Preliminary results of Commission pharmaceutical sector inquiry raise competition concerns

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On 28 November 2008, the Commission presented the preliminary findings of its sector inquiry into pharmaceuticals. The report (2) shows that originator companies engage in practices that can contribute to delayed generic entry. The report also states that originator companies use patent strategies aimed at blocking or delaying the development of novel medicines by competitors. This article explains the rationale for launching the sector inquiry and presents the preliminary findings.

1. Context

The pharmaceutical sector is essential for the health of Europe’s citizens, who need access to innovative, safe and affordable medicines. A lot of money is at stake: each European consumer paid almost €430 for medicines in 2007 and this amount will continue to increase as the population in Europe ages. The pharmaceutical sector is also important in terms of economic growth and sustainable employment. For instance, in 2007 the market for prescription and non-prescription medicines for human use in the EU was worth over €138 billion ex factory and €214 billion at retail prices. The sector employs more than 630 000 people in Europe. Most importantly, innovation in human medicines has enabled patients to benefit from treatments that were unimaginable a few decades ago.

2. Launch of the inquiry

Given the importance of a well-functioning pharmaceutical sector, the Commission launched a sector inquiry into pharmaceuticals on 15 January 2008. (3) The inquiry was initiated in response to signs that competition in the pharmaceutical market in the European Union may not be working well. This was indicated by a decline in innovation measured by the decreasing number of novel medicines reaching the market each year and by instances of delayed market entry of generic medicines. The inquiry sought to examine whether certain practices of pharmaceutical companies may be among the reasons for the generic delay and the decline in innovation. The inquiry focused in particular on those practices which originator companies may use to block or delay generic competition as well as to block or delay the development of competing originator products. As the industry is strongly regulated, the sector inquiry also collected comments from stakeholders on perceived shortcomings in the (implementation of the) regulatory framework.

In the course of the investigation, the Commission consulted widely with stakeholders such as industry associations, representatives of consumers and patients, insurance companies, associations of doctors, pharmacists and hospitals, the European Patent Office (EPO) and national patent offices, and national competition authorities. The Commission also carried out upfront inspections. Finally, the Commission gathered data on the basis of requests for information sent to over 100 pharmaceutical companies active in the EU as well as to various other stakeholders. The data relate to a sample of 219 substances used in prescription medicines for human use, which were sold in the EU in the period 2000 to 2007.

3. The preliminary findings

The Commission presented its preliminary findings at a public hearing on 28 November in Brussels. The preliminary report confirmed that there are delays in generic entry and a decline in innovation, and examined some of the possible causes, most prominently those stemming from company behaviour. The preliminary report confirms the key role of patent rights for the pharmaceutical sector as they allow companies to recoup their considerable upfront investments and to be rewarded for their innovative efforts. It does not identify individual cases of wrongdoing or offer any guidance on the compatibility of the practices examined with the EC competition rules. It provides the Commission with a factual basis for deciding whether further action is needed and what form it should take. The key pre-

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liminary findings of the sector inquiry with regard to the issues investigated can be summarised as follows:

3.1 Competition between originator companies and generic companies

**Impact of generic entry**

The sector inquiry confirmed that in many instances generic entry takes place later than could be expected. For a sample of medicines facing loss of exclusivity in the period 2000 to 2007, the average time to enter after loss of exclusivity was about seven months on a weighted average basis and still about four months for the most valuable medicines. On average, price levels for (originator and generic) medicines in the sample facing loss of exclusivity in the period 2000 to 2007 decreased by nearly 20% one year after the first generic entry, and about 25% after two years. Generic prices decreased significantly below these price levels.

On the basis of a narrower sample of medicines representing an aggregate post-expiry expenditure of about €50 billion in the period 2000 to 2007 in 17 Member States, the preliminary report estimates that generic entry brought savings of €14 billion. However, the savings from generic entry could have been about €3 billion more, representing a further saving of over 5% of total expenditure, if generic entry had taken place immediately after loss of exclusivity. This is a conservative estimate as certain effects (such as volumes) could not be considered.

**A “tool-box” of instruments**

The preliminary findings indicate that originator companies design and implement a variety of strategies (a “tool-box”) in order to ensure continued revenue streams from their medicines. The successful implementation of these strategies may have the effect of delaying or blocking generic entry. The preliminary report underlines, however, that company behaviour may not be the only cause for the delay of generic entry on the market.

**Patent clusters**

A strategy commonly applied by originator companies is to extend the breadth and duration of patent protection by filing numerous patents for the same molecule, forming so-called “patent clusters”. In some cases, individual blockbuster medicines are protected by up to 1,300 patents and pending patent applications in the EU, leading to uncertainty for generic companies seeking to enter the market without infringing an originator company’s patents or patent applications. In the period 2000 to 2007, originator companies also engaged in nearly 700 cases of patent litigation with generic companies in relation to the sample of products investigated. Generic companies won 62% of all cases where a final judgment was taken but it took on average 2.8 years for a final judgment to be reached by court.

**Patent opposition procedures**

The preliminary findings confirm that the opposition rate (i.e. the number of oppositions filed per 100 granted patents) before the European Patent Office (EPO) is consistently higher in the closest available proxy for the pharmaceutical sector than it is in organic chemistry and in all sectors (overall EPO average). Based on the sample investigated, generic companies almost exclusively opposed secondary patents. They prevailed in approximately 75% of final decisions rendered by the EPO (including the Boards of Appeal) during 2000 to 2007, either by achieving the revocation of the patent or by having its scope restricted. Even though generic companies are very successful in opposing originator companies’ secondary patents, approximately 80% of the final decisions took more than two years to obtain. The duration of opposition procedures (including appeal procedures) considerably limits the generic companies’ ability to clarify the patent situation of potential generic products in a timely manner.

**Patent settlements**

The sector inquiry also found that, between 2000 and 2008, more than 200 patent settlement agreements were concluded between originator and generic companies in the EU, with nearly half (48%) restricting the ability of the generic company to market its medicine. 45 settlements contained — in addition to the restriction — a value transfer from the originator company to the generic company, with direct payments to generic companies alone amounting to more than €200 million.

**Intervention at regulatory bodies**

Originator companies also intervened before national marketing authorisation and pricing and reimbursement authorities to call into question the quality or safety of generic products or to claim that the commercialisation of these products would violate their patent rights. Although originator companies were successful in challenging the decisions of national authorities in court in a limited number of cases, such interventions resulted in additional delays for the entry of generic products onto the market.

**Life cycle strategies for follow-on products**

Originator companies launched second generation (“follow-on”) products for 40% of the medicines
in the sample under investigation when they faced loss of exclusivity between 2000 and 2007, and undertook intensive marketing efforts with the aim of switching their patients to the new medicine prior to the market entry of a generic version of their first generation product. Patents on second generation products are sometimes criticised as weak by other stakeholders for showing only a marginal improvement for the patient and limited innovation (if any). Originator companies, on the other hand, argue that incremental innovation deserves adequate protection through patent rights. In many instances, originator companies used two or more instruments from the “tool-box” in parallel and/or successively in order to protect the revenue streams from their (best-selling) medicines.

3.2 Competition between originator companies

Patent strategies

As regards competition between originator companies, the preliminary findings of the sector inquiry show that originator companies engaged in so-called “defensive patent strategies”. Originator companies used patents falling into this category primarily to block the development of new medicines by their competitors and not to bring a new/improved medicine to the market. The sector inquiry also found at least 1 100 instances across the EU of overlaps between an originator company’s patents relating to a medicine in the sample under investigation and the R&D programme and/or patents held by another originator company for its medicines. These overlaps create significant potential for originator companies to find their research activities blocked, with detrimental effects on the innovation process.

Patent-related exchanges, disputes, litigation and oppositions

In many cases originator companies tried to settle potential disputes, for instance through licensing. However, in approximately 20% of the cases where a licence was requested the patent holder refused to grant it. Between 2000 and 2007 originator companies engaged in litigation against other originator companies in 66 cases concerning 18 different medicines in the sample under investigation. In 64% of the cases, litigation was concluded by means of a settlement agreement. The patent holders lost the majority (77%) of cases where final judgments were given (13). The preliminary findings also showed that, between 2000 and 2007, originator companies mainly challenged each other’s secondary patents. The applicant originator companies were very successful when challenging the patents of other originator companies. During that period, they prevailed in approximately 89% of final decisions rendered by the EPO (including the Boards of Appeal).

3.3 Comments on the regulatory framework

The pharmaceutical sector is highly regulated. In view of the importance of the regulatory framework for all actors, the Commission also collected comments on the regulatory framework applicable to the pharmaceutical sector. Stakeholders reported several perceived difficulties and shortcomings in relation to market entry due to the regulatory framework. As regards possible remedies, generic companies and originator companies agree on the need for a single Community patent and a unified and specialised patent judiciary in Europe. Stakeholders also highlighted certain concerns in relation to marketing authorisation and pricing and reimbursement procedures, which may contribute to delays in bringing pharmaceutical products to market.

4. Next steps

Based on a vast amount of empirical data, a large part of which had never been gathered before at a similar level of detail and accuracy, the preliminary report gives an in-depth analysis of company practices in the pharmaceutical sector. These practices can block or delay generic entry or the development of novel medicines by competitors.

On 8 July 2009, the Commission published the final report of the pharmaceutical sector inquiry, which takes into account the comments received during the public consultation. An article reviewing the findings of the final report will be published in the third edition of the Competition Policy Newsletter for 2009.