Pharmaceutical Patents in Europe: Radical Reforms Rather Than Getting Rid?

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1 Introduction

The coronavirus disease 2019 (COVID-19) pandemic has put the issue of health product patenting once again in the spotlight, especially because of vaccines. Here, we analyse whether it is still possible to balance commercial incentives (guaranteed to the industry by patents) on the supply side and the regulatory framework (set to support public interests) on the demand side. After summarising both pharmaceutical patenting and market exclusivity in general within the EU, we offer a proposal to reform the European regulations.

2 State of the Art

Intellectual property (IP) refers to creations of the intellect, such as inventions. The law assigns the creators a monopoly through IP rights that guarantee them protection for a certain period during which they can benefit commercially from the invention [1]. Although there are other tools to protect an IP (e.g. trademarks and copyrights), the patent is by far the most exploited by the pharmaceutical industry to protect research and development (R&D) investments [2]. A company can apply for different types of patents regarding a specific drug, a particular use of it, a manufacturing process, or a newer formulation.

Unlike pharmaceutical regulations, inspired by drugs as ‘merit goods’ for health, patent regulation is part of commercial law and thus lies outside public legislation. Patents are still national in the EU so are valid only in the countries in which the patentee applies for them. Therefore, although the patent systems of the member states are substantially

similar because key provisions have been adopted in line with the European Patent Convention [3], they are not yet fully harmonized within the EU. Patent claims can be filed through either the domestic patent offices or the European Patent Office (EPO), the executive body created in 1977 to grant patents together in all the European countries through a single procedure [4]. Once a patent is granted by the EPO, the patentee can choose to exploit it in all or a limited basket of countries, usually paying to EPO the centralized patent renewal fees (instead of the single national ones) to save time and money. In no way legally bound to the EU, the EPO has a staff of around 7000 (more than half in the Munich branch specialized in pharmaceuticals) and is self-financing, covering all its expenditures through patent fees.

Like in most developed countries, patent protection in the EU lasts 20 years. However, in response to the perceived inadequacy of the current market protection period offered by pharmaceutical patents compared with other industries—mainly because of the lengthy registration process of drugs before market approval—it has been possible for more than 2 decades to extend the original patent for up to 5 years through one supplementary protection certificate (SPC) [5].

In the absence of a common European patent law, each country has its own rules about patent infringement. In most countries, patent laws include so-called safe harbour provisions [6], which allow actions (i.e. trials or tests) that would otherwise be considered infringements for a limited term before the patent expires [7, 8]. However, since these exemptions were harmonized through directives—legal provisions that allow member states some freedom in national applications [6]—some differences remain at the domestic level, and this raises legal uncertainty throughout the EU countries [9]. Finally, the extreme option of a ‘compulsory license’ because of a compelling public interest—often cited for anti-COVID-19 vaccines in this period—is allowed in the EU, although it has not yet been formally adopted in all member states and is rarely applied in practice [9].

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Further opportunities for longer market exclusivity for the pharmaceutical industry were introduced in the EU more recently [10]. For instance, a 10-year exclusivity is granted to encourage R&D in the field of orphan drugs, and 2 additional years can be allowed for paediatric orphan drugs [11].

To sum up, the current state of IP for pharmaceuticals in the EU is quite confusing and can be difficult for those without expertise in legal issues to understand [12]. Beyond the persisting differences in patent legislation among member states, the various provisions on data and marketing exclusivity introduced by EU directives have made the current regulatory framework piecemeal and somewhat contradictory [13].

3 Vicious Circle

In general, pharmaceutical patents stem from tight collaboration between scientists and attorneys [14]. The main task of attorneys is to convince examiners that the applications fulfil the legal requirements for patentability and, later, to extend patent life as long as possible.

The first crucial decision concerns the timing of patent application, which can be filed as soon as the drug is synthesized to prevent others from copying it or delayed until the first trial to lengthen the protection [15]. The most effective means for extending patent protection on a successful drug is to obtain secondary patents by making series of modifications to the first invention [16], eventually generating an ‘invention cascade’. Typical examples of secondary patenting have been new indications, formulations, and/or dosages; ‘me-too’ drugs; and fixed-dose drug associations. These ‘ever greening’ strategies are often pursued to prolong patents through marketing tricks aimed at slowing down the launch of cheaper off-patent medicines [17, 18]. This often generates costly litigation, which can be ultimately considered a waste of public money, since they would not be supported without funding by third-party payers [12]. Yet data and marketing exclusivity provisions can be manipulated too, e.g. the regulation on ‘orphan drugs’ spurred new indications for mature anticancer drugs to treat rare tumours [19, 20].

Unsurprisingly, the current regulatory framework on pharmaceutical IP exclusivity has often been criticized [2, 21], with arguments about whether it remains fit for public purposes. Drastic proposals to ‘de-link’ R&D investments from financial returns have been raised to make regulations more responsive to the health needs of patients and society [17, 22]. However, full de-linkage might imply alternative financial sources (e.g. general taxation) to fund innovation development outside the monopoly of product supply.

4 Proposal

In light of the hot debate on pharmaceutical IP exclusivity, we depict a radically different European scenario based on three key points to (re)establish a more acceptable trade-off between public and private interests without necessarily getting rid of patents.

The first major change should concern the present management of pharmaceutical patents through the EPO and the parallel network of domestic offices. The EPO is a big organization that, from the public health viewpoint, is totally out of control [23]. Entirely funded by patent fees, it is thus also open to financial conflicts of interest [23]. On the other hand, domestic offices are unable to handle tricky patents such as those for pharmaceuticals so play a merely administrative role. We think the time has come to make the EU partly responsible (and financially accountable) for pharmaceutical patents by introducing a specific agency that could possibly be extended to also cover medical devices. This new agency could also better deal with non-EU patents, typically those from the US companies.

The second major issue is the excess of discretion by pharmaceutical companies in filing patents. The present situation of timely ‘smart choice’ on primary patents followed by an ‘invention cascade’ through secondary patents is unacceptable. It is time to limit this discretion and undermine the ‘patent jungle’. Primary patents could be restricted to substances with one declared indication, then secondary patents should be granted only to therapeutic indications that are very different from the first one, ruling out all other types of patents on manufacturing processes and formulations. This should contribute to decreasing litigation, as well as claims for compulsory licenses, which could be restricted to extreme circumstances requiring dramatic production volumes (such as the present pandemic) should the patentee refuse voluntary licensing.

The third issue is the shorter duration of market exclusivity on drugs compared with other goods at present. A sound move to re-align such a duration could be to guarantee a market exclusivity of 15 years only to compounds that start a clinical trial within 5 years from the granting date, thus discouraging opportunistic early filing of drugs with still doubtful therapeutic indications. Afterwards, the warranted duration could be progressively reduced, reflecting the delay in trialling, i.e. 14 years for drugs starting the first trial during the 6th year after the granting date, and so on. At the same time, the SPC tool and the extra regulations on exclusivity should be cancelled. Although these specific provisions were inspired by positive principles, they are also prone to manipulation by industry.

5 Comment

The regulation of pharmaceutical patents must be radically reformed in light of its relevance for public health. The present situation conflicts with the general patent concept, which stems from a bargain of IP rights in exchange for inventions disclosure, with secrecy being the only alternative to patenting. Moreover, pharmaceutical discoveries can flow into and depend on each other, with marketed products generated by discoveries from publicly funded research, as the present pandemic has dramatically reminded us. Indeed, this seems the right time to reform the European regulations on pharmaceutical patenting.

Declarations

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References

- World Intellectual Property Organization, WIPO (2004). What is Intellectual Property? WIPO Publication No. 450(E) ISBN 978-92-805-1555-0. p 25
- Cockburn I, Long G. The importance of patents to innovation: updated cross-industry comparisons with biopharmaceuticals. *Expert Opin Ther Pat*. 2015;25(7):739–42.
- Convention on the Grant of European Patents (European Patent Convention), 29 November 2000. <https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ma5b.html>.
- Gates C. Patenting the life sciences at the European Patent Office. *Cold Spring Harb Perspect Med*. 2014;4(12):a020792.
- Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.
- Kupecz A, Roos K, Dekoninck C, et al. Safe harbors in Europe: an update on the research and Bolar exemptions to patent infringement. *Nat Biotechnol*. 2015;33(7):710–5.
- Jaenichen HR, Pitz J. Research exemption/experimental use in the European Union: patents do not block the progress of science. *Cold Spring Harb Perspect Med*. 2014;5(2):a020941.
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004.
- Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems
- Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.
- Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for pediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004
- Garattini L, Padula A. Between pharmaceutical patents and European patients: is a compromise still possible? *Expert Opin Ther Pat*. 2017;27(10):1073–6.
- Feldschreiber P, Breckenridge A. After thalidomide—do we have the right balance between public health and intellectual property. *Rev Recent Clin Trials*. 2015;10(1):15–8.
- Gupta H, Kumar S, Roy S, Gaud R. Patent protection strategies. *J Pharm Bioallied Sci*. 2010;2(1):2–7.
- Raj GM, Priyadarshini R, Mathaiyan J. Drug patents and intellectual property rights. *Eur J Clin Pharmacol*. 2015;71(4):403–9.
- Spilker B. Guide to drug development—a comprehensive review and assessment. Philadelphia: Lippincott Williams&Wilkins; 2009.
- Mintzberg H. Patent nonsense: evidence tells of an industry out of social control. *CMAJ*. 2006;175(4):374–81.
- van de Vooren K, Curto A, Garattini L. Biosimilar versus generic drugs: same but different? *Appl Health Econ Health Policy*. 2015;13(2):125–7.
- Garattini S. Time to revisit the orphan drug law. *Eur J Clin Pharmacol*. 2012;68(2):113.
- Côté A, Keating B. What is wrong with orphan drug policies? *Value Health*. 2012;15(8):11–91.
- Dutfield G. Healthcare innovation and patent law's "pharmaceutical privilege": is there a pharmaceutical privilege? And if so, should we remove it? *Health Econ Policy Law*. 2017;12(4):453–70.
- Holmes D. Report urges controversial "delinkage" to foster new antibiotics. *Nat Med*. 2014;20(4):320.
- Garattini L, Padula A. Conflict of interest disclosure: striking a balance? *Eur J Health Econ*. 2019;20(5):633–6.