Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective

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Abstract

As patents grant monopolies, the patent system has a considerable impact on markets. When corporations use certain patent strategies, social welfare can be damaged. This article focuses on how corporations use patent strategies in the biomedical sector. Strategic patenting makes it possible to extend monopolies beyond the designated period and block competitors. Access to fundamental research can be restricted. Patients are disadvantaged by high monopoly prices for drugs, which can mean exclusion from treatment. It is argued here that as biomedical technologies are so vital to the welfare of people, and that in some cases are literally a matter of life or death for patients, this area of technology should not be controlled by private companies through their patent monopolies. The whole biomedical sector should be taken out of the ambit of the patent system.

Policy Implications

- Governments need to recognise that certain types of invention, which are vital to social welfare, should be exempt from patenting, as patents award a monopoly.
- There is now clear evidence that pharmaceutical companies manipulate the patent system in order to use the monopoly to dominate markets and control access to research. Biomedical innovations should not be patented.
- A partial dismantling of the patent system is necessary to remove biomedical inventions.
- Practical steps: Patents on biomedical technology need to be phased out and no new patents granted.
- Practical steps: a robust and stable system of remuneration by public funding must be implemented.

Patent system manipulation

The patent system has become the context in which many innovations reach society. Patented inventions are everywhere: from everyday kitchen items like coffee machines and cleaning products to inventions that have a significant global impact, such as advances in medicinal drugs, systems to purify water and increasing the harvest from crops. In return for disclosing the information necessary for others 'skilled in the art' to make the invention, inventors of new and useful products and processes are rewarded with a monopoly, usually for 20 years. The patent is the legal instrument that protects that monopoly.

The ideology behind the development of the patent system was to create a win-win situation: increased prosperity for inventors as they could make use of their market monopoly position to establish their reputation, recover research costs and make a profit, and increased prosperity and welfare for society which could benefit from these new inventions. But does the patent system deliver a win-win result?

The patent application must describe how to make the invention and this information is published during the patent application process. Typically applicants will keep this information to the absolute minimum necessary in order to obtain the patent. Patenting only selected aspects of an invention can obscure the overall configuration of the invention. The use by corporations of patents as strategic tools has further undermined the original goals of the patent system and skewered the patent bargain in favour of the inventor. Biomedical innovations are vital to healthcare: they should not be controlled by private companies through patent monopolies.

1. The patent monopoly

The monopoly awarded to the patentee gives the patent holder the right to exclude all others from making, using, selling, offering to sell, keeping the product or importing anything covered by the patent claims in all countries where patent protection has been granted. In general, this exclusionary right persists (if renewal fees are paid) until the expiration of the patent protection period. This yields the patent owner significant power.

Even Adam Smith, who considered most exclusive privileges to be detrimental to society, did not consider this to be the case with respect to patent monopolies. These, Smith considered, 'are harmless enough':

> For if the legislature should appoint pecuniary rewards for the inventors of new machines, etc.,

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> they would hardly ever be so precisely proportioned to the merit of the invention as this is. For here, if the invention be good and such as is profitable to mankind, he will probably make a fortune by it; but if it be of no value he also will reap no benefit. (Smith, 1762-3, p. 83)

This too was Jeremy Bentham's justification of the patent system: the utilitarian ground of efficiency. An exclusive privilege, Bentham argued, is 'of all rewards the best proportioned' (Bentham, 1843, p. 71). If the invention were not useful there would be no reward; if it was useful then the reward would be proportionate to its utility.

2. The distortion of the patent system: the patent as a strategic tool

As the economy has largely shifted from industrial manufacturing to high-tech, life science and information processing industries, intellectual property has become more and more important. Corporations have become increasingly aware of the potential of the patent, not just as a shield to protect against imitation, but as a strategic tool to block competition and dominate markets. Patents have come to have a broader strategic function in which innovation may only play a small part. Although many patents do not produce any income: 'In terms of strategy, though, the patent can be much more valuable' (Macdonald, 2004, p. 143).

Patent strategy is directly related to the business context. The Carnegie Mellon Survey of the US manufacturing sector in 1994 revealed that firms often used patents as strategic tools, rather than as simply a means of protecting an invention from wrongful imitation (Cohen et al., 2000). In their examination of motives to patent, Blind et al. (2009) recognised that, although protection from imitation was still the most important factor, 'the importance of the strategic motives to patent are confirmed' (Blind et al., 2006, p. 671).

Patent strategies

The decision to patent has become in part uncoupled from the original core purpose of the patent: to protect an invention from unfair imitation by other market participants. Larger firms, with the capital assets to pay for the cost of patenting, use their patent portfolios strategically.

Patents have become useful as bargaining chips; they provide leverage. Large patent portfolios are a means to get access to important co-operations or cross-licensing arrangements (Blind et al., 2009, p. 431). Yet while building the portfolio requires enormous legal costs, it contributes little to research incentives. Furthermore, these portfolios can be used not just to oblige competitors to take licences, but also the terms of these licences can restrict competitors to certain areas of technology (Barton, 2000).

Larger firms can afford to play the 'wrap around' strategy. Instead of applying for a single patent to cover an invention, other patents are filed around the main patent. These related patents lock down the discrete features of an invention. The tactic hinders entry to the market. Competitors will be put to time, effort and cost to fight their way through all the relevant patents covering the technology. Furthermore, the chance that the competitor's invention may infringe one of the many claims in one of the many patents is high. Not only can damages be awarded for infringement, but also an injunction. Injunctions prevent the party accused of infringement from producing any products that require the use of the technology covered by the infringed patent and all infringing products are removed from the market.

Patents may be used simply to block competitors. Using a patent as a blocking strategy is common practice (Neuhäusler, 2012). Defensive blocking is used to protect a firm's own freedom to operate: it does not want to be shut out by the patents of its rivals. An offensive blocking strategy is where patents are filed to cover products or processes that the firm *does not* intend to practice itself, but which could be viable alternatives to competitors. By patenting all conceivable alternatives, research by competitors that might threaten their own technological lead can be thwarted. As in general a patentee is under no obligation to license out its technology to another, the strategy can deter market entry or new product launch.

This offensive blocking of competitors by means of patents, 'is clearly a case of the patent system being used for purposes other than for which it was originally intended' (Blind, 2009, p. 436). However, both defensive and offensive blocking should be a policy concern, as they can reduce economic efficiency. Defensive patenting increases cost to firms without necessarily producing any benefit and offensive patenting can reduce technological progress and increase consumer costs by reducing competition (Thumm, 2004, p. 533).

Using data from a large-scale survey of patent applications, Torrisi discovered that a substantial share of patents remained unused and a substantial number of patent applications were filed to block other patents. There were institutional differences; there were more unused patents in Japan and the EU than in the USA. Although cautious to make generalisations about unused patents, as some unused patents are there to ensure freedom to operate or simply because of management inefficiency, Torrisi et al. did conclude that: '[o]ur results highlight that there might be substantial benefits that patent owners draw from being able to keep patent rights unused. These would have to be balanced against possible harm imposed on other economic agents' (Torrisi et al., 2016; , p. 1384).

These strategies show a disconnect with the original purpose of the patent system. Patent strategies impact on innovation, and this in turn impacts on society. Concern was already expressed quite forcibly some years ago by Turner:

> Surely when the framers of the [US] Constitution empowered Congress to grant monopolies to 'promote the progress of science and the useful arts', they did not envision the beneficiaries of this grant would use it to bury new technologies to protect

> market share or capital investments. (Turner, 1998, p.209)

Administrative failures

Patent offices have been struggling to cope with the increasing number of patent applications: in 2017, more than 3 million patent applications were filed worldwide (WIPO, 2018). This influx has resulted in substantial application backlogs, with an increasingly long time between the patent filing and the patent grant: five years is not unusual. Complaints of poor quality control have been made concerning the US Patent and Trademark Office as well as the European Patent Office (Abbott, 2004; Mabey, 2010). The WIPO recognised a consistent upward trend in patent filings is putting patent offices under enormous pressure (WIPO, 2017, p. 13).

Why are these administrative failings dangerous from a societal perspective? Patents grant a monopoly that can impact innovative processes for 20 years or more. Patents have been granted that should not have been granted. When an overly broad patent is granted, this can block further innovation by others. Broad patents may mean that access to vital research is not available because the results of that research are covered by patent claims. In particular, broad basic patents on fundamental research can block and deter follow-on research. The incentive to innovate is reduced (Barton, 2000; Henry and Stiglitz, 2010).[1] Back in 1966, the societal implication of overly broad grants was expressed clearly by the US Supreme Court when it rejected a broad claim covering a group of chemicals: 'Such a patent may confer power to block off whole areas of scientific development without compensating benefits to the public.'[2]

3. The exclusionary effects of patent system manipulation: the biomedical sector

Biotechnical inventions have a fundamental impact on healthcare, with applications in medical diagnosis, research tools and pharmaceutical drugs. Knowledge has become a very valuable asset. Its commercialisation opens up lucrative business opportunities. The strategic use of patents in the biomedical sector is intended to protect those business interests. However, those patent strategies have societal repercussions.

Intellectual property rights and biomedical research

A common argument is that there is a distinction between fundamental research and the application of that research; fundamental research should remain in the public domain, while applications can be the province of patents. That is a misguided distinction. As Eisenberg and Nelson point out, the conventional view that basic research is a public enterprise while applied technology is a private enterprise conducted in the hope of earning profits, ignores the ways in which basic science and applied technology can frequently overlap: public and private interest may then conflict (Eisenberg and Nelson, 2002). Fundamental research can become proprietary.

A patent should only give protection to an invention. According to US law, this invention must be 'useful' (35 US Code, Section 101) and the European Patent Convention 1973 (EPC) requires that an invention is capable of 'industrial application' (Art. 52, EPC). Patent law therefore mandates that there must be a practical application. Consequently, a patent does not extend to a discovery, the terrain of fundamental research, as this is explicitly excluded from patentability.

The line between 'discovery' and 'invention' has, however, become exceedingly thin, if non-existent, with respect to molecular technology. The current position with regard to genes and DNA sequences in effect marks a departure from the traditional doctrine that excluded discoveries from patentability. Genes are not new products; they exist in nature and therefore cannot be invented. Yet today, genes and gene sequences are patented as inventions, being regarded as 'products'. Even if a use of the gene or sequence is speculative, if a use is plausible at the time the patent is filed the utility requirement is fulfilled.

The EPC was amended to be brought into line with the terms of the European Directive on the legal protection of biotechnological inventions. This Directive states:

> An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, *even if the structure of that element is identical to that of a natural element*.[3]

Taking an apparently different track, in 2013 the US Supreme Court stated that the mere act of isolating a gene from its surrounding genetic material was not an act of invention. The court did accept synthetic cDNA as patentable, as this was created in the laboratory.[4] Scientists have voiced concern that what is often patented has not so much been produced but rather discovered, and is human genetic information rather than an invention (see for a summary of some of these arguments Bergel, 2015).

These developments in patent law have created a very real danger: researchers could be barred from accessing fundamental research, which in turn could hinder new knowledge and further innovation. Back in 1998, Heller and Eisenberg warned policy makers to be alert: more upstream rights could block downstream innovation. In this way, the private ownership of biomedical research could lead to fewer useful products for improving human health (Heller and Eisenberg, 1998). If genes and DNA sequences are patent protected, then the patent owner has the right to exclude all others from using that technology. This breach of the discovery/invention distinction is symptomatic of the expansion of patentable subject matter at a global level, extending property claims deep into biology and limiting the scope for accessible treatment and future research (David and Halbert, 2017).

The danger of private ownership of fundamental research became apparent with the commencement of the Human

Genome Project in the 1990s. The project turned into a struggle between publically funded scientists and private companies. Publically funded scientists worked hard to ensure that all their research would remain in the public domain and therefore published all their findings to prevent patent applications blocking access to research. Their attempts were not always successful. For example, one day before Mike Stratton was due to publish his paper on cancer genes in the journal *Nature* in 1995, the private company Myriad Genetics applied for a patent on BRCA1 and BRCA2, which were associated with breast cancer. The patents allowed it to charge for tests at a cost of $2,500 per patient. Licences for the use of its simpler tests for breast cancer by other labs cost several hundred dollars per patient, a cost that, given the nature of the American healthcare system, meant the test was not available for all female patients in the USA. By 2015, Myriad was worth over $3bn (Pollock, 2018, p. 64).

The leading patent offices, those in the USA, Europe and Japan, have granted thousands of patents claiming human DNA. Patent thickets have already emerged, with many of the sequences claimed in patents overlapping. For example, a gene with 15 exons could have a separate patent on each exon; there could be a claim on the complete sequence, as well as a claim on the promoter sequence. One illustration of the complexity of these overlapping patents is the difficulties encountered by researchers from the PATH foundation when they were trying to develop a malaria vaccine: they had to negotiate research use for the 39 different patents involved (Thomas et al., 2002). Thomas also points to the dangers of broad patents grants: 'Furthermore, because the majority of patents covering DNA sequences are what are termed per se claims, the applicant, in making the first claim, gains the right to all uses, including those that are as yet undiscovered' and '[a]n excessively broad patent that contains claims to all conceivable diagnostic tests creates a monopoly, such that there is little incentive to develop improved tests' (Thomas et al., 2002, pp. 1186–1187).

Some commentators are not convinced that patent monopolies have hindered follow-up research. Clark states that there is a lack of evidence that intellectual property protection measures have had a significant negative impact on academic biomedical research: 'In the face of no empirical evidence, the myth that patents inhibit biomedical research, publication and dissemination of knowledge is promulgated' (Clark, 2011, pp. 79–80). Caulfield et al. (2006), while acknowledging that there have been good reasons for concern, like Clark concludes 'the feared problems have not widely manifested'. However, Caulfield et al.'s research does point to one important exception: gene patents that cover a diagnostic test. Patent owners have asserted exclusivity or licence terms 'widely viewed as inappropriate' (Caulfield et al., 2006;, pp. 1892–1893).

The assertion of 'no empirical evidence' is certainly too strong. Examples of problematic access to fundamental technology do bubble to the surface. One such example is the position regarding zinc-finger proteins (ZFPs), which can bind almost all DNA sequences. The ZFP patent portfolio has been dominated by one firm in particular: Sangamo. Researchers found that Sangamo was highly selective in its choice of collaborators. Academic scientists therefore often took the risk of using the technology without a licence, hoping that Sangamo would not sue academics. However, even this did not solve the problem. The patents did not disclose all the necessary information. Vital knowledge remained in the Sangamo database and design rule set. Without this proprietary information scientists could not practice the claimed invention: 'More complete patent disclosure might also have obviated the need to generate various open science alternatives to the Sangamo platform' (Chandrasekharan et al., 2009).

These examples should not be dismissed as 'anecdotes'; they are important. They indicate that access by academics to fundamental research can be hampered. Nor do we know how many innovative start-ups or small firms have been hindered by blocking patents, too expensive licences, restrictive licence terms or threats of being sued for patent infringement. An assessment of the situation cannot be made simply by looking at litigated cases: litigated cases are always the tip of the iceberg.

The pharmaceutical industry

Pharma companies stress that medicinal drugs take years of research and development. The venture is also far from risk free: the drug may be a failure either because clinical trials fail, so approval is not given, or because it is not a commercial success. Based on a study at the Tufts Center, it has been estimated that the time needed for the development of a new drug, from initial stages through to approval, takes on average 11.8 years and will cost in the range of $802 million to $1.8 billion (DiMasi et al., 2003; Barazza, 2014). It is these costs, the industry argues, that justify the high price of the drugs. In a critique of the methodology used by the Tufts Center to explain a cost of $802 million, and the lack of public access to the data used for the study, Light and Warburton argue that such estimates should be treated with scepticism; these are 'mythical costs' to try to justify the high prices of drugs (Light and Warburton, 2011).

What is clear is that if the drug survives the patent process and the authorisation process, and turns out to be a blockbuster, huge profits can be reaped. For example, the Danish company Lundbeck grew rapidly in the 1990s primarily because of its anti-depression drug, Citalopram. Citalopram alone accounted for around 80 per cent of the company's sales by the end of the twentieth century, with large sales figures for Europe and the USA at that time bringing in kr. 720 million.[5] Similarly, Losec, a medicine for stomach ulcers, was so successful that it is estimated to have brought in between $15–30 billion for AstraZeneca, making AstraZeneca one of the largest global pharmaceutical companies (Granstrand and Tietze, 2014).

Many pharmaceutical companies have not been reticent to exert their monopoly position to ensure market dominance and satisfy their investors. However, with some

exceptions, a patent expires after 20 years. When the patent expires, the market for the drug opens up to generic drug companies. These generic drug manufacturers have not had to sustain the costs in development of the original brand manufacturers. This means that they can sell generic medicines considerably cheaper: on average 25% lower than the price of the brand drugs at the time of generic entry and 40% lower two years after entry. The share of the market by generic companies after two years is estimated at 45% (European Commission, 2009: paragraph 1560). It is not surprising, given the huge profits that a blockbuster drug can make for a company, that pharma companies will look to manipulate the patent system to prolong their market dominance.

The brand name drug companies have various strategies they can employ. They can wrap many patents around the original patent, resulting in patent clusters. Patents are filed for certain specific aspects of a single product, such as dosing, delivery systems and combinations. For example, depending on the medicine, the medicine may come with a proprietary inhaler or injector that is integrated into the product. Yet these combinations will be patented separately. Consequently, even after all the patents on the medicine expire, the remaining patents on the associated device, or parts of the device, can be sufficient to prevent generic entry (Beall et al., 2016).

The 'evergreening' strategy is a form of blocking mainly used in the pharmaceutical industry. As the patent system allows improvements and additions to be patented, inventions that are really just slight modifications of the old drug are patented. These secondary patents, usually filed just before the patent on the original drug expires and competition can start, each gain 20 years protection. The weaker patents are an attempt to prolong the patent protection of the original, much stronger patent. Although from the technical perspective only minor improvements may be involved, from an economic perspective these can be significant as patents for incremental improvement processes can be filed almost continually. Building and maintaining a patent network of new medical applications, improvements and substitutions is an effective evergreening strategy, also cutting down possibilities for 'invent around' attempts (Granstrand and Tietze, 2014). As Dwivedi et al. (2010, p. 324) notes: 'While most of these evergreening strategies conform to the letter of the law, very often they seem to undermine the spirit in which patent laws were created'.

Even when generic products do enter the market, patients will not always opt for the cheaper drug. Why? What should not be underestimated is the scope and intensity of the marketing campaigns of the brand name companies. Their aim is to ensure that patients switch to the second generation product by convincing them that the newer version is worth the extra money. Strategies include convincing marketing authorisation and pricing and reimbursement bodies, as well as doctors, that the generic product is less safe, less effective or of inferior quality (European Commission, 2009).

Another major strategy used by brand name companies is the so-called 'pay-for-delay' practice. This practice was one of the concerns that prompted the European Commission to launch its enquiry into the pharmaceutical industry in 2008. In a 'pay-for-delay' agreement, a generic manufacturer agrees to delay entry to the market in exchange for a value transfer. Instead of the claimant brand name company demanding damages from the generic company for infringement of its existing secondary patents, in reverse payment settlements the one accused of infringement is the one receiving payment. The generic company is basically paid simply to keep out of the patent owner's market, often also agreeing not to challenge the validity of the claimant's (secondary) patents. The parties can reach a settlement by in effect sharing part of the monopoly profit, the consequence being that prices are kept high (Choi et al., 2014).

Following the sector enquiry, the European Commission issued a number of decisions against brand name companies and those generic companies that had entered into agreements with them. In 2013, Lundbeck and four generic firms were fined €145 million, a decision confirmed by the General Court of the European Union in 2016: the agreement was *per se* illegal being a violation of EU competition law. Other pharma companies fined included Johnson & Johnson, Novartis and Servier. The Final Report by the European Commission observed: 'The additional costs caused by delays to generic entry can be very significant for the public health budgets and ultimately the consumer.' (European Commission, 2009, p. 1558).

These 'pay-for-delay' agreements have also been challenged in the USA. The Federal Trade Commission (FTC) was of the opinion that these agreements were infringements of competition law and that '[a]lthough both the brand name companies and generic firms are better off with such settlements, consumers lose the possibility of earlier generic entry'.[6] In the lawsuit the FTC brought against Actavis for agreeing to delay bringing its version of Solvay's AndroGel to market, the US Supreme Court did not categorise the agreement as *per se* illegal. It mandated that a 'rule of reason' approach should be used, reviewing such settlements on a case by case basis.[7] The FTC has remained committed to scrutinising pay-for-delay agreements.

The monopoly position has made it possible for pharma companies to charge high prices for their medicines. At times this has caused public outrage, particularly when the price of a drug rose considerably from one day to another. For example, the price of tablets containing the drug Daraprim, when acquired by Turing Pharmaceuticals, rose from $13.50 a tablet to $750 a tablet overnight, bringing the cost of treatment per annum for some patients to thousands of dollars. Cycloserine increased in price from $500 for 30 pills to $10,800 for 30 pills after it was acquired by Rodelis Therapeutics (Pollack, 2015).

The high price of some medications has caused concern in Europe too. Governments struggle in their negotiations with pharma companies. In the Netherlands, the government has expressed its dissatisfaction with the current situation in a report. One of the problems highlighted in this report is the patent monopoly:

> Another important cause of high prices is the extensive protection manufacturers obtain on their patents. This process was originally intended to stimulate innovation, but is currently used by the industry to maintain a monopoly – and thereby a high price - on new medications for as long as possible.

This has a significant impact on society:

> The way the pharmaceutical market works has led to innovation and new medicines which are extremely valuable for patients. But those patients, and in fact all Dutch people who pay insurance premiums, find themselves at a disadvantage because pharmaceutical companies have a monopoly when it comes to new medicines. Therefore, we need to seek a healthy balance between rewarding innovation and the affordability of medicinal care. (Ministry of Public Health, Welfare and Sport, the Netherlands, 2016: pp. 4, 13)

The price of medicines has become a matter of critical importance even for wealthier countries.

The pharmaceutical industry and developing countries

However, perhaps the largest group of patients excluded from the potential benefits of biomedical research are those in developing countries. Exclusion can originate in the very choice of which drugs pharma companies decide to develop. Their research tends to be market orientated. By the end of the twentieth century, only about one per cent of newly developed drugs were for tropical diseases, such as African sleeping sickness, dengue fever and leishmaniosis (Maurer et al., 2004). Companies aim to make a profit and satisfy shareholders. It is therefore not surprising that expensive R&D will be more geared up to the types of illnesses prevalent in developed countries, as these countries have more capital resources to pay the price for these drugs. As Stiglitz (2006: p. 1279) observed: 'Poor people cannot afford drugs, and drug companies make investments that yield the highest returns'.

Not only does the choice of which drug is developed significantly impact on developing countries: the imposition of stringent requirements for intellectual property protection under the TRIPS agreement is also a factor in access to treatment. This was made explicit in the World Bank report:

> Nothing is more controversial in TRIPS. It is conceivable that patent protection will increase incentives for R&D into treatments for diseases of particular concern to poor countries. However because purchasing power is so limited in the poorest countries, there is little reason to expect a significant boost in such R&D. Accordingly, many developing countries see little potential benefit from introducing patents. In contrast, potential costs could be significant. (World Bank, 2001, p. 137)

The Doha Declaration on the TRIPS Agreement in 2001 did confirm the right of countries to use compulsory licences to gain access to medicines. By issuing a compulsory licence, the government gives permission to a third party to produce the patented product or process without the consent of the patent owner. The drug so produced is much cheaper than the brand name drug at the monopoly price. This right has already been exercised on various occasions, for example by the South African authorities in 2003 in order to create more general access to AIDS medicines.

Does compulsory licensing therefore deal with any negative impact of TRIPS for developing countries, given that TRIPS hindered the use of cheaper, domestic generic versions of brand name patented drugs? Compulsory licensing is not without undesirable side effects. It has the potential to reduce incentives for pharma companies to innovate, and for tensions between the government authorising the compulsory licences and the governments of the patentees, which can have both political and economic implications (Flynn et al., 2009; Reichman, 2009). There have been indications that the USA is not entirely at ease when states order compulsory licensing of American pharmaceuticals (Nagan et al., 2017). Compulsory licensing may be an instrument to alleviate the strictures of the patent system to some extent, but it is not the entire solution.

4. Alternatives to the current patent system

Should the biomedical sector be excluded from the patent system? The patent system 'one size fits all' construction is a legacy from an industrial age. Trying to fit the inventions of the information age, with its software technology and life sciences, into a system of the industrial age is, at the least, problematic. Some consider that it must fail (Bessen and Meurer, 2008). Thurow too advocates that the patent system should not be the same for all types of innovation, but instead be adapted to fit the needs of different industries, types of knowledge and inventors. Nonetheless, he still believes stronger monopoly rights is the way forward: 'In our modern economies, private monopoly power should be less worrisome than it was when our patent system was originally set up' (Thurow, 1997: p. 101). Certainly with respect to the biomedical sector, this sweeping assertion is rather hard to understand.

The patent reform approach

There have been calls for the reform of the patent system. Reform is needed to redress administrative shortcomings, requiring more thorough and stringent patent examination and ensuring bad or overly broad patents are not awarded. Suggestions have also been made for a review of the patent duration period, which in many jurisdictions is standardly 20 years. Posner argues that intellectual property presents a more serious problem of rent seeking (an excess of revenue over cost) than physical property does. Limiting the duration of the property right would be one way of cutting down its

value to the owner and thereby reducing the amount of rent seeking (Posner, 2002).

The abolition of intellectual property rights

There are those who dismiss the whole concept of intellectual property as antiquated, economically inefficient and detrimental to consumers. David (2017) contends that in an era of digital networks, characterised by rapid and global knowledge dissemination, the public good is best served by a sharing-based economy, rather than a system of intellectual property protection designed to limit market entry.

Boldrin and Levine argue that patents need to be abolished entirely in favour of other legal instruments that are less open to lobbying and rent seeking. Looking at the pharmaceutical sector, they concluded that the current system is not working well: '[t]here are a number of ways to reduce the risks and cost of developing new drugs, rather than just trying to ratchet up patent protection' (Boldrin and Levine, 2013, p. 19). Like Pollock (2018), they advocate an incremental dismantling of the patent system, by gradually decreasing patent monopolies. The dismantling of the entire system of intellectual property is the ultimate goal.

State funding, rewards and prizes

State funding for medical research already exists to some extent, both directly and indirectly. Looking at the USA, Light and Warburton (2011, p. 41) suggest that: 'A reasonable guess is that half of corporate R&D expenses are paid for by taxpayers over the long term'. They also point out that basic research, which may lay the foundations for the later development of specific drugs, is also regularly carried out at universities or government research labs.

Stiglitz (2006) advocated the introduction of a medical prize fund. The fund would be structured so as to give large rewards for cures or vaccines for diseases like malaria that affect millions, and smaller rewards for drugs that are similar to existing drugs but may have slightly different side effects. These prizes could be funded by governments in advanced countries. In the case of diseases that afflict developing countries, the funding could be part of development assistance. The intellectual property would be made available to generic drug companies.

The idea of publically funded rewards, rather than a monopoly, is not new. In Britain, Parliament granted substantial sums of money as rewards to certain individual inventors in the period 1750–1825. For example Edward Jenner received a grant from Parliament of £10,000 in 1802 and a further £20,000 five years later for his research into the smallpox vaccine. Many organisations also had reward schemes (MacLeod, 1988). Reward systems were seen as an alternative method for encouraging innovation. However, these initiatives were ad hoc, rather than a coherent, comprehensive system of public funding.

If the patent monopoly is to be removed, then a stable system of public funding would have to be implemented. It could counter the two types of losses patent monopolies create. Consumers have to pay a higher price because the patent owner sells the product at the monopoly price. But there is also a 'deadweight cost': there are fewer transactions because of the high cost. From an economic perspective a deadweight loss is inefficient. Shavell and Van Ypersele (2001) experimented by developing a model of innovation to show the comparison between reward systems and patent systems, in which the reward system was shown to be superior to the patent. The reward gave inventors the incentive to innovate, and there was no deadweight loss from monopoly pricing. They did acknowledge in their analysis, however, that the government's knowledge about the social value of innovations was important to the performance of the reward system. The presumption was that the government could obtain the necessary information about demand and gain sufficient information on sales data. In a reward system, drugs would be much cheaper and more widely available, leading to significant increases in consumer welfare.

Pollock (2018) argues that in order to present a viable alternative to the patent system, remuneration rights must be both technically and politically feasible. He argues that such rights are technically feasible because the infrastructure is already in place: we already determine who owns innovations, we already share rights between multiple innovators, and paying creators from a remuneration rights fund would be fairly straightforward in accordance with the usage and value created by the innovations (to be overseen by independent assessors). Political feasibility would require adequate and sustainable financing of the funds, and a robust governance structure and legal status for the funds. Again, he believes these requirements can be fulfilled because the intellectual property regime stands model for the necessary mechanisms; global, international agreements. The remuneration framework is compatible with the legal frameworks that have been developed by TRIPS, which also has built in flexibilities. However, practicalities dictate that there would have to be a transition period. Older patents would expire and no new patents would be granted.

Pollock (2018) does refer to a potential impediment: it would require the existing monopoly holders to support the change, or at least not actively oppose it. For the pharma companies, this would mean the USA setting up a remuneration fund for medicines that would have to be as richly endowed as the total amount of money spent on patent medicines today, so that the companies need not lose out.

This potential impediment should not be underestimated. Pharmaceutical lobbies are immensely influential in the USA. Pharma companies spend by far the most on lobbying in the USA (Center for Responsive Politics, 2018). The right to lobby is protected by the US Constitution under the 'right to petition the government' in the first amendment. Lobbyists have a responsibility to inform lawmakers on the issues of their expertise in order to help Congress make informed decisions. They may financially support political candidates who back their positions, resulting in an industry amounting to billions of dollars every year. Since the early 2000s corporate lobbying expenditures have consistently exceeded the

combined House-Senate budget (Drutman, 2015). Pharmaceutical lobbying has also had an impact on federal healthcare legislation (Burcescu, 2016). Pharmaceutical lobbying will be a hurdle to any attempt to implement a law transferring biomedical research and drug development to a remuneration system rather than a patent monopoly system.

5. Evaluating the patent system and alternatives with respect to the biomedical sector

Suggestions for patent reform are aimed at modifying the patent system, but not dismantling it. The award of a monopoly would still be maintained. However, is that monopoly desirable with respect to biomedical inventions? Is the removal of the monopoly necessary in order to prevent corporations using their patents as strategic tools to dominate the markets for pharmaceuticals and dictate their terms to consumers and researchers alike?

Patent monopolies enable biotech companies not only to dictate access to sectors of biomedical research but also the price of the drugs that develop from that research. Filing many patents around the same invention can deter market entry by others. Patent protection can be extended well beyond the statutory period by patenting incremental improvements, additions and complementary items. Competitors can be blocked from the market by an offensive blocking strategy. Although competition law has the potential to deal with abuses like 'pay-to-delay' agreements, such agreements could never be instigated without the patent system allowing the brand name companies to continuously patent minor, incremental improvements and additions.

Nor does the patent system guarantee an efficient and comprehensive dissemination of knowledge in return for the patent monopoly. Without doubt, patent databases are a significant source of technical information, but what is disclosed in a patent specification is the absolute minimum necessary to obtain the patent. Creating a specification that is no more than adequate in order to obtain the patent is one of the skills expected of the patent attorney. The rest of the information remains secret. Private corporations control the access to their know-how, patents and biomedical databases.

There are inventions that are so vital to social welfare that it is simply not appropriate to allow private companies to regulate access to those inventions through the strategic use of patent monopolies. The biomedical sector is one such sector: it must be taken out of the ambit of the patent system. The risk that there will be patients who are excluded from all the benefits innovative research can bring is too great. Biomedical patents need to be phased out and replaced with robust public funding schemes.

Conclusions

A distinction needs to be drawn between different sorts of inventions. With reform, the patent system may be a 'harmless enough' practice for certain types of non-essential products and processes. However, pharmaceutical drugs are a very different category of goods. Monopoly prices in this sector do not determine what kind of mundane, everyday items we might wish to purchase. They determine access to treatment for illnesses and in some cases lifesaving drugs. It is evident from the way that firms use patenting as a strategic tool that access to drugs should not be a matter left to the market; access to research that can affect humankind should not be up to whether a private company is prepared to license its technology.

The present patent system is deeply flawed. It can be manipulated by those who know how to play the patent game. Men like Adam Smith and Jeremy Bentham considered a patent system to be harmless because if consumers did not like a new product, they could simply opt not to buy it. In the case of pharmaceuticals that element of choice does not always pertain; that product may be absolutely necessary and there may be no substitute. Even if there is a generic version, a patient may have been informed that the substitute is inferior.

The patent system is not perfect. The alternatives suggested to the patent system would not be perfect either. In a remuneration system there would be disputes about what the correct value of the innovations should be. An independent monitoring system, accepted internationally, would be essential. Neither should it be presumed that replacing the patent system with open access would mean that proprietary information would be shared by corporations. Establishing a stable, trusted and practical alternative to the patent system for biomedical technology will not be easy, but it is necessary. The role of governments will be of fundamental importance if biomedical patenting is to be replaced by a coherent system of public funding.

Governments need to recognise that not all sectors of technology should be subject to patent monopolies. Certain technologies must be exempt because they are too important to the wellbeing of the planet and its inhabitants to be left to the control of private companies. Social welfare dictates that the entire biomedical sector should be taken out of the ambit of the patent system: access to medicines, diagnostic tests and research tools must remain open access and the price of drugs should not exclude the poor from treatment.

Even such a partial abolition of the patent system would be a radical move. Will governments be prepared to initiate such a radical change? It would be a mammoth task, it will be fiercely opposed by pharma companies, but it has to be the way forward.

Notes

1. Barton, 2000; Henry and Stiglitz, 2010; Merges and Nelson, 1990; Pollock, 2018
2. *Brenner v Manson*, 383 U.S.519 (1966), p. 534.
3. European Directive 98/44/EC (1998) [My italics] Available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0044&from=EN;
4. *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), Available from: https://supreme.justia.com/cases/federal/us/569/12-398

5. http://www.referenceforbusiness.com/history2/27/H-Lundbeck-A-S.html and H. Lundbeck A/S, Lundbeck annual report 1999, 2000, p. 11
6. FTC's statement to the US Congress in 2009, cited in Choi et al. (2014), p. 44.
7. FTC v Actavis, No. 12–416, 570 US (2013).

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