Arch. Immunol. Ther. Exp. (2010) 58:1–5
DOI 10.1007/s00005-009-0059-0

VARIA – ETHICS

Different Facets of Competition in the Pharmaceutical Sector: Preliminary Findings of the European Commission's Sector Inquiry into Pharmaceuticals

Filip Borkowski

Received: 18 May 2009 / Accepted: 10 June 2009 / Published online: 27 January 2010

Abstract The pharmaceutical sector is a part of today's economy in which the relationship between patents and competition has been receiving increasing attention. The European Commission's inquiry into this sector adds to the ongoing debate. Its Preliminary Report, published in November 2008, explains and quantifies a number of practices adopted by individual companies operating in the sector. The Report focuses on two strands of interplay between pharmaceutical companies. The first focus is on competition between originator and generic companies and the second relates to competition among originators themselves. The Report's observations on the former provide us with some important insights into the potential ways of raising barriers to the timely entry of cheaper, off-patent products, while scrutiny of the latter adds to our understanding of the current rate of introducing new innovative products into the market. The study is completed by a number of observations on the sector's regulatory framework. The presentation below follows the order of findings described in the Report.

Keywords Competition · Patents · Generic competition · European Commission

Introduction

The relationship between patents and competition is undoubtedly one of the focal points of the current discussion on the pharmaceutical sector's future. While the patent system is essential to propel innovation, guaranteeing adequate returns to those who have brought truly new products to the market, competition rules are key to insuring that the benefits of alternative research routes are not relinquished and to assure that when a given patent expires, the pre-expiry price of the patented good is brought to a lower level by generic competition. In the context of an ageing population, this market-based cost containment method is vital to keep the national healthcare budgets at sustainable levels. It is easy to show that both patents and competition are indispensable for the pharmaceutical sector to enable it to meet the often divergent expectations with regard to a desired higher pace of introducing new innovative therapies on the one hand and the budgetary necessity of cost containment measures on the other.

The presentation below largely follows the structure adopted in the Preliminary Report. However, to put the sector inquiry in the institutional context, the main presentation is preceded by some remarks on the process and on the sector. Then the first focus of the Commission's inquiry is introduced, which concerns practices by originator companies that can delay generic entry. Thereafter the presentation turns to practices that can contribute to a decline in innovation. It ends with the main comments on the regulatory framework the Commission received in the course of the exercise.

This article is based on the Preliminary Report of the European Commission's inquiry into the pharmaceutical sector and on the public presentation of said report which took place on November 28, 2008, in Brussels. However, the views presented herein by the author may not under any circumstances be regarded as an official position of the European Commission.

F. Borkowski (✉)
European Commission, DG COMP,
Pharmaceuticals Sector Inquiry Task Force,
J-70 05/06, Rue Joseph II/Jozef II-straat 70,
1000 Brussels, Belgium
e-mail: filip.borkowski@gmail.com

Sector Inquiries

The sector inquiries conducted by the European Commission's Directorate General for Competition are based on Article 17 of Council Regulation 1/2003[1] that foresees such an instrument in cases "*where the trend of trade between Member States, the rigidity of prices or other circumstances suggest that competition may be restricted or distorted within the common market*". The current inquiry into the pharmaceutical sector is not the first; the Commission has already looked into other sectors, namely telecoms, energy, and financial services. As a certain novelty, the pharmaceutical sector inquiry (Pharmaceutical Sector Inquiry; Preliminary Report (DG Competition Staff Working Paper)—Internet: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf) started with upfront inspections. This investigative tool proved to be very useful for understanding the underlying strategies of companies and their implementation in practice. The Commission subsequently sent information requests to the stakeholders concerned. The gathered data allowed the Commission's services to conduct the in-depth analysis required to complete the preliminary findings, which were presented to the public in the form of a Preliminary Report in November 2008. The presentation was followed by a public consultation period that ended in January 2009. At the moment of writing, the work continues, with the aim of publishing the Final Report in early summer 2009.

Prior experience indicates that sector inquiries deliver multiple results. They enhance and objectivize general information available on the investigated sector. In many instances the better understanding of the competition mechanisms within a given sector may itself lead to pro-competitive adjustments by market participants. By their nature, sector inquiries enable casting more light on the nature of the problems preventing effective competition. Precise knowledge in this respect allows for reflection on the instruments best suited to solve concrete issues. Apart from the above-mentioned possibility of self-regulation by market participants, the instruments may include subsequent competition enforcement, regulatory actions, as well as legislative changes. Therefore the findings of sector inquiries are not usually limited to factual observations relating to the companies' behaviors, but also cover policy recommendations on broader regulatory changes which may, in many instances, be indispensable to solving those competition problems that are directly rooted in the regulatory framework.

[1] Council Regulation 1/2003 is the main document setting out procedures for the enforcement of the EC competition rules (Article 81 and Article 82 of the EC Treaty).

Pharmaceutical Sector's Competitive Structure

To simplify the analytical framework, it can be assumed that there are only two types of players: originator and generic companies. These two types of players have distinctively different business models. While originator companies are characterized by high R&D expenditures, high margins on patented medicines, and a high dependency on blockbusters, their generic competitors operate on a more commodity-like market with low R&D expenditures.

First Focus: Competition between Originator and Generic Companies

This part of the Preliminary Report tackles two important issues, namely the economic impact of generic entry and the instruments that can be used by originator companies to protect themselves against generic entry. The instruments are often referred to as the "toolbox". The analysis was carried out on the basis of a sample of 219 medicines. These medicines were mostly either blockbusters and/or well-selling medicines facing loss of exclusivity in the period of 2000–2007. This is a wide sample, covering approximately 50% of the total prescription market. However, the fact that the findings were based on this sample should be born in mind, in particular when any quantitative findings are being discussed.

Generic entry is often delayed, but once it occurs, the effects are substantial. After 1 year, the price decrease is on average almost 20% and after the first 2 years almost 25%. By comparison, the price of medicines without generic entry remains by and large stable. The overall figures obviously hide some significant differences between medicines and between Member States. For example, Member States such as Denmark and Sweden see prices dropping much more sharply than the average. Based on a subsample representing an aggregate post-expiry expenditure of about € 50 billion over the period of 2000–2007, the Preliminary Report estimates that this expenditure would have been about € 14 billion higher without generic entry. In addition, the savings from generic entry could have been about € 3 billion more if generic entry had taken place without delay after the loss of exclusivity date.

The sector inquiry looks at the patent strategies of originator companies in detail. This does not mean that the Commission questions the fundamental importance of patent rights and their efficient enforcement; it cannot be emphasized enough that nowhere in the Preliminary Report does the Commission question the key role of patents in enabling originator companies to recoup investment and be rewarded for innovative efforts. That said, the Report cannot remain silent about the existence of patent clusters aimed at extending the scope and duration of protection.

Originator companies themselves internally acknowledge that creating more and more patents covering all kinds of secondary aspects leads to patents which are increasingly weaker. The following quote from an originator company well illustrates the phenomenon: *The strategy today is to try and provide a solid protection for the substance (has a limited time though) and a portfolio protecting different aspects of product providing extended protection both in brea(d)th and time but inevitable less solid and robust.*[2]

Patent strategies are also visible in terms of hard data. Originator companies can protect their best-selling medicines by filing up to 1,300 patents EU-wide. Each of these patents has a life of its own on the national level. A graphic analysis of patent filings[3] over time shows significant differences between the "conventional" life cycle of a patent portfolio, regularly claimed to be the typical one, and the "late" life-cycle patent portfolio, in which the bulk of filings are made late in the process. It is worth noting that the latter is often seen amongst the top-selling medicines. Such a distribution profile may suggest that patents are used for strategic purposes, in which the patent system is instrumentally exploited to extend product protection over time. This would also mean that in some cases, patent filings may not necessarily reflect an unconstrained scientific research process.

Extensive patenting may eventually lead to patent disputes and litigation. In the sector inquiry, almost 460 patent disputes taking place out of court and almost 700 litigations were found. Patent disputes and litigation proceedings were started by originator companies in 91 and 54% of the cases, respectively. Of the sample of 700 litigation cases, final judgments were passed in 149. The Preliminary Report divides the final outcomes of litigation into two groups, referred to as "GEN's success" and "ORI's success" depending on whether the final outcome eventually allowed the generic to enter or not. This basic division shows that generic companies prevailed overall in more than 60% of the cases. To provide the right context for interpreting this figure it should also be mentioned that the litigation cases reported to the Commission concerned 68 medicines of the 219 considered in the inquiry. This means that the reported litigation cases involved a non-negligible part of the market. Furthermore, and not surprisingly, court cases were more frequent with respect to high-selling medicines.

As regards the time required to obtain a final judgment, the sector inquiry indicates that this is on average 2.8 years. This is a period of uncertainty. Moreover, in half of all the cases in which an originator company requested an interim injunction ordering the generic not be sold, such an injunction was granted. This makes 112 cases with interim injunctions, and an interim injunction and its ban lasted on average for 18 months.

Another interesting finding regarding patent strength is the ratio of rejected and amended patents in the European Patent Office's (EPO) opposition procedures. Opposition procedures allow the interested parties to request a review by the EPO of whether it rightly granted a patent. These procedures are an important tool for opponents, such as generic companies, to ensure patent quality. The Preliminary Report finds that in 75% of opposition procedures in which a final decision was reached, generic companies managed either to eliminate the originator's patent or reduce it in scope. Opposition procedures can be an efficient legal remedy for generic companies to challenge weak patents. However, almost 80% of procedures take more than 2 years before a final decision is reached, and in some extreme cases it can take up to 9 years.

The next instrument in the toolbox are settlement agreements. Patent settlements are commercial agreements between parties to resolve patent-related disputes and litigation. For the period of 2000–2007, the companies reported more than 200 settlement agreements relating to EU markets and covering almost 50 medicines. For nearly half of them a limitation of generic entry was found. The Preliminary Report classifies settlement agreements according to their content. In the sample of reported settlements there were 45 agreements for which a value transfer from an originator to a generic company took place. The value transfer can take different forms. For instance, it can consist of a distribution agreement, a license agreement, or an agreement with direct payments. There were 22 patent settlements of the last type for a total sum of € 200 million. From an antitrust perspective, these agreements are interesting, as one may ask whether the payments served the purpose of keeping a potential competitor out of the market. Of course, there are also other valid reasons for such payments. No one should jump to any hasty conclusions.[4]

Another instrument that can be applied by originator companies to delay generic entry is intervention before national authorities in the process of regulatory approval that generic companies need for their products. Typically, originator companies argue that the generic product is not equivalent, not safe, or not effective. In a number of cases,

[2] All the quotes presented in the Preliminary Report are based on the documents gathered in the course of the Commission's sector inquiry.

[3] For the graphs see Figures 47–51 in the Preliminary Report, pp. 146–149.

[4] In this context it is also interesting to follow the ongoing debate on the same issue in the US. Federal Trade Commission, whose chairman, John Leibowitz, recently declared that the FTC will continue to focus its enforcement efforts on stopping so-called "pay-for-delay" agreements that keep cheaper generic drugs off the market. He also supported a legislative solution in the form of a bill to ban "reverse payments" to generic makers.

originator companies also argued that marketing authorization or pricing and reimbursement status cannot be granted to the generic product because the original product is still patent protected; this is the so-called "patent linkage". In this respect it is interesting to note that marketing authorization bodies are not entitled under EU law to verify the patent status of a generic product. However, this does not seem to stop originator companies from making the argument, as evidenced by a number of cases reported in the sector inquiry. Furthermore, it was observed that when the initial intervention before the authority did not lead to the desired result, originator companies took the national authorities to court. Interestingly, the originator companies won only 2% of the cases launched against marketing authorization bodies in which patent infringement or safety issues were raised. Likewise, the originator companies were only successful in 19% of cases against marketing authorization bodies regarding data exclusivity. These interventions can have significant consequences. When comparing the durations of approval procedures in which an intervention took place and procedures in which no such intervention took place, it was observed that the latter lasted on average 4 months longer.

The last instrument in the toolbox list presented in the Preliminary Report is the use of life-cycle strategies for follow-on products. These strategies are labeled by generic competitors as "ever-greening". The generic industry argues that second-generation products are often based on first-generation products and that they have similar modes of action. The Preliminary Report confirms that originator companies launched second-generation products for 40% of the medicines in the sample. Significant marketing and promotional efforts are undertaken when a switch is envisaged. The timing of the switch is also of great importance, as can be illustrated with the following quote: *if [generic products] come together with or prior to the [second generation product], the switch rate is dramatically reduced. Once [generic products] come in, it becomes difficult to get switches from the old product.*

Individual instruments are often used in parallel. For the top 30 best-selling medicines, originator companies had recourse to as many as five different instruments to protect the revenue stream of their best-selling products.[5] Obviously, this can lead to cumulative delays.

Second Focus: Competition between Originator Companies

The second focus of the sector inquiry is competition between originator companies themselves. In this part, the Preliminary Report explains practices comprising patent strategies, patent-related exchanges, and patent litigation. The list of issues will be extended in the Final Report by a section on agreements between originator companies.

As already underlined, patents are very important for encouraging and rewarding innovative efforts. Their importance is not questioned. That said, attention must also be drawn to the so-called "defensive patents". These can be described as patents which are not foreseen to be used for innovation, but primarily for the purpose of blocking the development of competing products. The following quote by one of the originator companies casts light on this practice: "*We [originator company] identify options to obtain or acquire patents for the sole purpose of limiting the freedom of operation of our competitors*". The Preliminary Report contains more quotes of the same caliber on this subject.

The sector inquiry also tried to estimate the potential scope of patent "conflict" between originator companies. In total, at least 1,100 instances of an overlap of a product or R&D project of one originator company and the patents of another were found. In view of this, requests for licensing and their refusal were also reviewed. The sector inquiry found 99 cases in which a license was requested. In this sample, the granting of such a license was refused in nearly 20% of cases.

The Preliminary Report also includes findings on patent litigation between originator companies. Almost 40% of the respondent originators were involved in patent litigation with another originator. Two-thirds of the cases were settled, the majority of these settlements containing a license agreement.

Third Focus: The Regulatory Framework

As indicated at the beginning, the Preliminary Report also summarizes the main comments on the regulatory framework the Commission received in the context of the exercise. Many comments were made in particular on laws governing patents, market authorizations, and pricing and reimbursement systems.

With regard to the patent system, the most important message is the broad support of both generic and originator companies for the creation of a Community patent and for unified and specialized Community jurisdiction in the EU. This is also very strongly supported by the findings of the sector inquiry. It was found that in 11% of the cases, conflicting judgments were rendered, putting legal security into question. Last but not least, the total cost of patent litigation analyzed in the Preliminary Report was estimated at € 420 million.

The Preliminary Report also notes that generic companies and some originator companies called upon patent offices and, most prominently, the EPO, to which most applications go, to ensure a high quality of patents granted

[5] See Figure 131 in the Preliminary Report, p. 317.

and effectively counter patent strategies that may cause unnecessary delays, such as an abusive use of divisional applications.[6]

With respect to procedures governing marketing authorizations, companies, industry associations, and national agencies reported most prominently about bottlenecks that can lead to obstacles to and delays of market entry. Some originator companies also said that they would favor further international harmonization of marketing authorization procedures, in particular between the EU and the US.

With respect to pricing and reimbursement procedures, originator companies particularly complained about the delays and uncertainties created by the national procedures. Such delays reduce the time during which originator companies can reap the benefits of their innovation. Finally, generic companies voiced some concerns about delays in the pricing and reimbursement procedures resulting from additional requirements introduced by some Member States. They pointed in particular to the fact that some Member States request evidence that the patents of the originator companies are not violated.

Conclusions

The Preliminary Report contains strong evidence that competition in the pharmaceutical sector in the European Union is not working as well as it should. Certain company practices as well as shortcomings in the current regulatory framework are believed to contribute to this situation. The Commission continues its work on the sector inquiry with the aim of publishing the Final Report by mid-summer of 2009. The Final Report will be enriched by the results of additional analyses undertaken after the issue of the Preliminary Report and, last but not least, by the comments stemming from the public consultation process.

[6] Divisional application is a type of patent application which contains matter from a previously filed parent application but is procedurally treated independently.