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I. BACKGROUND OF THE PHARMACEUTICALS SECTOR INQUIRY

On November 28, 2008 the European Commission published its preliminary findings on the inquiry into the pharmaceutical sector in the European Union. The preliminary report shows that originator companies engage in practices that can contribute to a delay of generic entry. The report also found that originator companies use patent strategies aimed at blocking or delaying the development of novel medicines by competitors.

The preliminary report closed the first phase of the pharmaceutical sector inquiry launched by the European Commission under Articles 81 and 82 of the EC Treaty in January 2008 in response to information 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.

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The inquiry focused in particular on company behavior taking into account that sector inquiries are competition inquiries. As the pharmaceutical industry is highly regulated, the sector inquiry, however, also collected comments from stakeholders on the perceived shortcomings in the regulatory framework.

During the course of the sector inquiry, the Commission held meetings with the industry associations at the European level, representatives of consumer and patients associations, insurance companies, doctors, pharmacies, wholesalers, hospitals, the European patent office (“EPO”) and national patent offices, and national competition authorities. The Commission also carried out inspections at the start of the inquiry. The Commission gathered data on the basis of requests for information sent to a number of originator and generic companies active in the EU, as well as to other stakeholders such as regulatory authorities and associations representing wholesalers, insurance companies, and others. The data concern a sample of 219 substances used in prescription medicines for human use, which were sold in the EU in the period 2000 to 2007.

II. PRELIMINARY FINDINGS

The preliminary report confirms that there is a delay of generic entry and a decline in innovation. It submits that company behavior has contributed to these observations. The preliminary report underlines the key role of patent rights for the pharmaceutical sector. It does not identify individual cases of wrongdoing or provide any guidance on the compatibility of the practices examined with EC competition rules.

The key preliminary findings of the sector inquiry can be summarized as follows:

A. Competition Between Originator and Generic Companies

1. 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 percent one year after the first generic entry, and about 25 percent after two years. Obviously, 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 EURO 50 billion in the period 2000 to 2007 in 17 Member States, the preliminary report estimates that generic entry brought savings of EURO 14 billion. However, the savings from generic entry could have been about EURO 3 billion more, representing a further economy of over 5 percent 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.

2. A "Tool-box" of Instruments

The preliminary findings indicate that originator companies design and implement a variety of strategies in order to ensure continued revenue streams from their medicines.

The companies themselves speak of a so called “tool box” of strategies and instruments. The successful implementation of these strategies may have the effect of delaying or blocking generic entry. The preliminary report underlines, however, that company behavior may not be the only cause for the delay of generic entry on the market.

3. Patent Clusters and Patent Litigation

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 can be 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. Originator companies accept that these patents may be more vulnerable to challenge. A statement from a strategy document of a large originator company illustrates this:

[...] Inevitably there will be patents covering products on the market that can be, and will be challenged [...] 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 [the] product, providing extended protection both in brea(d)th and time but inevitable less solid and robust.

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 percent 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. In 11 percent of the final judgments reported, courts in different EU Member States gave

conflicting judgments on the issue of the validity or infringement of the same underlying patents. The total cost of patent litigation in the EU in the cases reported is estimated to exceed EURO 420 million for the period 2000 to 2007.

4. Patent Opposition Procedures

The preliminary findings confirm that the opposition rate (i.e. the number of oppositions filed per 100 granted patents) before the 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, i.e. not the patent protecting the original compound. They prevailed in approximately 75 percent 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' patents, approximately 80 percent 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.

5. 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 percent) restricting the ability of the generic company to market its medicine. Forty-five 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 EURO 200 million.

6. Intervention at Regulatory Bodies

Originator companies also intervened before national marketing authorization and pricing and reimbursement authorities to call into question the quality or safety of generic products or to claim that the commercialization 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 contributed to delaying the entry of generic products onto the market.

7. Life Cycle Strategies for Follow-On Products

Originator companies launched second generation ("follow-on") products for 40 percent of the medicines in the sample under investigation which 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 criticized 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.

B. Competition among Originator Companies

1. Patent Strategies

As regards competition among originator companies, the preliminary findings of the sector inquiry show that originator companies implement 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 Research and Development (“R&D”) program and/or patents held by another originator company for its medicines. These overlaps create potential for originator companies to find their research activities blocked, with potential detrimental effects on the innovation process.

A quote from a strategy document of a large originator company provides an illustration of this:

Defensive patents (“limited list” patents) serve to protect compounds closely related to [our company’s] candidates or products. They do not cover [our company’s] candidates or products. They protect compounds that would be of interest to a direct competitor.

2. Patent-Related Exchanges, Disputes, Litigation, and Oppositions

In many cases originator companies tried to settle potential disputes, for instance through licensing, but faced a refusal to license in 20 percent of the cases where a license was requested. Between 2000 and 2007, 40 percent of originator companies engaged in litigation against others; in nearly two thirds of cases litigation was concluded by means

of a settlement agreement. The patent holders lost the majority (77 percent) of cases where final judgments were given (13). The applicant originator companies were very successful when opposing the patents of other originator companies prevailing in nearly 89 percent of final decisions rendered by the EPO (including the Boards of Appeal).

C. Comments on the Regulatory Framework

In view of the importance of the regulatory framework for the pharmaceutical sector, the Commission also gathered comments by stakeholders on the perceived difficulties and shortcomings in the regulatory framework in relation to market entry. As regards possible remedies, generic companies and originator companies agree on the need for a single Community patent and a unified and specialized patent judiciary in Europe. Stakeholders also highlight certain concerns in relation to marketing authorization and pricing and reimbursement procedures, which may contribute to delays in bringing pharmaceutical products to market.

III. NEXT STEPS

The Commission is now working on its final report which will take into account the comments received during the public consultation, which ended on January 31, 2009. The final report is expected in summer 2009. As a follow-up action, the Commission and/or national competition authorities may launch investigations to enforce the competition rules in the pharmaceutical sector. The Commission may also consider making recommendations to improve the regulatory framework.