

## **ANTI-COMPETITIVE STRATEGIES HAMPER ACCESS TO MEDICINES IN EUROPE**

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### **Introduction**

An unprecedented number of Europeans are living longer. In the next decade, most 'baby boomers' will retire from the workforce. Meanwhile, the birth rate in Europe continues to fall and, as a result, there will be fewer people to contribute to social security systems, jeopardising the financial support base for our health insurance.

Seniority brings new health challenges, often in the form of age-related and/or chronic diseases, requiring long-term medical interventions. European governments are eyeing their pharmaceutical expenditure to cut costs, while expensive brand or originator medicines compound health care bills. Some patients and consumers, particularly those in Eastern Europe, pay out-of-pocket expenses for the medicines they are prescribed. This disparity raises questions about equitable access across the European Union.

Because of their integral importance to our health and wellbeing, essential medicines need to be affordable and accessible for all European consumers in spite of cuts to social services and health budgets. This article examines how governments could guarantee access to high quality, safe and effective medicines in the face of Europe's aging population, changing health needs and rising pharmaceutical expenses

### **I. Medicines Monopolies under the Patent System**

Patents are an important factor in medicines prices. Patents on medicines bestow exclusive property rights to the inventor, typically a pharmaceutical company, for a finite period of time in return for the disclosure of the innovation. In the case of medicines, the inventor or originator company is also granted the sole right to use the (pre-) clinical data to support the product's application to enter the market (called data exclusivity).<sup>1</sup> During the patent life and/or period of data exclusivity, the originator company has the exclusive right to produce, use and sell the medicine and to use (pre-) clinical data relating to the product. This exclusivity prohibits competitors from replicating relatively inexpensive and simple manufacturing processes and selling a medicine with the same active ingredient for a fraction of the originator price.

Generic medicines can guide medicines prices to an affordable level after patents and/or data exclusivity expires. Containing the same active

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<sup>1</sup> European Commission (EC) Directorate General for Competition (DG Competition), 'Pharmaceutical Sector Enquiry - Final Report' 2009, p. 6. At: [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf) (12 December 2010).

ingredient(s) as the originator products, generic products are held to the same safety, quality and efficacy standards as all medicines on the market. The onset of generic competition has been reported to yield on average a 20% price reduction in medicines prices one year after the first generic entered the market. Medicine prices continued to drop on average to 25% of the original price after two years of competition.<sup>2</sup> Research from the *Katholieke Universiteit* Leuven has demonstrated that increased substitution of generics for originator products can deliver substantial savings. In a study of 11 European countries, generic substitution for only 10 active substances was shown to reduce public expenditure on these pharmaceuticals by 21% to 48%.<sup>3</sup>

Patents create a monopolistic environment favouring high prices. The high revenues relating to monopoly prices are meant to reward and stimulate innovation, although the drug development pipeline is drying up and the formulation of medicines that offer therapeutic advance has slowed down. Data from *Prescrire*, an independent bulletin providing information on treatments and healthcare strategies, shows that none of the products that entered the French market in 2004 were considered a 'real advance' while only six medicines offered 'an advantage' compared to those already on the market.<sup>4</sup> An unprecedented number of blockbuster (originator) medicines will lose patent protection in 2011 and 2012.<sup>5</sup> The impending threat of generic competitors fuels originator companies to maintain market exclusivity and maximise profits from existing patents. The main strategies used to this end are litigation, defensive patenting and marketing. Evidence shows that companies prioritise expenditure on medicines promotion to the detriment of medical innovation in order to secure a greater market share for their product. Between 2000 and 2007, originator companies worldwide spent on average only 17% of their turnover from prescription medicines on research and development, and 23% on marketing and promotional activities.<sup>6</sup>

European competition law safeguards against the abuse of dominant market positions that patents and intellectual property rights allow. Article 81 of the Treaty of the European Community (EC Treaty) specifically prohibits any undertakings that aim to prevent, restrict or distort competition within the common European market.<sup>7</sup> Article 82 prohibits the abuse of a dominant position on the common European market.<sup>8</sup> Despite these protective mechanisms, originator companies pursue patent strategies to keep competing generics off the market as long as possible.

## II. Anti-competitive Strategies that Delay Generic Entry

Immediate generic entry after a patent has expired can guarantee the greatest price cuts and maximum savings. However, on average, generics

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<sup>2</sup> EC DG Competition 2009, *supra* note 1, p. 28.

<sup>3</sup> S. Simoens & S. De Coster, 'Sustaining generic medicines markets in Europe', Research Center for Pharmaceutical Care and Pharmaco-economics at Katholieke Universiteit Leuven 2006, p.11. At: [http://198.170.119.137/doc/simoens-report\\_2006-04.pdf](http://198.170.119.137/doc/simoens-report_2006-04.pdf) (05 January 2011).

<sup>4</sup> *Prescrire International*, 'A review of drugs in 2004', 2005-14, p. 1.

<sup>5</sup> *Nature Reviews Drug Discovery*, 'The patent cliff steepens', 2011-10, p. 12-13. At: <http://www.nature.com/nrd/journal/v10/n1/full/nrd3356.html> (04 January 2011). See also Wall Street Journal Blogs, 'Patent Cliff Looks More Like Mt. Everest for Medco', 2010 at: <http://blogs.wsj.com/health/2010/11/02/patent-cliff-looks-more-like-mt-everest-for-medco/> (04 January 2011).

<sup>6</sup> EC DG Competition 2009, *supra* note 1, p. 48.

<sup>7</sup> Official Journal of the European Communities 325, 24/12/2002, pp. 0064 – 0065. At: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12002E082:EN:HTML> (12 December 2010).

<sup>8</sup> *Idem*, p. 0065.

enter the national market only 12 months after loss of data exclusivity.<sup>9</sup> Much of the delay of entry for generics can be attributed to originator companies' use of anti-competitive strategies identified in the Pharmaceutical Sector Enquiry concluded by the European Commission Directorate General for Competition in 2008. The Sector Enquiry uncovered trends in company behaviour that could give rise to an infringement of EC Article 81 and 82 on Competition Law. The two primary problematic strategies are defensive patenting and vexatious litigation, both of which could induce a plethora of other anti-competitive methods.

### **II.1. Defensive Patents**

Originator companies engage in *defensive patents* by creating 'patent thickets'; numerous – often weak or frivolous – patents around their blockbuster product. By patenting molecules related to the main product, originator companies create uncertainty around product patents. In doing so, patent thickets also establish enforceable rights that can block competitors from developing products in that area. The manufacturing and sale of products related to the originator may infringe on one of those many trivial patents, even though the blockbuster may be off patent.

Exploration is essential to innovation, but the uncertainty for competitors due to patent thickets and the threat of patent infringement, however frivolous, can deter research and development. While defensive patenting does not embody a breach of EU Competition Law in itself, these strategies do tend to impede competition and innovation and do not serve the intended purpose of patents - to stimulate innovation and to share knowledge.

### **II.2. Litigation**

The threat of litigation dissuades generic companies from exploring or launching a medicine, even in situations where the infringement is disputable or where the patent could be invalid. If faced with litigation, small and medium generic enterprises would have difficulty meeting their own legal costs, let alone those of the originator company, should it be successful. Litigation is a costly threat that generic companies face in attempting to market some of their products. Besides, litigation yields inconsistent and unpredictable results. A common EU patent does not exist; patent rights are actually a bundle of national rights examined and upheld in diverse ways across Member States. Due to the interconnectivity of patent rights in Europe, litigation initiated in one EU Member State could lead to litigation across all. However, the Sector Enquiry identified contradictory judgments between Member States in 11% of the cases examined.<sup>10</sup>

In some cases, the generic medicine in question could face interim injunctions during the period of the litigation, forcing the generic company to take its medicine off the market. Health care systems deprived of this low-cost generic would be forced to pay inflated prices for an originator product. Yet, generic companies have been successful in 60% of the litigation cases examined in the Sector Enquiry.<sup>11</sup> This precedent not only allows the generic product in question to return to the market, but also opens up competition to other generic products. However, the health insurance systems are not reimbursed for costs incurred during the injunction. Generic companies can pursue compensation for lost profits if the generic prevails.

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<sup>9</sup> EC DG Competition 2009, *supra* note 1, p. 70.

<sup>10</sup> *Idem*, p. 237.

<sup>11</sup> *Idem*, p. 364.

**Conclusion**

Generics can liberate public budgets from excessive pharmaceutical costs. However, the anti-competitive strategies outlined in this article can artificially extend the market dominance of a best-selling originator medicine, prolonging company profits at the expense of the public purse and obstruct widespread access.

The patent system was envisioned to protect the company's capital investment and to regenerate the costs it incurred in research and development. Now, however, it seems to be providing incentives to engage in anti-competitive practices and to develop strategies that hamper innovation, contrary to citizens' interest.

In times when health budgets face constraints, engaging in practices that inflate the costs of medicines for health care funders and patients is an irresponsible approach. Governments need to ensure universal access to medicines, meeting changing public health needs within the limitations of their national health budgets. Therefore, it is crucial to ensure at least fair and effective competition in the pharmaceutical market which allows for prices to drop, making medicines more affordable and stimulating broad and equal access across Europe.