EU COMPETITION LAW UPDATE

European Commission Issues Its Preliminary Report In Its Inquiry Of The Pharmaceutical Sector

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On November 30, 2008, the European Commission released its Preliminary Report in connection with its investigation of the EU pharmaceutical sector (the "Pharmaceutical Sector Inquiry"). The Commission launched the Pharmaceutical Sector Inquiry in January 2008 because it felt competition in the sector might be distorted, noting that the number of new chemical molecules coming to the market seems to be in decline, and generic manufacturers do not appear to enter the markets as quickly as would be expected.

The Preliminary Report distinguishes between so-called originator companies that patent new products, and generic companies that produce copies once the patents have expired. It examines whether practices by originators create obstacles to market entry for generics and competing originators. The Commission states that it has also considered shortcomings in the regulatory system, although this was not the focus of the inquiry.

Importantly, the Preliminary Report does not attempt to provide any guidance on the circumstances under which individual practices described would constitute an infringement of EU competition law. Nonetheless, in a press release accompanying the report, Competition Commissioner Neelie Kroes said: "the Commission will not hesitate to open antitrust cases against companies where there are indications that the antitrust rules may have been breached."

I. FEATURES OF THE PHARMACEUTICAL MARKET

The Preliminary Report notes that a substantial proportion of the profits of originators come from "blockbuster" products, and that originators have significant economic incentives to extend the earning potential of those products for as long as possible because a number of blockbuster products have lost (or are about to lose) their patent protection. An industry trend noted by the Commission is that originator companies are having difficulty "refilling the pipeline" with new products.

The Commission claims that generic entry takes place on average around 6.5 months after expiration of patent exclusivity, and suggests that certain strategic conduct by originator companies may contribute to the observed delays.

II. COMPETITION BETWEEN ORIGINATORS AND GENERICS

The Commission identifies a number of practices that originators may use to try to ensure continued revenue streams for their patented medicines by restricting generic access to the market:

- **Filing numerous patent applications across the EU in relation to a single medicine ("patent clustering").** The Preliminary Report notes that the number of pharmaceutical-related patent applications before the European Patent Office almost doubled during the relevant period (2000-2007), with the patent portfolios in relation to a blockbuster product often increasing throughout the product's lifecycle. According to the Commission, some blockbusters are protected by up to 1,300 current or pending applications in the EU. In addition, there are "divisional patent" applications, which allow an originator to split an initial application. These applications continue to be examined even if the original application is withdrawn or revoked. The Commission also notes that much of the patent-related litigation in the EU concerns "secondary patents" (*e.g.*, process patents), and that generics have succeeded in around 75% of the litigation involving such patents. The Commission suggests that such patent clusters may delay generic entry, by making it more difficult for generic companies to challenge weak patents in order to clear the path for entry.

- **Engaging in high volumes of disputes and litigation with generic companies.** The Commission acknowledges as a general matter the right of originators to enforce their patent rights in court. However, the Commission implies that in certain instances litigation may be "problematic" when it deters or delays generic entrants. The Commission obtained information on at least 1,300 patent-related disputes and litigation procedures between originators and generics during the relevant period, and found that generics were successful in 62% of the 149 cases in which a final judgment was obtained (although this figure may vary depending on how the data is analyzed. For example, success rates vary depending on which side initiated the litigation or depending on the type of patent involved.) The Preliminary Report observes that the total cost of reported pharmaceutical litigation in the EU between 2000 and 2007 is estimated to have exceeded €420 million. The

Commission finds that the cost and delay may make it difficult for generics to clarify the patent situation of potential generic products in a timely manner. The Commission stresses that the creation of a Community patent and a Community patent jurisdiction would considerably simplify patent litigation.

- **Concluding settlement agreements with generics that may delay generic entry to the market.** The Preliminary Report states that originators and generics concluded more than 200 settlement agreements during the relevant period. The Commission divided these into agreements that place no restriction on generic entry to the market, and agreements that restrict generic entry in some way. Within this second category, the Commission further divided the agreements into those where no "value transfer" passed from the originator to the generic, and those where the generic received value in some form, such as a direct monetary payment or a royalty-free license. The implication of the report is that this second sub-category may require further scrutiny. The Preliminary Report notes that the U.S. Federal Trade Commission has scrutinized agreements of this sort as potentially anticompetitive. In contrast, Commission officials stated during the presentation of the Preliminary Report that the other categories of settlements that do not involve a value transfer from the originator to the generic should generally not raise concerns.

- **Intervening in national procedures for the approval of generic medicines.** The Commission notes that originators have intervened in respect of generic applications for marketing authorization and pricing/reimbursement status at a national level, claiming that generic products are not as safe or effective as the branded product or invoking their patent rights vis-à-vis regulatory bodies. The Commission suggests that such a "patent linkage" in regulatory proceedings conflicts with EU law because patent issues are irrelevant for the grant of marketing authorizations or pricing and reimbursement approvals under the relevant regulations and directives. It is not clear, however, whether the Commission considers this to be an issue of Member State compliance with EU law or whether it envisages holding private companies liable for making use of remedies offered under national regulatory systems. In addition, the Preliminary Report identifies other strategies by originators such as attempting to exercise influence over distribution channels and supply sources for ingredients needed to produce a particular medicine, and running marketing campaigns to undermine the quality of generic alternatives.

- **Launching "second generation" medicines.** The Preliminary Report suggests that originators launched second generation medicines in relation to 40% of the sampled medicines that lost exclusivity during the relevant period. The Preliminary Report states that originators achieved this by investing heavily in intensive marketing, with a view to converting patients to the new medicine prior to the entry of a generic version of the first generation product. The Commission suggests that the launch of second generation products can help delay generic entry if patients are successfully switched to the second generation product prior to patent expiration and the second generation product is protected by additional patents, although it does not present data to support this claim.

III. COMPETITION BETWEEN ORIGINATOR COMPANIES

The Preliminary Report notes that originators also employed "defensive patent strategies" to block the development of new and competing medicines by other originators, referring to situations in which originators file patent applications without intending to bring their own new/improved products to the market. The Preliminary Report cites 1,100 instances in which a patent held by an originator overlapped with R&D and/or patents held by another originator. The Commission considers that this creates significant potential for originators to block rivals' research activities, which will have a detrimental effect on innovation. The implication is that this behavior is an important explanation for the drop in new molecules launched by originators.

Further, the Commission observes that a patent-holder refused to grant a license in approximately 20% of the cases where an originator has requested a license from another originator to settle a potential patent dispute.

IV. COMMENTS ON THE REGULATORY FRAMEWORK

The Preliminary Report states that originators and generics both support the creation of a single Community patent (in place of the current bundling of national patents), as well as a unified and specialized European patent judiciary (in place of the existing national system of patent litigation).

In addition, companies, industry associations and agencies all reported bottlenecks in marketing authorization procedures. The Preliminary Report points to a lack of adequate resources for this task. Some originators would support a harmonization of national marketing authorization procedures.

Originators were critical of national pricing and reimbursement procedures, and attributed delays to the fragmentation of the national decision making-process, the use of health technology assessments and cross-border reference pricing systems. Delays are also the main complaint of the generics companies. In addition, originators expressed concern about expenditure control, in particular therapeutic reference pricing (and the inclusion of patented and non-patented products in the same groups). Conversely, generics support the wider use of this practice because, in their view, it can facilitate market entry.

The Commission is soliciting comments from the public on the Preliminary Report. Comments are due on January 31, 2009, and the Commission expects to issue its Final Report in the spring of 2009.

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