently undergoing an important stage of development, especially concerning the way Articles 101 and 102 TFEU are enforced. And the Commission and the European Courts are now urged to abandon formalism and to convey economic analysis into the legal scrutiny of anticompetitive business practices. A new awareness among legal scholars about the findings of economics on the welfare effects of parallel trade - especially in the long term - thus led to question the approach that the Commission and the European Courts had endorsed for almost forty years.

This *revirement* suggested that there might be scope for improvement in the current policy towards parallel trade. However, how and to what extent this change should have been performed appeared far from clear.

Against this backdrop, I analysed the impact that parallel trade of pharmaceuticals has on consumer welfare, both in a static and in a dynamic sense. This examination aimed at determining whether the current legal treatment of parallel trade

in pharmaceuticals pursued at a EU level reflects the findings of economic theory, whether there is scope for a change, and, if so, on what basis the latter should take place.

The analysis led me to reach the following conclusions:

1. The literature shows that price regulation does not impede price competition and that health care systems take appropriate measures in order for public finances to benefit from cheaper products. Parallel trade brings savings that accrue to consumers (or national health care services) in two ways: directly, when they buy parallel traded products, and indirectly, by exerting a competitive pressure on the price of original products.
2. The magnitude of these savings is, however, disputed. It depends on several issues: on the number of parallel traders operating in the importing markets, on general competition conditions in such markets, on firms' strategies that limit the ability of traders to compete on prices, but, most of all, on appropriate regulation that encourages market penetration from imported products.
3. Price negotiation procedures are the most efficient pass-through mechanisms that avoid the appropriation of savings from the traders. When parallel trade takes place in equilibrium, the latter plays like a threat that increases the bargaining power of authorities and insurance funds *vis-à-vis* the companies in price negotiations for domestic products. Thus, provided that appropriate regulation is in place, parallel trade serves allocative efficiency purposes.
4. There is no clear-cut evidence about the effect that parallel trade brings in terms of price harmonisation. My personal explanation of this ambiguous result is that regulation often pulls in a direction opposite to harmonisation. This does not mean that the baseline of the Commission's policy on parallel trade is flawed. It rather appears that parallel trade is one of the many tools used by the Commission to achieve 'negative harmonisation' in a market where 'positive harmonisation' is currently experiencing an *impasse*.

5. The strand of the EU case law that affirmed that antitrust analysis should take into account the legal and economic context in which the business practices are put in place, cannot be interpreted as if for an infringement of competition law rules to be alleged it is always necessary that final consumers are concretely deprived of the advantages of effective competition in terms of supply or price. Otherwise restrictions in the upstream market, which are unlikely to have immediate effects on consumers, would seldom be caught. In light of this, agreements restricting parallel trade of pharmaceuticals can be still presumed to have negative effects, albeit negligible, in the market and should be thus considered anticompetitive in their object, and not only in their effects when the latter are concretely demonstrated.
6. The relevant literature shows that the relationship between parallel trade, profitability and R&D incentives is ambiguous. It is therefore not possible to rely on the presumption that the extra money earned through the elimination of parallel trade always generates a higher level of innovation. On the contrary, a case-by-case analysis is necessary to ascertain the existence and the magnitude of these efficiencies.
7. Economics does not support a minimalist vision of antitrust law when innovation incentives are at stake. Thus, also under Article 102 TFEU, even in the absence of an exemption paragraph equivalent to Article 101(3) TFEU, the existence and magnitude of efficiencies gains related to abusive conducts of dominant companies should be proved and balanced against the negative effects deriving from foreclosure.
8. Attributing the burden of proof to parties according to their 'proximity' to the evidence and facts that constitute the object of the proof seems to be more appropriate both on substantial and on procedural grounds. It follows that under Article 102 TFEU, claimants should prove the anticompetitive effects of a corporate

conduct and the defendant should substantiate the existence of efficiencies that outweigh the consumer harm, along the style laid down by Article 101(3) TFEU.

9. The proof of efficiencies cannot be provided with certainty but it requires a prognosis. Thus the test for efficiencies should be flexible enough to account for a forward-looking perspective. Efficiency gains should be proven and reviewed in light of a standard of proof based on the preponderance of evidence, i.e. the defendant should produce sufficiently proved facts that allow the judge to infer the reasonable conclusion that the realization of efficiency gains from the anticompetitive business practice is more probable than not.
10. Restrictions to parallel trade may be allowed or may be prohibited, depending on the type of product involved, on the economic and legal environment in which the undertaking operates, on the competition conditions, and most of all, on the ability of parties to discharge their burden of proof in relation to the magnitude of savings for consumers and to the losses entailed by parallel trade and to the likelihood that these may jeopardize the level of investment in innovation.

This work has contributed to the competition law literature by showing that there are grounds, not to change, but to improve the current legal treatment towards parallel trade in pharmaceuticals. The enforcement pursued so far, in fact, overlooked the dynamic aspects of a policy that potentially gives rise to unlimited parallel trade. My claim, thus, is that in the assessment of restrictions to parallel trade account should be taken of the efficiencies eventually deriving by such restrictions in terms of increased innovation. This measurement should be afterwards weighed against the negative effects for consumers coming from the restrictions, in terms of reduced savings.

This claim goes along with the process of modernisation of EU competition law, whose supporters advocate for a more economic approach in the enforcement of competition provisions.

The embracement of this methodology is not, however, plain. The attempt to apply it to parallel trade showed that in so doing several tradeoffs arise: the practical

difficulties related to an effect-based approach increases the risk of losing procedural economy; also, the application of economic theory to EU competition law cannot leave aside the market integration goal.

Within this work, I tried to suggest a legal standard that helps judges form a judgement that reflects market reality, that is workable and that is line with the *acquis communautaire* at the same time. But I am aware that at this stage there is ample scope to further refine these proposals. Their further exploration is going to be the object of my future research.

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Dutch Summary

Het onderwerp van deze studie is de antitrustwetgeving in relatie tot de parallelhandel in farmaceutische producten.

De hernieuwde academische belangstelling voor dit vraagstuk is terug te voeren op de jurisprudentiële kentering die zich sinds kort voltrekt in het spoor van het proces dat wel de ‘modernisering van het Europese mededingingsrecht’ wordt genoemd.

Tot voor tien jaar was het beleid van Europese instellingen met betrekking tot parallelhandel helder, eenduidig en gebaseerd op een degelijke jurisprudentie, zowel wat betreft het vrije goederenverkeer als de vrije mededinging. Parallelhandelsbeperkingen werden als negatief ervaren om een tweetal complementaire redenen: zij vormden een obstakel niet alleen voor de merkenconcurrentie maar ook voor de grensoverschrijdende handel. Door belemmering van de vanouds daarmee verbonden prijsdruk waren parallelhandelsbeperkingen schadelijk voor de consument, en werkten deze de integratie van de interne markt tegen doordat de nationale markten langs de grenzen werden afgesloten.

Echter, sinds het *Bayer*-arrest zijn de visies van de Commissie en die van de rechtbanken binnen de Unie uiteen gaan lopen. Het waren met name de rechtbanken die op grond van de bevindingen van de economische theorie betwijfelden of de parallelhandel in farmaceutische producten inderdaad wel zo heilzaam zou zijn voor de consument. Om die reden stelden rechters zich op het standpunt dat alleen indien was aangetoond dat de handelwijzen van ondernemingen daadwerkelijk nadelig uitvielen voor de consument, deze als verboden moesten worden beschouwd. Ook werd geopperd rekening te houden met de mogelijkheid dat de praktijken van deze bedrijven, zelfs als deze tegen de mededingingsregels indruisten, gerechtvaardigd zouden kunnen worden uit efficiëntieoverwegingen, namelijk vanwege de prikkel tot innovatie bij farmaceutische bedrijven die hun verwachte winst in gevaar zien komen door de parallelhandel.

Deze ontwikkelingen volgend, rijst de vraag of er ruimte bestaat om veranderingen te bewerkstelligen in het beleid dat momenteel binnen de Unie wordt gevoerd op dit terrein, en op welke grondslag dit dan zou moeten geschieden.

Het moderniseringsproces dwingt de Commissie en de rechtbanken binnen de Unie er nu toe om in plaats van een buitensporig formalistische toepassing van het Europese mededingingsrecht te kiezen voor een meer economische benadering. Hoe dit moet worden vormgegeven is echter verre van duidelijk.

Met name moet worden geconstateerd dat de recente jurisprudentie niet echt een verhelderend licht werpt op de grenzen van dit nieuwe beleid voor de parallelhandel: wollige formuleringen, procedurele hinderpalen en ambigu bewijsmateriaal - om maar te zwijgen van het partijpolitieke debat waardoor maar al te vaak het dispuut tussen partijen wordt aangezwengeld - resulteerden in een aantal knelpunten die nader onderzoek verdienen.

Ook doet zich de noodzaak gevoelen deze ontwikkelingen op elkaar te laten aansluiten door middel van algemeen aanvaarde principes die zijn opgebouwd in veertig jaar jurisprudentie.

Hieruit volgt dat er momenteel nog voldoende ruimte is voor onderzoek en suggesties over hoe de nieuwe benadering van de parallelhandel moet worden vormgegeven.

De studie vangt aan met de analyse van de huidige situatie op de Europese farmaceutische markt in termen van het ontstane overschot, investeringen in onderzoek en ontwikkeling, en werkgelegenheid. Ook wordt gekeken naar de voortgang van het harmonisatieproces. Het beeld dat uit deze analyse naar voren komt is dat van een grote en groeiende markt die evenwel achterblijft bij die van de VS en Japan. De hoofdoorzaak van dit gebrek aan concurrentievermogen kan worden gezocht in de versnippering van de markt. Feitelijk geldt dat, ook al heeft de Europese Commissie een bepaalde vorm van gecentraliseerde regelgeving gecreëerd, de prijsvorming van geneesmiddelen en de daarmee verband houdende besluitvorming nog altijd het exclusieve domein zijn van de lidstaten, gelet op het feit dat de private uitgaven van de farmaceutische sector

grotendeels worden gefinancierd door nationale overheden. Door deze budgettaire gegevens neigen overheden er in feite toe vast te houden aan hun soevereiniteit op het terrein van de gezondheid. Hierdoor ontstaat een versnipperde markt, vooral op prijsniveau.

De hardnekkigheid waarmee prijslieden zich voordoen, heeft economische mogelijkheden geschapen voor arbitrage, oftewel parallelhandel. Vooral sinds het eind van de jaren negentig heeft deze zich ontwikkeld tot een bloeiende tak van industrie, met name in het Verenigd Koninkrijk, Zweden en Duitsland. De belangrijkste variabelen waaruit deze ontwikkeling kan worden verklaard, zijn de afname van de handelskosten dankzij de harmonisatie van de wetgeving inzake het vergunningstelsel voor het in de handel brengen van farmaceutische producten, de geneesmiddelenbewaking, de vereisten voor bijsluiters en verpakkingen van via parallelhandel op de markt gebrachte producten, alsook de nieuwe marktmogelijkheden die zich aandienen door de toetreding van nieuwe landen binnen de Unie (Spanje, Portugal, Zweden) en, niet in de laatste plaats, door het - reeds aangestipte - gunstige wettelijke klimaat.

Deze ontwikkeling bracht onrust teweeg bij de farmaceutische ondernemingen, die betwijfelden of parallelhandel binnen een strak gereguleerd kader inderdaad wel leidt tot lagere prijzen voor de consument, en zelfs vreesden dat parallelhandel hun prikkel tot innovatie zou kunnen ondergraven door afkalving van hun winsten.

In deze studie worden dan ook de volgende macrovragen geanalyseerd:

3. is de farmaceutische sector een 'speciale' sector waarin regelgeving zo diep is doorgedrongen dat parallelhandel geen enkele invloed heeft op de prijzen van oorspronkelijke producten;
4. heeft parallelhandel een schadelijk effect op farmaceutische innovatie?

Daarbij is de eerste vraag gesplitst in een drietal deelvragen:

- d. is prijsregulering van dien aard dat er geen concurrentie mogelijk is;
- e. levert parallelhandel in farmaceutische producten besparingen op voor de consument en de nationale gezondheidszorg;
- f. en van welke omvang zijn deze besparingseffecten?

Het antwoord op deze drie deelvragen kan worden gegeven door de kenmerken van de nationale regelgevingen voor de farmaceutische sector en de economische grondgedachten daarachter te onderzoeken in het raam van een verkenning die de belangrijkste Europese lidstaten bestrijkt, met bijzondere aandacht voor de landen waar import plaatsvindt: Zweden, Denemarken, het Verenigd Koninkrijk en Duitsland. Dit geldt met name voor de mechanismen die voeding geven aan de onderhandelingsprocedures tussen de instanties voor gezondheidszorg en farmaceutische bedrijven, een en ander om zicht te krijgen op de rol die de parallelhandel speelt met betrekking tot de onderhandelingsruimte van partijen. Deze verkenning wordt aangevuld met een analyse van de theoretische en empirische literatuur over het effect van parallelhandel op de prijzen van farmaceutische producten.

Uit deze analyse blijkt dat prijsregulering geen belemmering vormt voor prijsconcurrentie en er binnen de gezondheidszorg adequate maatregelen worden genomen om de prijsdaling van producten positief te laten uitwerken voor de overheidsfinanciën. Parallelhandel leidt tot besparingen die op twee manieren voordeel opleveren voor de consument (of de nationale gezondheidszorg): langs directe weg wanneer producten worden gekocht die via parallelhandel op de markt komen, en langs indirecte weg door concurrentiedruk uit te oefenen op de prijs van oorspronkelijke producten.

De meningen zijn echter verdeeld over de orde van grootte van deze besparingen. Deze is afhankelijk van verschillende factoren zoals het aantal partijen in de parallelhandel dat actief is op de importmarkten, de algemene concurrentieomstandigheden binnen deze markten, bedrijfsstrategieën die handelaren beperken in hun mogelijkheden om op prijs te concurreren, maar bovenal een adequate regelgeving die de marktpenetratie van geïmporteerde producten stimuleert.

Prijsonderhandelingsprocedures zijn het meest effectieve middel om besparingen te realiseren zonder partijen in de parallelhandel te belasten. Wanneer parallelhandel plaatsvindt in een evenwichtig kader, vormt dit een bedreigende factor die instanties en verzekeringsmaatschappijen ten opzichte van ondernemingen meer bewegingsruimte geeft in prijsonderhandelingen over binnenlandse producten. Mits sprake is van

adequate regelgeving, verhoogt parallelhandel derhalve de efficiëntie bij het realiseren van besparingen.

Er is geen duidelijk bewijs dat parallelhandel van invloed is op prijsharmonisatie. Een mogelijke verklaring daarvoor is dat regelgeving zich dikwijls beweegt in een richting die tegengesteld is aan harmonisatie. Dit wil niet zeggen dat de basis van het beleid van de Commissie inzake parallelhandel ondeugdelijk is. Eerder blijkt dat parallelhandel een van de vele instrumenten is die de Commissie gebruikt om 'negatieve harmonisatie' te bewerkstelligen in een markt waarin 'positieve harmonisatie' momenteel in een impasse verkeert.

Vervolgens worden de antitrustimplicaties van deze resultaten onderzocht: gegeven het feit dat de prijsvorming van geneesmiddelen niet geheel is afgeschermd van de mededingingsregels en -procedures, mag redelijkerwijs worden aangenomen dat parallelhandel, de regelgeving ten spijt, besparingen oplevert. Elke parallelhandelsbeperking blijft dan ook van mededingingsbeperkende aard, ongeacht de effecten daarvan. In dit geval is er reden om vast te houden aan de traditionele juridische visie op parallelhandelsbeperkingen, ook in de farmaceutische sector.

Vervolgens spitst de discussie zich toe op het bestaan van een relatie tussen parallelhandel en de prikkel bij farmaceutische bedrijven om te innoveren.

Uit de economische theorie blijkt dat de hoogte van de verwachte winst invloed kan hebben op de intensiteit van onderzoeks- en ontwikkelingsactiviteiten, namelijk op de hoeveelheid middelen die wordt geïnvesteerd in innovatie, en daarmee op het productieniveau van de onderneming. Deze kwestie bleef echter onderbelicht in de geraadpleegde arresten. Feit is dat toen door twee verschillende advocaten-generaal in het ene geval (advocaat-generaal Jacobs in de zaak *Syfait I*) uitgebreid werd betoogd dat sprake is van een dergelijke relatie in de antitrustanalyse en in het andere geval (advocaat-generaal Colomer in de zaak *Syfait II*) het bestaan van deze relatie even stellig werd ontkend, het Europese Hof van Justitie het gehele dispuut terzijde schoof en herclassificeerde als louter betrekking hebbend op winstvorming.

Het bestaan van een relatie tussen parallelhandel en farmaceutische innovatie is als zodanig geen onderzoekspunt. Echter, door deze relatie door te lichten zou inzicht kunnen worden verkregen in de mate waarin besparingseffecten een rol spelen in de antitrustanalyse.

De studie geeft tevens een overzicht van de economische literatuur die, van de schumpeteriaanse theorie van constructieve destructie tot de meest recente ontwikkelingen in de theorie van de industriële organisatie en in de empirische literatuur over de gezondheidseconomie, voorspellingen doet over het bestaan van een positieve correlatie tussen het verwachte rendement uit farmaceutische innovatie en het niveau van de investeringen in onderzoek en ontwikkeling.

Op deze grondslag wordt het innovatiepatroon in de geneesmiddelenindustrie verder onderzocht, met bijzondere aandacht voor de relatie tussen octrooien, winstvorming en de prikkel bij ondernemingen om te investeren in innovatie. Ook wordt de literatuur over de relatie tussen parallelhandel, winstvorming en innovatie geanalyseerd en besproken.

De desbetreffende literatuur laat zien dat de relatie tussen parallelhandel, rendement en de prikkel tot investering in onderzoek en ontwikkeling niet eenduidig is. Er moet dan ook niet van worden uitgegaan dat het extra geld dat wordt verdiend met de eliminatie van de parallelhandel altijd een hogere graad van innovatie oplevert. Integendeel, een analyse per individueel geval is noodzakelijk om het bestaan en de omvang van deze besparingseffecten te kunnen vaststellen.

Hieruit volgt dat de economische theorie geen steun biedt voor een minimalistische visie op de antitrustwetgeving voor zover het de prikkel tot innovatie betreft. Derhalve dient mede op grond van artikel 82 EG, ook bij afwezigheid van een vrijstellingsparagraaf in de trant van artikel 81(3) EG, het bestaan en de omvang van besparingseffecten die verband houden met laakbaar gedrag van ondernemingen met een dominante positie te worden aangetoond en afgewogen tegen de negatieve effecten van uitsluiting.

Marktanalyse kan niet ophouden op het punt waarop is vastgesteld dat er besparingen zijn gerealiseerd. Bij de analyse van de welzijnsimplicaties van activiteiten ter beperking van de parallelhandel moet een tweetal dimensies worden onderscheiden: het verlies bij een statische vorm van besparing en de winst bij een dynamische vorm van besparing. Deze facetten dienen volgens een bepaalde *rule of reason* te worden gemeten en tegen elkaar te worden afgewogen om zicht te krijgen op het algemene effect dat zij hebben in de markt.

Een dergelijke afweging vooronderstelt echter een volwaardige marktanalyse wier complexiteit de rechtbanken altijd omzichtig uit de weg zijn gegaan. De hindernissen die inherent zijn aan deze *rule of reason* doen zich gevoelen wanneer de effecten in de markt niet zo evident zijn en het onderzoek toekomstgericht is. In zaken op het gebied van de parallelhandel vormt dit laatste het meer problematische aspect: ofschoon de theoretische literatuur een relatie voorspelt tussen deze vorm van mededinging en innovatie, is er geen empirisch materiaal voorhanden ter staving daarvan.

Met andere woorden, de belangrijkste hinderpaal die marktanalyse te kostbaar zou kunnen maken is het leveren van het bewijs voor het bestaan en de omvang van besparingseffecten.

De studie richt zich vervolgens op de manieren waarop rechtbanken zich trachten te bevrijden uit de impasse die een volwaardige marktanalyse met zich meebrengt. De belangrijkste juridische instrumenten zijn vooronderstellingen en het leggen van de bewijslast bij partijen naargelang van de feiten en het oogmerk waarmee zij hun stellingen poneren. Daaruit volgt dat de uitkomst van een zaak wordt bepaald door het vermogen van partijen de rechter te overtuigen van het bestaan van dergelijke feiten. Dit houdt op zich weer in dat de wijze waarop de bewijslast door partijen wordt gedragen en de aard van de bewijsnorm in dit verband van cruciaal belang zijn.

De beste manier om te komen tot een analyse die recht doet aan de realiteit van de markt zonder de procedurele efficiëntie al te veel geweld aan te doen, is de bewijslast bij partijen te leggen naargelang van de graad waarin zij in directe relatie staan tot het

materiaal en de feiten die het bewijs vormen. Hieruit volgt dat de eiser op grond van Artikel 82 EG de concurrentieverstorende effecten van de handelwijzen van een onderneming dient aan te tonen en dat de verweerder volgens de lijnen die zijn uitgezet in Artikel 81(3) EG het bestaan van besparingseffecten die in het voordeel van de consument werken, dient te motiveren.

Toch blijft de vraag bestaan welke bewijsnorm dient te worden gehanteerd om het bestaan van besparingseffecten te kunnen vaststellen. Feit is dat er niet met zekerheid bewijs kan worden geleverd van besparingseffecten, maar dat daarvoor een prognose noodzakelijk is. Zodoende zouden de onderzoekscriteria voor besparingseffecten flexibel genoeg zijn voor een toekomstgerichte analyse. Besparingseffecten dienen te worden aangetoond en beoordeeld in het licht van een bewijsnorm op basis van de doorslaggevendheid van het bewijsmateriaal, dat wil zeggen dat de verweerder voldoende onderbouwde feiten dient aan te dragen waaruit de rechter in redelijkheid de conclusie kan trekken dat concurrentieverstorende bedrijfspraktijken naar alle waarschijnlijkheid leiden tot een hogere graad van efficiëntie.

Deze studie wil een bijdrage leveren aan de literatuur over het mededingingsrecht door aan te tonen dat er gronden zijn om veranderingen te bewerkstelligen in de huidige juridische visie op de parallelhandel in farmaceutische producten. In feite wordt bij de wetshandhaving tot dusver voorbijgegaan aan de dynamische aspecten van een beleid dat in potentie leidt tot onbeperkte parallelhandel. De stelling is dan ook dat bij de beoordeling van parallelhandelsbeperkingen rekening moet worden gehouden met besparingseffecten die uiteindelijk uit deze beperkingen resulteren in termen van intensievere innovatie. Deze resultaatmeting moet nadien worden afgewogen tegen de negatieve effecten die voor de consument resulteren uit deze beperkingen in termen van lagere besparingen.

Hieruit volgt dat parallelhandelsbeperkingen kunnen worden toegestaan dan wel kunnen worden verboden naargelang van het betreffende type product(en), de economische en wettelijke omstandigheden waaronder de onderneming opereert, de concurrentieverhoudingen, en bovenal de mogelijkheid van partijen om aan te tonen dat de consument aanzienlijke besparingen ten deel valt of dat parallelhandel leidt tot grote

verliezen die het niveau van de investeringen in innovatie bij farmaceutische bedrijven in gevaar zouden kunnen brengen.

Front cover picture: The spiral effectively symbolizes human progress. As much as progress is a relative concept, the spiral represents both evolution and involution, depending on the point of observation. This work is about pharmaceutical innovation, which can be at the same time highly beneficial and very harmful for human wellbeing, depending on the purposes for which it is conducted. My drawing was inspired by some of Pierre Alechinsky's paintings.