Anticompetitive patent acquisitions in the pharmaceutical industry

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Abstract

Pharmaceutical companies use various strategies to protect their market monopoly. One of such practices is an acquisition of a patent developed by a third party. Such acquisitions allow pharmaceutical companies to strengthen their market power by extending the life of the product; for instance, by acquiring patents that cover alternative non-infringing versions of the monopolist's own product, or acquiring the patent that covers an improvement of its current product. Both the US and EU case law condemn such practices as an abuse of monopoly power. This Article discusses patent acquisitions in the pharmaceutical industry focusing on two recent EU and US cases investigated by the competition authorities.

Keywords: pharmaceutical patents, patent acquisitions, Perindopril, Bioval, anticompetitive behaviour, monopolisation, abuse of dominant position.

Introduction

Access to medicines is increasingly becoming a priority matter not only for developing countries, but also for developed countries. Prohibitively high prices on drugs, coupled with the decreasing level of innovative and effective new medicines that reach the market, have become a bitter reality that the world is facing today. Therefore, states are determined to protect patients by facilitating generic competition through various legal and economic mechanisms, while also encouraging originator companies to engage in research and development of innovative medicines.[1]

The problem of access is exacerbated by the fact that, while undertaking an important role of developing drugs and bringing them to market, pharmaceutical companies may also engage in business practices that cause a restricted access to medicines by charging high prices on their products or reducing their

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1 See e.g., Report of United Nations Secretary General's High Level Panel on Access to Medicines, 'Promoting Innovation and Access to Health Technologies' (September 2016) <http://www.unsgaccessmeds.org/final-report/> accessed 12 October 2016.

availability by other means. When such situations occur, competition law plays a crucial role in protecting public interests.[2]

Competition authorities of the EU and US are very active in policing abusive behaviour of pharmaceutical companies given the key importance of the industry. In 2008, the EU Commission launched an investigation into the EU pharmaceutical industry acknowledging that it was not working well, and pursuing the goal of finding the reasons for this problem.[3] It found that originator companies use a variety of instruments to extend the commercial life of their medicines that contribute to the delay of generic competition.[4] These practices include patent filing strategies, life cycle strategies for second generation products,[5] reverse payment agreements,[6] patent-related exchanges and litigation, oppositions and appeals, interventions before marketing authorisation and/or pricing and reimbursement bodies. While some practices, such as patent filing and life-cycle strategies, remain only a 'concern' of the competition authorities, other practices, such as reverse payment agreements, have gained considerable attention from competition authorities in different jurisdictions.[7] Also, among the practices under the vigilant control of the competition authorities are acquisitions of externally-developed patents. This Article will discuss anticompetitive patent acquisitions in the pharmaceutical industry with a specific focus on two recent EU and US cases investigated by the competition authorities.

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2 WTO, WIPO, WHO, 'Promoting Access to Medical Technologies and Innovation: Intersection between public health, intellectual property and trade' (2012) 76 <https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2013_e.htm.> accessed 12 October 2016; OECD, 'Annex to the Summary Record of the 121st Meeting of the Competition Committee held on 18-19 June 2014. DAF/COMP/M(2014)2/ANN6/FINAL' (10 February 2015) <http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/M%282014%292/ANN6/FINAL&doclanguage=en> accessed 12 October 2016; UNCTAD, 'The role of competition in the pharmaceutical sector and its benefits for consumers' (2015) <http://unctad.org/meetings/en/SessionalDocuments/tdrbpconf8d3_en.pdf> accessed 12 October 2016; see also Duncan Matthews and Olga Gurgula, 'Patent Strategies and Competition Law in the Pharmaceutical Sector: Implications for Access to Medicines' European Intellectual Property Review, Forthcoming; Queen Mary School of Law Legal Studies Research Paper No. 233/2016, available at SSRN <http://ssrn.com/abstract=2779014>.

3 Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003 (Case No COMP/D2/39.514). See also European Commission, 'Pharmaceutical Sector Inquiry: Final Report' (8 July 2009) <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> accessed 12 October 2016.

4 Communication from the Commission, 'Executive Summary of the Pharmaceutical Sector Inquiry Report' (2009) 10 < http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/> 12 October 2016.

5 Tahir Amin, Aaron S. Kesselheim, 'Secondary Patenting Of Branded Pharmaceuticals: A Case Study Of How Patents On Two HIV Drugs Could Be Extended For Decades' (2012) Vol.31, No.10 Health Affairs, 2286 <http://content.healthaffairs.org/content/31/10/2286.long> 12 October 2016; See also Chilton, Adam S., 'India's Evolving Patent Laws and the WTO Obligations: The Rejection of Abbott Laboratories' Application for a New Kaletra Patent' (2011) Journal Articles, Paper 4281 <http://chicagounbound.uchicago.edu/journal_articles/4281> 12 October 2016.

6 The FTC Press Release, 'FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected By Anticompetitive Tactics' (28 May 2015) <https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill> accessed 12 October 2016; Federal Trade Commission Staff Study, 'Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions' (January 2010) 3 <http://www.ftc.gov/os/2010/01/100112 payfordelayrpt.pdf> accessed 12 October 2016; See also Olga Gurgula, 'US Supreme Court decision on reverse payment agreements: new era in patent litigation settlements – FTC v Actavis, Inc.' (2013) Vol. 3 No. 4. Queen Mary Journal of Intellectual Property 325.

7 See. e.g. Case T-472/13 *Lundbeck v Commission;* Case AT.39612 - Perindopril (Servier) (2014), para 2799 (Perindopril decision) < http://ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=1_39612> accessed 12 October 2016; *FTC v Actavis, Inc*., 570 US __(2013), slip op.

1. Patent acquisitions by pharmaceutical companies

Patent acquisitions are generally viewed as pro-competitive as they facilitate dissemination of knowledge. A transfer of the technology to those who are capable of using it, in theory, should ensure its effective utilisation, and lead, for example, to the development of more efficacious active substances or lower production costs.[8] Acquisition of a patent developed by a third party may also be anticompetitive, when it strengthens monopoly power of a dominant firm and eliminate competition.[9]

External patent acquisitions that may enhance dominant position may relate to patents on *improvement* or *substitute* (alternative) technologies. Improvement patents relate to the acquirer's own monopolistic product and improve it either in terms of quality, act as an essential component of a product or extend its market exclusivity. Such an acquisition may allow the monopolist to extend its monopoly beyond the period of a basic patent that covers its product.[10] Patents that cover alternative technologies are generally acquired in order to remove the access to those technologies from the market and prevent rivals from using them. Such acquisitions essentially eliminates potential or actual competition and maintains monopoly power with respect to the acquirer's own product.[11] As a general presumption, an acquisition by a dominant company of exclusive rights to an alternative technology is an exclusionary practice.[12]

In the pharmaceutical industry, external patent acquisitions allow pharmaceutical companies to strengthen their market power by extending the life of the product; for instance, by buying out patents that cover alternative, non-infringing versions of manufacturing processes of the monopolist's own product or acquiring the patent that covers an improved formulation of its existent product. Both the US and EU case law condemn such practices as unlawful monopolisation or an abuse of dominant position.

1.1. The EU Commission decision in Perindopril: acquisition of alternative technologies

In order to protect its product against generic competition, pharmaceutical companies use various strategies. These strategies are usually used together, so that if one has failed to achieve the attempted result of blocking competitors, another will ensure that the protection is maintained. The typical example of such a toolbox employed by pharmaceutical companies is the *Perindopril* case. [13] In 2014, after its in-depth investigation, the EU Commission concluded that Les Laboratories Servier, a French

8 Perindopril decision (n 7), para 2799.

9 Fiona M. Scott Morton and Carl Shapiro, 'Strategic Patent Acquisitions' (2014) 79 ANTITRUST L.J. 463, 470-79; Christopher R. Leslie, *Antitrust Law and Intellectual Property Rights: Cases and Materials* (2011, Oxford University Press) 444.

10 See e.g., *In re Bioval Corp*. 2002 WL 727033 (FTC No. 011 0094, 23 April 2002) <https://www.ftc.gov/enforcement/cases-proceedings/011-0094/biovail-corporation> accessed 12 October 2016; Herbert Hovenkamp et al., IP and Antitrust: An Analysis of Antitrust Pronciples Applied to Intellectual Property Law (Wolter Kluwer, 2011 Supplement).

11 See e.g., Perindopril decision (n 7).

12 Herbert Hovenkamp et al. (n 10).

13 Perindopril decision (n 7).

pharmaceutical originator company, violated EU competition law by engaging in patent acquisitions and reverse payment settlements with respect to its most successful blockbuster drug Perindopril, an angiotensin converting enzyme inhibitor used for the treatment of cardiovascular diseases (e.g. high blood pressure). In its decision, the Commission drew a broad picture of Servier's anti-generics strategy that had the objective to delay or prevent generic entry by making use of a great variety of instruments.

The Commission found that Servier started to devise, constantly update and implement its anti-generics strategy from the late 1990s onwards. The main objective of the company was to postpone generic entry that on the most important markets, such as the UK and France, would happen, in principle, after the expiry of the perindopril compound patent, i.e. in 2003/2005 respectively. By means of its strategies, however, Servier succeeded in substantially delaying generic entry. As was noted by Servier itself for the UK market, its anti-generics strategy had been very successful: '*4 years gained = great success*'.[14]

As one of the most important elements of Servier's anti-generics strategy, the Commission described Servier's patenting practice. The initial patent protection of Perindopril was based on several key patents that cover its basic compound, as well as its processes of production and synthesis. Servier knew that after the expiration of the compound patent, it could only rely on the protection of its secondary process patents. However, Servier was not confident in relying solely on these process patents, as they would not afford absolute protection against generic entry, because competitors might develop alternative non-infringing production processes.[15] Therefore, it was decided to strengthen the patent protection for Perindopril by means of filing for blocking patents. The strategic objective was to neutralise the arrival of generics through blocking all the non-infringing alternatives that could potentially be industrialised.[16]

Despite the general success of this strategy in preventing generic competition, some generic companies, nevertheless, tried to develop alternative non-infringing methods to produce Perindopril or to obtain different crystalline forms of Perindopril which were not patent protected. Non-infringing technologies available for the manufacture of Perindopril were, in any case, limited and required substantial investment and research by the generic companies.[17]

When Servier found out that a few generic companies successfully developed non-infringing formulations of Perindopril, it pursued the tactic of their acquisition in order to remove the possibility of potential competition. Such acquisitions meant that these technologies would no longer be available for generic companies seeking to enter the market with an alternative non-infringing form of Perindopril that was not patent protected by Servier.[18] When explaining the reasons behind the patent acquisition of alternative technologies for the production of Perindopril developed by generic firms, Servier stated that the purpose of such an acquisition was to improve their manufacturing processes and thus increase production capacity while optimising production costs. However, as the Commission found, in contrast to this statement, the purpose of an acquisition was to strengthen the protection of its own forms of Perindopril.

14 ibid, para 4.

15 ibid, para 115.

16 ibid, para 117.

17 ibid, para 140.

18 ibid, para 139.

In particular, Servier concluded two agreements, which removed alternative technologies from the market. It also acquired patents in the context of its patent settlement agreements with two other competitors. Although the first acquisition was not disclosed by the Commission in its decision, it mentioned that Servier acquired a patent application and a 'chemical dossier'. It further stated that the seller was at the advanced stage of developing Perindopril API (active pharmaceutical ingredient), that did not infringe any of the Servier's patent rights, and applied for a process patent for this API. The seller also entered into negotiations with a generic company with respect to the marketing of the API by this generic company. This agreement effectively ended any independent development of Perindopril based on the acquired process.[19]

The second acquisition of an alternative technology was from a Swiss company Azad that included a patent application and related international extensions and know-how transfer (that included four synthesis routes for the manufacturing of Perindopril). Servier acknowledged that the Azad patents did not infringe on Servier's patents and agreed to acquisition in order to 'strengthen the defence mechanism for its own alpha, beta and gamma forms of Perindopril'. For the Azad assignment, Servier committed to pay the amount of EUR 13,374,243. As a consequence of this acquisition Azad terminated all activities involving Perindopril and ceased to be a potential source of API for generic companies.[20] As was concluded by the Commission, the purpose of acquisition was to 'hamper generic entry rather than to pursue efficiencies from the acquired technology'.[21] The Commission further found evidence that Servier did not use the acquired technology and listed it among patents qualified as protective measures against generics, i.e. 'blocking patents'.

Servier also closely followed the development of two advanced sources of Perindopril which obtained, or were close to obtaining, a marketing authorisation: Krka and Lupin. Being in litigation with these two companies over the infringement and validity of Servier's patents and revocation action against its core patent[22] respectively, Servier concluded a patent settlement agreement with both companies, which also included a transfer of their technologies to Servier.[23]

The Commission concluded that these acquisitions deviated from competition on the merits, as those technologies were not excluded from the market because of Servier's superior technology, but because Servier aimed to strengthen its protection against generic entry, removing independent sources of competition by means of acquisitions.[24] Therefore, the Commission found that patent acquisitions are considered to be a violation under Article 101 TFEU. It was also found that the combination of the patent acquisitions and the reverse payment settlements amounted to an abuse of a dominant position by Servier pursuant to Article 102 of the Treaty.[25]

19 ibid, para 246.

20 ibid, paras 149-150.

21 ibid, para 2776.

22 '947 patent a crystalline form of perindopril.

23 ibid, paras 2780-2781.

24 ibid, para 2881.

25 ibid, para 9.

1.2. The FTC Decision in Bioval: acquisition of an improvement patent

In 2002, *In re Bioval Corp.*[26], the FTC claimed that the Biovail Corporation's acquisition of an exclusive patent license for Tiazac was illegal. The Commission further claimed that in order to maintain its monopoly, Biovail wrongfully listed the acquired license in the U.S. Food and Drug Administration's 'Orange Book' for the purpose of blocking generic competition of its Tiazac drug. The Commission considered these actions as a violation of Section 7 of the Clayton Act and Section 5 of the FTC Act, as well as considered them as unlawful monopolisation in violation of Section 5 of the FTC Act.

Thus, Bioval is a producer of Tiazac, a diltiazem-based prescription drug used to treat high blood pressure and chronic chest pain. Patent protection on the Tiazac active ingredient expired, but it was still covered by a patent on its extended-release formulation. Tiazac was approved for sale in the US in 1995, and Bioval started to market it shortly after. It was an important product for the company with the sales of almost $200 million in 2000. In 1998, a generic company, Andrx Pharmaceuticals, Inc., submitted an ANDA to the FDA to market a generic version of Tiazac. At that time, the only patent listed in the Orange Book as claiming Tiazac was '791 patent, which covered the aspect of the extended-release formulation of Tiazac. In response to the submission of the generic company, Bioval filed a patent infringement lawsuit, alleging that the generic version would infringe the '791 patent. This triggered a thirty month stay provision, precluding the FDA from granting a final approval to the generic. The Court of Appeals for the Federal Circuit (the CAFC) confirmed the lower court decision to reject the claim, holding that the generic version did not infringe upon the Bioval's patent. The FDA tentatively approved generic version which means that it would have been eligible for the final approval upon expiration of the 30 month stay, which the FDA would have granted on 13 February 2001. However, because of the Bioval's anticompetitive actions, the final approval was not granted.

In December 2000, the US '463 patent was granted to the founder of DOV Pharmaceuticals. The product covered by this patent is a unique formulation of diltiazem (the same active pharmaceutical ingredient as in Biovail's Tiazac), which combines both an immediate-release and an extended-release form of diltiazem. In January 2001, Bioval managed to obtain an exclusive licence on this patent and immediately listed it in the Orange Book, alleging that it covered the approved formulation of Tiazac. According to the FTC, Biovail was aware that the '463 patent did not cover the Bioval's formulation of Tiazac and, therefore, it did not need this patent in order to manufacture and sell its existing drug, and it could have continued to do so without infringing the '463 patent. However, the consequence of such a listing was that the FDA was no longer permitted to grant Andrx final approval to launch its generic version of Tiazac in February 2001. Andrx, instead, was required to file a new certification to the FDA concerning the '463 patent, further delaying its market entry. In subsequent court proceedings, Bioval alleged that the '463 patent covered a new formulation of Tiazac that Biovail developed only after it acquired the exclusive license and listed the '463 patent, rather than covering the version of Tiazac that Biovail had been marketing. However, at the same time, in contrast to its position in the court, Bioval made the FDA believe that the '463 patent covered its current product and therefore should be listed.[27]

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[26] *In re Bioval Corp*. 2002 WL 727033 (FTC No. 011 0094, 23 April 2002) <https://www.ftc.gov/enforcement/cases-proceedings/011-0094/biovail-corporation> accessed 12 October 2016.

[27] According to the FTC: 'On March 20, 2001, the FDA notified Biovail that its new formulation of Tiazac was not approved by the FDA under the Tiazac NDA, and that the FDA would de-list the '463 patent from the Orange Book unless Biovail amended its certification to indicate that the '463 patent claimed the version of Tiazac that the FDA had approved. On March 26, 2001, Biovail submitted a signed declaration to the FDA stating that "Biovail hereby confirms its belief that the '463 patent is eligible for listing in the FDA's Orange Book in connection with Biovail's drug product Tiazac." This declaration did not clarify whether the term "Tiazac" as used by Biovail meant FDA-approved Tiazac (as the FDA required) or Biovail's revised form of the product, which practices the '463 patent.' See 2002 WL 727033

The FTC in its complaint stated that Biovail did not need a license, especially an exclusive one, to the '463 patent in order to make and sell its FDA-approved Tiazac product. Biovail's acquisition of the exclusive license to the '463 patent raised substantial barriers to entry into the relevant market and gave Biovail the power to exclude competition, thereby protecting Biovail's monopoly in the relevant market. The FTC and Bioval entered a consent decree, under which Bioval agreed to divest the exclusive licence related to the '463 patent.

Conclusions

External patent acquisitions, although encouraged by patent law, may nevertheless raise antitrust concerns. This article discussed two examples of such anticompetitive conduct. In the *Perindopril* case, a dominant firm acquired patents from other pharmaceutical companies, which succeeded in developing alternative, non-infringing formulations of the monopolist's product, in order to remove these technologies from the market and in this way eliminating potential competition. In the *Bioval* case, the monopolist pursued the aim of extending its monopoly power through acquisition of an exclusive patent licence that covered improvement of its own product and that also allowed the company to eliminate competition. Both monopolists pursued the same goal, i.e. strengthening and extending monopoly power by means of patent acquisitions.

The competition authorities when analysing these patent acquisitions took into account the market position of the acquirers at the time of the acquisitions. In particular, they found that the companies possessed substantial market power, and that such acquisitions strengthened their monopoly positions. The analysis also took into account the nature, number and value of the patents acquired in relation to the market for competing products, whether the acquirer intended to use the acquired patents and whether the acquirer needed an acquisition of exclusive rights in order to produce its current product. Finally, it may be inferred from the analysis above that the acquisition may be found anticompetitive when its purpose is to 'hamper generic entry rather than to pursue efficiencies from the acquired technology'.[28]

To conclude, because of the crucial importance of the pharmaceutical industry, and the consequences that anticompetitive strategies of pharmaceutical companies may have with respect to access to medicines, the competition authorities should be encouraged to pursue these practices more vigorously. Control of patent strategies in the pharmaceutical industry will facilitate generic competition that benefits consumers. It will also force pharmaceutical companies to direct their resources away from the strategies that harm competition and stifle innovation and towards the research and development of new or improved medicines.

(FTC No. 011 0094, 23 April 2002) <https://www.ftc.gov/enforcement/cases-proceedings/011-0094/biovail-corporation>.

[28] Perindopril decision (n 7), para 2776.