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European Commission's Pharmaceutical Sector Inquiry Report Finds Certain Practices May Delay Entry of Generic Medicines

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On November 28, 2008, the European Commission published its preliminary report and findings in connection with the sector inquiry it launched late last year on competition in the pharmaceutical sector. The Commission acknowledges that patents are vital to providing pharmaceutical companies with an incentive to innovate and that patenting activities and litigation are generally legitimate. The report, nonetheless, concludes that "originator" companies (*i.e.,* those that bring new products to market) have employed a "tool-box" of patent practices and product lifecycle strategies (*e.g.,* multiple patent applications; vexatious litigation, follow-on medicines and secondary patents) that may have the object or effect of delaying or blocking the entry of generic and other new medicines. (We discuss the specific practices that the Commission analyzed in greater detail below.) If such delays could have been avoided, the Commission believes substantial cost savings would have been achieved through the more timely purchase of lower-priced medicines.

The Commission's report does not reach any conclusions on whether some or all of the identified strategies infringe EC competition law; however, the Commission fined AstraZeneca €60 million in 2005 for allegedly providing misleading representations to patent offices in the EU to restrict the entry of generic medicines to the market. Last year, the Commission also started proceedings against Boehringer for alleged misuse of the patent system in the area of chronic obstructive pulmonary disease drugs.

The Commission may seek to bring additional enforcement actions against others as a result of information learned during the sector inquiry. Any attempt by the Commission to define or create new distinctions between legitimate and anticompetitive patenting, litigation, and product development activity is likely to prove controversial, particular if it limits the ability of firms to seek patent protection for incremental or other innovations.

Pharmaceutical firms, especially those that may employ some or all of the "tool-box" of practices mentioned in the report, will need to evaluate their own practices in light of the report's findings and closely monitor and follow any Commission enforcement activity in this area to see whether the law is expanded or clarified in some way.

Finally, while the report recognizes that aspects of European regulations relating to patents, marketing authorisations, and pricing and reimbursement decisions can affect the competitive process and contribute to delays for new and generic medicines, it does not provide specific recommendations for reform. The Commission does, however, note "that significant cost and efficiency improvements could be achieved by creating a Community patent and unified patent judiciary" and appears to offer its general support for efforts to improve other regulatory procedures that may contribute to delays for both new and generic products. It remains to be seen what, if any, reforms may take place in these areas, but proposals for a Community patent and unified patent judiciary have been pending for many years and have yet to be adopted.

The Commission has invited interested parties to submit comments on the report before January 31, 2009, and expects to issue a final report in the spring or summer of 2009.

Report's Main Findings

More Timely Entry of Generic Medicines Could Result in Substantial Cost Savings.

- Between 2000-2007, the Commission estimates that it took an average of 7 months for generic medicines to enter the market after the loss of patent exclusivity for the top 219 selling substances it analyzed. The delay was estimated to be only 4 months for the top selling medicines.
- If these delays could be eliminated, the Commission estimates that costs savings of at least 5% could have been achieved if generic entry were instantaneous. This amounts to approximately € 3 billion of the €57 billion in post-expiry expenditures for the studied medicines, which account for nearly 50% of prescription medicines sold in the EU over the covered seven-year time period.

Originator Companies Employ a Tool-Box of Measures That Extend the Life of Their Medicines and May Delay or Block Generic Entry.
The Commission's report finds that "originator" companies have employed a "tool-box" of patent practices and product lifecycle strategies that may have the effect of delaying or blocking the entry of generic and other new medicines. While the Commission repeatedly indicates that the sector inquiry report is not intended to provide guidance on the competition law aspects of these practices and strategies, the Commission is clearly analyzing them, in part, to determine whether any enforcement actions are necessary.

The following practices and strategies were analyzed and discussed in the Commission's report:

Patent Filing and Enforcement Strategies. The Commission acknowledges that patent protection offers financial rewards for investment made to develop new products. In recent years, however, the Commission found that companies have increasingly sought to create "patent clusters" or "patent thickets" for the same medicine and use divisional patents to extend the breadth and duration of their patent protection. Divisional patent applications allow the applicant to split the initial application into multiple narrower applications. These patent applications have a life of their own; the examination may continue even if the parent application is revoked or withdrawn.

While the report recognizes that incremental innovations can be of significant importance, the Commission cites quotes from internal company documents that purport to show that patentees often view these as weak patents and that a sole or important objective behind these strategies has been to delay or block entry of generic medicines.

The Commission also found that generic companies were successful in opposing secondary patents of originator companies before the European Patent Office; in approximately 75% of cases studies, the patents were revoked or restricted. Nonetheless, for the vast majority of cases, it took more than two years to obtain this result, and the Commission concluded that this limits the ability of generic companies to clarify the patent situation in a timely manner – thereby contributing to their delayed entry after the patent exclusivity period.

Patent Litigation. The report recognizes that the enforcement of patent rights in courts is generally legitimate, but goes on to highlight that companies' internal documents indicate that litigation is not always initiated on the merits, but to deter or create obstacles for generic entrants.

The report also notes that originator companies primarily invoke secondary patents during litigation, and that generic companies have won the majority (62%) of cases in which a final judgment was given.

In addition, the average duration of patent litigation cases is almost 3 years, and in 11% of case going to final judgment, two or more different courts in different EU Member States gave conflicting judgments on the same issue of patent validity or infringement. This legal uncertainty contributes to the delay of generic entry.

Patent Settlement Agreements. The report is again explicit that the report is not intended to provide guidance on the competition law aspects of patent settlement agreements. Nevertheless, the report highlights the factors and decision-making process that companies go through when entering into such arrangements. It also discusses the ongoing controversy in the U.S. over the legality of patent settlement agreements involving "reverse payments" from originator to generic

companies and a restriction on the generic's entry into the market.

The report notes that the inquiry revealed 23 agreements involving direct payments exceeding € 200 million and also revealed the existence of another 22 agreements involving some other value transfer or "side deal" (*e.g.,* license or distribution agreement).

The Commission appears to be studying the purpose and effects of these agreements and remains in ongoing consultations with US antitrust agencies concerning these issues. Firms entering such agreements will need to carefully assess the antitrust and competition law risks.

Administrative Interventions. The report also highlights the fact that originator companies intervene in administrative proceedings before national authorities for marketing authorisations and pricing/reimbursement status. Originator companies may intervene to argue that generic products are less safe, less effective and/or of inferior quality. Marketing authorisations, according to the Commission, were granted on average four months later when such an intervention took place.

Marketing and Distribution Activities. The report concludes that originator companies do not simply promote their own medicines to healthcare providers, but also adopt practices designed to question the quality of generic medicines.

The report observes that originators may send warning letters or institute litigation against wholesalers that distribute generic medicines. The Commission also identified instances in which generic companies were cut off from sources of supply for an active ingredient after an acquisition by or agreement with an originator company.

Originator companies are also increasingly adopting direct-to-pharmacy distribution models, which the Commission fears may "lead to less competition at the wholesale level and possibly render it more difficult for smaller originator and generic companies to enter the market."

Life Cycle Strategies for Follow-on Products. The report also finds that originator companies increasingly launch second generation/follow on medicines shortly before expiration of the patent exclusivity period for the first generation drug. This is usually accompanied by intense marketing to shift demand and submitting new (and sometimes allegedly weaker) patent filings for the second generation product. The Commission concludes that the successful implementation of these strategies decreases significantly the probability that generic companies will gain a significant share of the market.

Conclusion

The Commission's sector inquiry has already created some uncertainty in the pharmaceutical industry on practices that raises difficult issues involving the intersection of intellectual property and competition law. The report leaves the most difficult competition law questions open, but it does provide clear insight into the practices and activities on which the Commission is focusing its concerns.

It remains to be seen where the Commission ultimately believes the line should be drawn between, on the one hand, legitimate patenting, litigation, product development, marketing and distribution activities that are designed to protect innovation and competition on the merits and, on the other hand, unlawful anticompetitive conduct that has the purpose and effect of deterring entry or facilitating collusion. Some clues are already available in the Commission's 2005 case against AstraZeneca and current proceedings against Boehringer.

The Commission will most likely look to bring one or more enforcement actions as a result of its inquiry. Depending on the exact target and scope of any such proceeding, the Commission may establish additional precedent in this complex area of the law. The Commission could also attempt to issue more general guidance on its enforcement position on these issues and/or provide its support to other legislative reforms (*e.g.*,introduction of Community patents and unified judiciary) that could further reduce some of the perceived barriers that delay new or generic medicines reaching the market.