

Pharmaceutical innovation and non-patent protection

This issue of *Pharmaceuticals Policy and Law* provides an international overview of the main instruments for the non-patent protection of pharmaceuticals that addresses pertinent legal issues in WTO, Japanese, US, and EU law. The concept of non-patent protection relates to the area beyond the regular patent protection of 20 years. It essentially encompasses three mechanisms of protection: first, a period extending the term of patent protection (the so-called ‘patent term extension’); second, a period of protection against the submission of marketing authorisation applications that do not contain full data but refer to the originator’s data (so-called ‘data exclusivity/data protection’ [1]); and third, a period of protection against the marketing of similar medicinal products (so-called ‘market exclusivity’).

The economic and political purpose of the above-mentioned instruments is, in principle, to boost R&D in pharmaceuticals. In the pharmaceuticals sector, product innovation is the crucial cornerstone to delivering financial rewards to companies and to generating health benefits for patients. There are a number of unique features involving innovation in this sector [2]. For instance, the process of R&D is closely interwoven with the regulatory process. After the preclinical phase, which usually takes three to four years to complete, regulatory clearance is typically required to start clinical testing. After the three phases of clinical trials that follow, the sponsor may apply for marketing approval if the review is believed to be complete in terms of safety and efficacy. The approval process takes time, but the review time by the authority itself represents only a small proportion compared with the time spent leading up to application for approval. Overall, it takes around 12 to 13 years to bring a drug to market [3]. The latest study released in 2012 estimated that the average R&D expenditure on a new chemical or biological entity was €1,172 million (US\$ 1,506 million) in 2011) [4]. In the words of the European General Court (EGC): ‘[. . .] the medicines sector is characterised by the importance of competition by innovation. R&D is costly and risky.’ [5]. Consequently, the different non-patent protection schemes that have been invented over recent decades by the legislators of countries that have strong pharmaceutical sectors aim at encouraging and rewarding companies to undertake R&D activities relating to innovative medicines.

More recently, the pharmaceutical sector seems to be in substantial transition with respect to the relationship between cost and innovative productivity. Thus, it is argued that the time lapse between the filing of the patent and the actual marketing of the product is ever increasing, rendering any chance of recouping the R&D expenditure more and more uncertain [7]. Moreover, it seems that R&D productivity may have declined in recent years. Many large pharmaceutical companies may not have

pipelines that are sufficiently valuable to offset the loss of revenue owing to the imminent expiration of patents [8]. Eventually, the rising cost of healthcare will become an increasingly precarious issue in many developed countries, putting downward pressure on drug prices [9]. Because further product innovation is even more essential under such circumstances, it could well be argued that non-patent protection instruments are more valuable and necessary than ever and, therefore, they should even be extended. Indeed, legislators have shown willing to introduce additional exclusivities in recent years, at least with respect to special types of medicines, such as the six-month exclusivity for paediatric drugs in the EU [10] and the exclusivities for the first interchangeable biological product and biosimilar biological products in the US [11]. A study published in January 2011 was the first to calculate the financial and social costs of limiting access to trial data. This study found that although extending the term of exclusive access would lead to higher drug costs in the short term, it would also generate more than 200 extra drug approvals in the US and greater life expectancy over the next several decades [12].

However, this is only one side of the coin. As is the case with pharmaceutical patents, non-patent protection has also come under scrutiny in recent years. For example, in a 2009 report the US Federal Trade Commission took the stance that innovative products should not receive additional market exclusivity beyond the terms of their patents because such rewards would “direct scarce R&D dollars toward developing low-risk clinical and safety data for drug products with proven mechanisms of action rather than toward new inventions to address unmet medical needs” [13]. More and more critical voices are being heard from academic experts. For example, it has been asked whether there is a hypertrophy of exclusivity rights [14].

Of course, the appropriate balance between promoting innovation and fostering dynamic competition is very hard to strike. Through the articles featured in this edition of *Pharmaceuticals Policy and Law*, the contributing leading legal experts have attempted to draw an almost complete and unbiased picture of the legally and politically contested area of non-patent protection instruments.

The editors hope that the volume will be valuable to any person wishing to understand better the intricacies and pitfalls of this field of pharmaceutical law and its pivotal relevance to the whole healthcare sector.

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References

- [1] The term “branded exclusivity” is not that common but nevertheless is *stricto sensu* preferable to “data exclusivity” or “data protection”, the latter also being flawed by its ubiquitous usage, because a second applicant’s reference to the data in the pioneer manufacturers’ dossiers does not involve the disclosure of such data to this company or to the public.

- [2] Cf. N. Kiriyaama, *Trade and Innovation: Pharmaceuticals*, OECD Trade Policy Working Paper No. 113, 1 April 2011, TAD/TC/WP(2010)28/FINAL, <http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=TAD/TC/WP%282010%2928/FINAL&docLanguage=En>, p. 7, 15 *et seq.*
- [3] H. Grabowski, *Patents, Innovation and Access to New Pharmaceuticals* (July 2002), http://levine.sscnet.ucla.edu/archive/grabow-patents_innov.pdf, p. 19; EFPIA, *The Pharmaceutical Industry in Figures, 2013*, http://www.efpia.eu/uploads/Figures_Key_Data_2013.pdf, p. 6.
- [4] J. Mestre-Ferrandiz, J. Sussex and A. Towse, *The R&D cost of a new medicine*, Office of Health Economics, London, December 2012.
- [5] EGC, Case T-168/01 *GlaxoSmithKline Services v Commission*
- [6] ECR II-2969, para 271.
- [7] D. Delcourt, *Public health and the preservation of economic competitiveness: The European supplementary protection certificate for medicinal products*, *JIPLP* 4(6) (2009), pp. 439–444, at p. 441.
- [8] N. Kiriyaama, *op. cit.*, p. 19 *et seq.*
- [9] N. Kiriyaama, *op. cit.*, p. 10.
- [10] Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, pp. 1–19).
- [11] Section 351(k)(6) and (7) of the Public Health Service Act (PHSA) (42 U.S.C. 262), as amended by Title VII, Subtitle A (“Biologics Price Competition and Innovation Act of 2009), section 70002(a)(2) of The Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111–148, 124 Stat. 119 (2010), H. R. 3590–3686.
- [12] D.P. Goldman et al., *The Benefits From Giving Makers Of Conventional ‘Small Molecule’ Drugs Longer Exclusivity Over Clinical Trial Data*, *Health Affairs* 30 (2011), 184.
- [13] Federal Trade Commission, *Emerging Health Care Issues: Follow-on biologic drug competition, June 2009*, <http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf>, p. 27.
- [14] C.R. Fackelmann, *Patentschutz und ergänzende Schutzinstrumente für Arzneimittel im Spannungsfeld von Wettbewerb und Innovation*, Cologne, Munich 2009, p. 553 *et seq.*