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PharmaNostra Under Fire

André P. den Exter
Institute of Health Policy and Management
Erasmus University Rotterdam
Roterdam
The Netherlands
denexter@bmg.eur.nl

To the Editor: As a response to claims that pharmaceutical industry, ie, "PharmaNostra," was preventing market access to generic producers, European Commission for Competition launched a thorough investigation. In July 2009, after more than a year of investigation, Neelie Kroes, European Commissioner for Competition, published a comprehensive report, painting an alarming picture of antitrust behavior of pharmaceutical industry (innovators) (1).

Such outcome presents a challenge for the European Commission, which is supposed create an ideal business environment for pharmaceutical multinationals and at the same time ensure access to medicines for all.

PharmaNostra, to cover the costs of research on new drugs, requires generous patent protection. Patenting new drugs creates a monopoly for innovators, with artificially high prices and limited affordability of medicines. By admitting generic medicines (ie, patent-expired medicines) to the pharmaceutical market, PharmaNostra's monopoly will be annulled, with lower prices as a result. However, PharmaNostra's unpleasant role of hindering market access to generic producers makes medicines unnecessarily expensive. Since most prescription medicines are financed by social health insurance, it is in the interest of European Union member states to achieve low prices.

OUTCOME OF SECTOR RESEARCH

To protect its market share, PharmaNostra makes use of several controversial techniques. Effective delay tactics include "infringement of patent" litigation procedures against generic companies and customers (hospitals and pharmacies), despite patent expirations which make the allegation unfounded. Due to deliberate deception, competitors and customers will subsequently abstain from "patent infringements." This tactic is open for judicial review, but this takes a considerable amount of time (3 years on average), which will help PharmaNostra delay market access to generic products. And when it comes to "blockbusters" – products with a market value of several billion Euros – every month of delay is crucial.

Another method involves the agreement between PharmaNostra and generic manufacturers to pay the generic manufacturers compensation for postponing market participation. Parties will share the monopoly profit as a result. Such patent payment agreements hamper free competition and harm consumers. When parties cannot agree on the level of compensation, acquisition by PharmaNostra is an alternative. Thus, the new owner acquires control of the introduction of the new generic medicine.

Other interventions focus on national authorization of generic medicines. Authorization is a prerequisite for all medicines prior to market access. One of PharmaNostra's delay tactics is challenging such registration, while holding registration authorities liable for a "breach of patent." During the subsequent legal proceedings, a majority of such claims will be withdrawn, allowing authorization and therefore market access, but with a considerable delay. A similar practice occurs when local authorities are involved in healthcare package decision-making.

Finally, prior to patent expiration, PharmaNostra may decide to introduce a "second generation" medicine. Put simply, rather than in powder form, the "new" drug will then be offered in a tablet form, thereby extending patent rights.

WHERE TO GO?

The examples confirm PharmaNostra's reputation as a group of unscrupulous entities without any social responsibility. This is also confirmed by the 2008 report of United Nation's Special Reporter on Health, which formulated the guidelines on PharmaNostra's role in achieving global access to medicines (2). As early as in the consultation stage, major pharmaceutical companies failed to cooperate and rejected responsibilities as formulated by the United Nations guidelines. Apparently, it is PharmaNos-

tra that determines the need and necessity for the introduction of new medicines and its timing.

Recognition of its social responsibility by upholding United Nations guidelines on essential medicines is a step in the right direction. Without doubt, the pharmaceutical market cannot survive without such ethical imperatives. Abuse of property rights as identified in the Commission's report (1) should be sanctioned and patients' rights require protection. In addition, Member States should speed up the introduction of a so-called "European patent," replacing the current combination of 27 national patents. Supposed patent breaches can be exclusively reviewed by the European Patent Court (European Court of Justice), which will improve the quality of patents and avoid unnecessary delay.

References

1 European Commission. Pharmaceutical sector inquiry. July 8, 2009. Available from: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry. Accessed July 8, 2009.

2 Office of the United Nations High Commissioner for Human Rights. Human rights guidelines for pharmaceutical companies in relation to access to medicines. Available from: http://www2.ohchr.org/english/issues/health/right/. Accessed July 9, 2009.