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9 July 2009 | 01

European Law and Competition

Increased Scrutiny:

The Final Report on the Sector Inquiry into the Pharmaceutical Sector

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The European Commission published yesterday the Final Report on its Inquiry into the Pharmaceutical Sector (Report)[1]. The Report confirms the Commission's preliminary findings that generic entry does not always take place as early as it potentially could under the current legal framework, but reflects a more conciliatory tone towards the exercise and role of Intellectual Property (IP) rights than the somewhat harsh-toned preliminary report. The Commission nevertheless suggests that, although a variety of other conditions might play also an important role, "company practices are amongst the causes", and proposes to apply "increased scrutiny" under EU competition law to the sector.

This note contains a preliminary analysis of the main findings of the Report and of the actions proposed by the Commission.

The Inquiry

Since 2004, Regulation (EC) 1/2003 empowers the Commission to initiate inquiries into specific sectors of the economy where it thinks competition may be restricted. These inquiries are not meant (in principle at least) to identify wrongdoing by individual companies, but rather to identify perceived market malfunctions. Further to previous inquiries into sectors such as energy, banking and insurance, the pharmaceutical inquiry was initiated in January 2008, after the Commission conducted, for the first time in this context, surprise inspections ("dawn raids") to the premises of several pharmaceuticals companies.

The Commission published a report with its preliminary findings on 28 November 2008 (further dawn raids were conducted a few days before the Report was published), and initiated a public consultation which lasted until 31 January 2009. A large number of submissions were received, representing a wide variety of stakeholders, including pharmaceutical and generics companies, sectoral associations, public bodies, law firms and associations and academics. Certain submissions were highly critical of the preliminary findings, and of the hostile tone towards business conduct which were believed to be standard practice in the pharmaceutical sector. The comments received led to a number of adaptations of the preliminary report.

[1] The Report and accompanying documentation is available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.

MAIN FINDINGS OF THE REPORT

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The voluminous (600-page long) final report is essentially an updated and revised version of the November 2008 preliminary report. Drawing on the extensive information collected during the inquiry (both from information requests and from dawn raids), the Commission concludes there are a number of difficulties encountered by generics companies in entering the market once a patent protecting a medicine has expired, and that the "results of the sector inquiry suggest that the behaviour of companies contributes to the generic delay". According to the Commission, pharmaceutical companies use a "variety of instruments" to extend the commercial life of their medicines, such as:

- **Patent filing strategies**, through the filing of numerous patents for the same drug (forming so-called "patent clusters"), in order to prolong the lifetime of the original patent. According to the Report, "statements in internal documents" collected in the course of the inquiry point at the awareness by patent holders that "some of their patents might not be strong". However, the Report also recognizes that identifying the most promising patent strategies in order to protect their assets "is key for their innovative efforts". Further to comments from the European Patent Office ("EPO"), the Commission acknowledges that patent applications are evaluated only on the basis of the statutory patentability criteria by the patent offices, and not on the basis of "underlying intentions of the applicant". In addition, the Commission welcomed recent initiatives of the EPO to limit the possibilities and time periods during which voluntary divisional patent applications can be filed.

The report recognises however, that "enforcing patent rights in court is legitimate and a fundamental right guaranteed by the Europea Convention of Human Rights"

- **Patent-related exchanges and litigation**. One of the controversial topics of the preliminary report concerned the critical observations towards the initiation of patent infringement court proceedings, including preliminary injunctions. Statistics showing that the majority of cases were won by generic companies led the Commission to suggest in the preliminary report that the pharmaceuticals companies' "claims could not be substantiated" and that such behaviour would attract antitrust scrutiny. In the Report, and subsequently to extensive comments during the public consultation, it is expressly recognized that "enforcing patent rights in court is legitimate and a fundamental right guaranteed by the Europea Convention of Human Rights", and that it is an effective means of ensuring that patents are respected.

- **Patent opposition procedures and related appeals before patent offices**, which mainly consist of pharmaceutical companies opposing each other's secondary patents.

In approximately half of the settlements in question the generic company's ability to market its medicine was restricted

- **Settlements between innovative and generic companies** to resolve patent litigation, many of which contain a value transfer between the pharmaceutical and the generic company (either in the form of a direct payment, license, distribution agreement or "side deal"). The Commission notes that in approximately half of the settlements in question the generic company's ability to market its medicine was restricted, and that litigation where direct payments take place has attracted antitrust scrutiny in the USA. It also observes that most of the submitted agreements whose parties hold market shares higher than 20% contain some kind of exclusivity or non-compete obligation, the average duration of which was eight years.

The Commission specifically looks at the litigation against pricing authorities in Portugal as "a special case", in that most claims are based on patent infringement only

- **Intervention before, and litigation against, regulatory authorities granting market authorisation ("MA") and pricing/reimbursement status to generics**, claiming that generic products were less safe, less effective, of inferior quality, or that they violate existing patent rights. Besides noting critically that final court judgments where largely favourable to the generics companies, and that the inquiry "produced evidence that such practices generated significant additional revenues on a number of originator products", the Commission restates its position in the preliminary findings that, according to EU legislation, market authorization and pricing bodies cannot take patent rights into account in assessing requests of generic companies ("patent linkage").

  References to Portugal. In this regard the Report closely mirrors the views of the Preliminary Report. The Commission specifically looks at the litigation against pricing authorities in Portugal as "a special case", in that most claims are based on patent infringement only. The inquiry observed in this context that the price approval procedure was suspended when innovative companies launched legal proceedings against decision granting MAs based on alleged patent violation, and reiterates that under EU law patent rights should not be taken into account in MA and pricing/reimbursement procedures.

- **Marketing and promotion actions** aimed at doctors and pharmacists putting into question the quality of generics, and attempts to influence distributors and active pharmaceutical ingredient producers.

- **Life-cycle strategies for Second Generation Products**. The Launching of second generation (follow-on) products immediately before the original patent is set to expire, in some cases followed by the withdrawal of the first-generation product. However, the report recognises that incremental research is important, as it can lead to significant improvements of existing products.

- **Increase of direct-to-pharmacy (DTP) distribution**, which could lead to less competition at the wholesale level and would make it more difficult for generic companies to enter the market.

- **Cumulative use of practices against generic companies**. According to the Report, the combined use of patent and other strategies/instruments may increase the likelihood of delays in generic entry. However, the Commission, acknowledging the comments received during the public consultation, clarifies that "the use of several instruments that are in themselves legitimate does not necessarily render their combination contrary to competition rules". Rather, a case-specific analysis to establish the precise effects of the conduct on generic entry would be required.

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Finally, the report confirms the initial findings that the regulatory framework of the pharmaceutical sector has a number of shortcomings. Despite the differences in views on some of the findings set out in the Preliminary Report, the Commission notes a broad consensus among the stakeholders on the need to create a Community patent and a unified patent judiciary as a solution to eliminate the causes of a number of the identified delays in generic entry, such as administrative delays in granting MA and inherent uncertainty of patent litigation in national courts.

CONCLUSIONS AND PROPOSED ACTIONS

1. Intensify competition law scrutiny. The Commission declares that where appropriate it will not hesitate to make "full use of its powers" under antitrust, merger control and state aid rules. The express acknowledgement that both IP rights and competition are necessary to promote innovation, and that the existence and exercise of IP rights can only be an infringement in "exceptional circumstances", are welcome clarifications. However, the Commission warns that "certain practices will remain under scrutiny", such as:

The use of "specific instruments" by pharmaceuticals companies will remain under scrutiny "if used in an anti-competitive way"

- Defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts and/or the refusal to grant a license on unused patents, in particular where innovation was effectively blocked;

- The use of "specific instruments" by pharmaceuticals companies in order to delay generic entry, "if used in an anti-competitive way", especially in the case of "clear indications that submissions by a stakeholder intervening before a MA or pricing body was primarily made to delay the market entry of a competitor";

- Agreements "that are designed to keep competitors out of the market", in particular where the motive of the agreement is the "sharing of profits via payments form originator to generic companies to the detriment of patients and public health budgets". The Commission is considering "further focused monitoring" of those settlements "with a potential to adversely affect European consumers;

2. "Urgent need" for the establishment of a Community patent and creation of a unified litigation system. The Commission will continue to make all efforts leading to the rapid adoption of these instruments, further to increased support received from the pharmaceutical sector during the inquiry.

3. "Streamlining" the Market Authorisation and pricing processes. In this regard, the Commission states it will focus on the full implementation and effective enforcement of the regulatory framework. In particular, the Commission will "act against patent linkage", as according to its interpretation of the applicable Community legislation, MA and pricing bodies cannot take the patent status of the originator medicine into account when deciding on market authorisations of generic medicines. The Commission also calls upon national regulatory bodies to "significantly accelerate approval procedures for generic medicines". In this context, national bodies are urged to disregard third party submissions during the assessment of an application for a MA or pricing/reimbursement status, as well as to ensure that submissions by third parties "that cannot be excluded" (pursuant to national law) "are well documented and made transparent towards the applicant". In any event, national bodies "should make all necessary efforts that submissions do not necessarily lead to delays for the applicants".

The Commission will "act against patent linkage"

COMMENT

The Final Report contains a number of welcome clarifications to the most controversial preliminary findings of November 2008, such as that innovator companies' rights to identify the most promising patent strategies are key for their innovative efforts, that defending patents from infringement by third parties is a fundamental right under EU law, and that the exercise of an IP right, although not immune from competition law intervention, will constitute an infringement only in exceptional circumstances.

Specific enforcement action is already underway in a number of cases

However, the Commission also reported the intention to apply increased scrutiny under EC competition law to the sector and to bring specific cases "where appropriate". Considering that the enforcement of IP rights is generally legitimate, it is hoped that the Commission will take action only in the absence of innovative behaviour and where there is clear evidence of anticompetitive intent. According to the Report, specific enforcement action is already underway in a number of cases, including the investigation into *Servier* and a number of generic companies confirmed yesterday by the Commission[2].

Finally, the Report also puts a considerable pressure on the Member States to "fully implement and effectively enforce" the existing regulatory framework, especially regarding the so-called "patent linkage". As suggested during the public presentation of the preliminary report in November 2008, the Commission may initiate infringement proceedings under 226 of the EC Treaty against those Member States whose authorities take into account, in the framework of MA and pricing procedures, existing patent rights which might be breached by the entry of the generic medicines requesting the MA and pricing status. It should nevertheless be noted that this remains only the Commission's opinion on the interpretation of the applicable EU legislation, since the European Court of Justice has not ruled on this matter.

[2]MEMO/09/322, of 8 July 2009, *"Antitrust: Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies"*.

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