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THE EC PHARMACEUTICAL SECTOR INQUIRY: GETTING REAL

INTRODUCTION

Art. 17 of Regulation n°1/2003 provides the European Commission (Commission) with a legal basis to conduct sector inquiries in markets where "the rigidity of prices or other circumstances suggest that competition may be restricted."

The main purpose of sector inquiries is to determine the extent to which any such restrictions are primarily caused by individual company behaviour or rather by other factors, in particular shortcomings in the regulatory framework. In the former case, the Commission's competition department (DG for Competition or DG COMP) will step up its antitrust enforcement activity pursuant to Art. 81 EC and Art. 82 EC. In the latter case, DG COMP will support other Commission departments in their efforts to make the EC regulatory framework more competition-friendly. In the past, the outcome of sector inquiries has usually shown a combination of "tough" antitrust enforcement activity and "soft" competition advocacy.

On January 15, 2008, the Commission launched a pharmaceutical sector inquiry. In its view, the market was functioning in a sub-optimal manner in terms of price competition (i.e., delays in generic entry) as well as non-price competition (i.e., decline in innovation). The inquiry therefore focused, on the one hand, on competition between originator companies and generic companies and, on the other hand, on competition between large and small originator companies.

PRELIMINARY REPORT IN NOVEMBER 2008

On November 29, 2008, the Commission issued its preliminary report. Although it stated—over and over again—that this report merely aimed at reflecting the results of a fact-finding exercise, most observers came away with the impression that the Commission had already made up its mind and was planning to launch a major enforcement crusade against various types of allegedly anti-competitive market behavior engaged in by the large originating companies. Put simply, these observers formulated a triple critique:

1. The Commission seemed ready to challenge individual company behavior under Art. 81 EC and 82 EC that was not only widespread in the industry, but also perfectly in line with settled patent law—a reality that it seemed to completely ignore.

Brussels
+32 (0)2 290 7800

Denver
+1 303.863.1000

London
+44 (0)20 7786 6100

Los Angeles
+1 213.243.4000

New York
+1 212.715.1000

Northern Virginia
+1 703.720.7000

San Francisco
+1 415.356.3000

Washington, DC
+1 202.942.5000

2. The Commission was turning a blind eye to possible restrictions of price competition between generic companies.
3. The Commission was grossly underestimating the regulatory barriers to market entry of generic medicines (and indeed of patented medicines).

FINAL REPORT IN JULY 2009

Main Takeaways

On July 8, 2009, the Commission issued its Final Report—a much more balanced report, not just in tone, but also on substance.[1] While it is early to predict the future, the Commission's answer to the triple critique seems to be as follows:

1. Enforcement actions under Art. 81 EC or Art. 82 EC will be carefully selected and the Commission will bear in mind that the protection of intellectual property rights is a key element in the promotion of innovation, particularly in the pharmaceutical sector "because of the necessity to address current and emerging health problems and the long life cycle of medicines (including long development periods)."[2]
2. Although competition between generic companies is important, it was not the focus of the sector inquiry "as any price fixing and/or market allocation agreements between competitors would be caught by Art. 81 EC." In other words: everybody knows—or should know—that these agreements are *per se* unlawful and a sector inquiry was neither a necessary nor an adequate tool to detect or assess outright cartel behavior.
3. There is considerable room for improving the regulatory framework in the area of patent law and of marketing authorizations, pricing, and reimbursement regimes. These improvements should all be geared towards "minimizing the risks of anti-competitive behavior in future."

This Advisory will examine the first answer in more detail.

Selective Antitrust Enforcement under Art. 81 EC and Art. 82 EC

In its Final Report the Commission highlights—from the outset—the fact that the sector inquiry ties in with several other Commission initiatives that are part of its Lisbon agenda, including its "Industrial Property Rights Strategy" and its sector-specific "Innovative Medicines Initiative." This opener may seem so broadly worded that it means little in practice. However, one should be aware that all Commission departments, including DG COMP, are expected to justify the use of their human resources with reference to the Lisbon agenda. Paying lip service to the objective of strengthening Europe's knowledge-based industry is not enough. The Commission departments must link the allocation of their resources to the Lisbon agenda in their annual work programs.

Before reviewing more closely the various company practices that were scrutinized in the course of the pharmaceutical sector inquiry, the Commission also clarifies a terminological point: references to terms like "defensive patenting," "patent clusters" (or "thickets"), or "secondary patents" are not meant to bear a negative connotation. For instance, as regards defensive patenting, the Commission observes that "it is an inherent feature of a patent system to grant exclusive rights" and that it "should therefore not be understood to mean that these patents are of a lower quality or value." These remarks may sound slightly apologetic, but their importance should not be underestimated. They suggest that DG COMP acknowledges that the repeated references to these practices, in spite of their inherent capacity to delay or prevent potential competition, were one-sided and unbalanced. That being so, one should not jump to the conclusion that DG COMP has now abandoned its concerns with regard to these practices.

In its Final Report, the Commission does not reveal much about its enforcement priorities in the pharmaceutical sector for the near future. However, let us try to identify issues that seem to be of particular interest to it.

General Prognosis

Standard of Legality. All we learn from the Final Report is that the Commission will apply Art. 81 EC or Art. 82 EC "wherever required by the Community interest,"

that it will determine whether such an interest exists "on a case-by-case basis," and that it will take account of "the legitimate objectives to protect innovation and the regulatory framework." As to pending cases, the Commission only refers to the dawn raids it conducted at the premises of several companies located in different Member States a few days before it issued its preliminary report in November 2008. In its Final Report, the Commission does *not* clarify which standard of legality it will use to assess whether or not individual company conduct is unlawful.

However, as far as Art. 82 EC is concerned, the Commission's Guidance Paper on enforcement priorities regarding exclusionary abuses (published in February 2009) will no doubt provide the basis for such assessments.[3] The Commission accepts that it bears the burden of proving that a defendant is truly dominant, that its conduct produces significant, actual or potential, foreclosure effects to the detriment of its competitors and of consumers, and that the targeted competitors have no means of putting into effect a countervailing strategy. Unfortunately, in its Guidance Paper the Commission does not recognize that it should also prove that the allegedly abusive conduct does not make commercial sense *but for* the aim of excluding (or substantially lessening) competition.

Exclusionary Intent. This is a recurring issue in all Art. 82 EC cases (and occasionally in Art. 81 EC cases) that is intimately related to the previous issue. In its Guidance Paper, the Commission confirms that evidence (usually found in internal company documents) of a strategy to exclude competitors "may be helpful in interpreting the dominant undertaking's conduct." The Commission seems to recognize (i) that it is actual conduct in the market that matters, not planned conduct that may never materialize, and (ii) that the market conduct must be assessed in an objective manner, not with reference to more or less aggressively formulated subjective intentions. Not surprisingly, the Commission does not address this issue in its Final Report but, interestingly, it does refer to the viewpoint expressed by the European Patent Office (EPO), who argues against a scrutiny of the intent of applicants in applying for patent rights for purposes of competition law. After all, patent protection confers upon the patent holder the power to exclude competition. Exclusionary intent therefore seems a useless concept for the assessment of patent applications

Role of National Competition Authorities. The Commission repeatedly states that it will enforce its antitrust policy "in close cooperation with the national competition authorities" (NCAs). Given the fact that since 2004 the Commission has operated an extremely well-oiled European Competition Network (ECN) with these NCAs, which enables them to allocate enforcement cases to the best-placed authority and to assist each other in conducting dawn raids, one would not expect anything else. However, let us also keep in mind that several Member States have conducted their own sector inquiries in the pharmaceutical or health sectors and that the ECN Forum also hosts two subgroups where the ECN members can discuss antitrust policy in these sectors.[4] In line with the case allocation criteria set forth in a Notice from 2004, NCAs are likely to take up their responsibility where the centre of gravity of possibly unlawful conduct lies in their jurisdiction (e.g., when originator companies bring meritless claims before national regulatory authorities or bring equally meritless court actions in support of such interventions) (*infra* points 20-21).[5]

In its Final Report, the Commission explicitly adds that "action can also be taken at national level and in areas which were not the primary focus of the inquiry or are outside its scope." This might refer in particular to distribution issues, including parallel trade. In this respect, the Commission observes that "in line with the opening decision, the inquiry does not address in detail potential shortcomings in the distribution chain, which is currently subject to a market monitoring exercise."[6]

Competition Between Originator and Generic Companies

In this section, we give a brief overview of the five main instruments found in what the Commission continues

to describe as the "toolbox" of life cycle management instruments that originator companies can use to delay generic entry. We will start with patent settlements because these are the only type of practice for which the Commission plans specific monitoring action in the near future. Patent clustering (also dubbed strategic patenting) comes next, followed by the launch of follow-on (or second generation) products, court litigation, and intervention before the national regulatory authorities. At the end of this section, we will also examine whether, in the Commission's eyes, the *cumulative* use of these tools increases the risk that individual company conduct be found unlawful.

Settlements. Agreements between originator and generic companies that restrict the generic company's ability to market its medicine and also contain a value transfer from the originator company to the generic company, either in the form of a direct payment or in the form of a license, distribution agreement, or a "side-deal," appear to be the Commission's short-term top priority, at least in terms of "further focused monitoring." The Commission is particularly concerned that the parties to these agreements aim at "sharing of profits . . . to the detriment of patients and public health budgets." It acknowledges that "this monitoring would have to take duly account of the administrative burden imposed on stakeholders and will be limited in time until the Commission has gathered sufficient information on the subject matter to decide whether further action is needed."

Patent Clusters (Strategic Patenting). The Commission keeps a low profile with regard to the filing of numerous patent applications for the same medicine, noting first of all that it is "a common practice." Furthermore, while the Commission observes that documents gathered in the course of the inquiry confirm that "an important objective" of this approach is to delay or block the market entry of generic medicines, it recognizes that all patent applications need to be evaluated "on the basis of the statutory patentability criteria by the patent offices, not on the basis of underlying intentions of the applicant." Moreover, while it identifies "uncertainty" for generic competitors as the main concern about patent clusters, especially where the generic company as well as the patent holders themselves may have doubts about the validity of a particular patent, the Commission stops short of hinting at any concrete follow-up enforcement action.

With respect to another patent filing strategy known as "divisional patent applications" (which seek to split an initial parent application), the Commission observes that these usually extend the examination period of the patent office and thus also delay generic market entry. However, it recognizes that these applications are as such "legitimate" and it notes that, in any event, in March 2009, the EPO took measures to "raise the bar" by limiting the circumstances and time periods in which voluntary divisional patent applications can be filed.[7] In light of this regulatory remedy, it is highly doubtful that DG COMP might ever challenge this practice, alone or in combination with other practices.

Follow-On (Second Generation) Products. It would also seem unlikely that DG COMP will challenge the practice consisting in the launch of a second generation medicine, typically some time before the loss of exclusivity of the first generation medicine, by which the originator company might seek to limit the impact of market entry of generic products corresponding to the first generation product by shifting prescribers and patients to the new product (which will not face generic competition). The Commission stresses the importance of incremental research. Moreover, while it reports that the successful launch of a follow-on product may jeopardize the generic company's chances to gain a significant share of the market, it nowhere states that these launches could be as such unlawful. Let us also remember that in *Astra Zeneca* the Commission did not challenge the launch of Losec™ tablets as follow-on medicines but rather the launch of these tablets *and* the immediate withdrawal and market deregistration of Losec™ capsules in some countries in order to deprive the manufacturers of generic capsules of the possibility to obtain market authorization via the abridged procedure.[8]

Court Litigation. The Commission has no difficulty admitting that enforcing patent rights in court is perfectly "legitimate" and constitutes a "fundamental right guaranteed by the European Convention on Human Rights." Given the strict standard of proof required to demonstrate that litigation is vexatious and thus abusive under Art. 82 EC—a standard which the Commission set for itself many years ago in *ITT-Promedia* and which the Court of First Instance upheld—enforcement activity under Art. 82 EC seems highly unlikely here as well, unless the court action is manifestly baseless.[9]

Interventions Before National Regulatory Authorities. In contrast, given their statistically much poorer success record, originators' interventions before the national regulatory authorities that are competent to grant market authorizations, approve prices, or take reimbursement decisions seem to meet with more skepticism. While the Commission seems to take the view that it is not normally the best placed antitrust authority to look into the merits of these practices, it invites injured parties to bring the matter under the attention of the "relevant" (i.e., national) competition authorities in case of "*clear* indications that a submission by a stakeholder intervening (…) was *primarily* made to delay the market entry of a competitor/applicant" (italics added for emphasis). However, one would think that such indications cannot be relevant, unless the submission itself is objectively baseless on the merits.

Sometimes the originator company's intervention before national regulatory authorities raises an issue of interpretation of the EC regulatory framework. This is the case for "patent linkage" claims that seek to make the market authorization of a generic medicine subject to the patent (application) status of the originator medicine. According to the Commission, such claims have no merit. It invites Member States to give "full implementation and effective enforcement" to the EC regulatory framework which—according to the Commission–confines the role of the market authorization authorities to checking whether or not the generic product meets the required quality, safety, and efficacy criteria. However, it adds that originator companies can invite national courts to deal with the patent status and determine whether there is a patent infringement.

With regard to these interventions before national regulatory authorities, the Final Report also contains a number of competition advocacy proposals. Thus, the Commission recommends that Member States provide automatic pricing and reimbursement status for generic medicines that are equal to the original products. Similarly, it encourages them to introduce legislation that facilitates generic uptake, such as prescription by substances rather than brands.

Cumulative Use of Instruments Against Generic Entry (Toolbox). The Commission devotes an entire section of its Final Report (and a separate Fact Sheet, annexed thereto) to this theme, explaining how the combined use of several or all of the above mentioned life-cycle instruments may significantly increase legal uncertainty on the side of generic companies and, as a consequence, significantly increase the likelihood of delays to generic entry (¶¶ 1050-1081). However, the Commission hastens to add that "this does not purport to imply that if legitimate uses of several instruments are combined, such a combination would not be legitimate" (¶ 1065) and "causality can only be established on a case-by-case basis" (¶ 1058).

Competition Between Originator Companies

The Commission also seems to adopt a cautious approach. Once more, it states that it does not aim to provide guidance on whether certain types of practices could be considered compatible or not with EC competition law since "such an assessment would require an in-depth analysis of the individual practice taking into account the factual, economic and legal background" (¶ 1088). On the other hand, the Commission will "further investigate whether individual company behavior may have fallen foul of the competition rules (*ibidem*). The Commission seems to take a particular interest in two specific types of practices that may—in its view—unduly restrict competition between originator companies.

Defensive Patenting. This practice refers to patent applications regarding "inventions which the applicant considers to have little or no prospect of being developed and/or commercialized and/or which, once granted, the company holds primarily to protect itself against actual or potential competition" (¶ 1118).

At first sight, this practice might seem problematic, given the fact that Art. 82 EC *sub b* expressly prohibits dominant companies from "limiting production, markets or technical development" and that in *Microsoft*, the Commission—supported by the Court of First Instance—has interpreted this Treaty provision broadly.

However, it would seem to us that the Commission would—at the very least—have to demonstrate—not via second-guessing *ex post* but based on internal company documents—that the applicant knew it had no realistic prospect of using its patent to develop and/or commercialize a new medicine. Admittedly, several quotes from internal company documents suggest that the Commission takes the view that it has collected *ex ante* evidence of clear intent on the side of an originator company to block competition of other originator companies. Even so, we take the view that the Commission should also examine to what extent patent law requires the patent holders to work their protected inventions and, if so, to what extent patent law itself remedies any non-compliance with this requirement.

All in all, the Commission warns that "defensive patenting strategies that *mainly* focus on excluding competitors without pursuing innovative efforts and/or the refusal to grant a license on unused patents will remain under scrutiny in particular in situations where innovation was effectively blocked" (italics added for emphasis). However, the Commission seems to recognize that defensive patenting should not raise serious concerns if these other originator companies can either obtain a license from the successful applicant or build on the information disclosed in the patent applications.

Settlements and Other Agreements. The Commission notes that many agreements between originator companies appear to concern the commercialization phase rather than the research and development phase. Referring to the contracting parties' combined market share (exceeding 20%), to the presence of several exclusivity clauses (e.g., exclusive supply, exclusive licensing, non-compete obligation), and to the average duration of these agreements (on average eight years), the Commission seems to be suggesting—without stating it in so many words—that many originator companies may have entered cooperation arrangements that fall outside the scope of its block exemption regulation for research and development.[10]

CONCLUSION

In its Final Report, the Commission has done a much better job than in its preliminary report at placing the results of its fact-finding exercise in their proper market context by recognizing the patent law reality at the "upstream" level of research and development activity as well as the regulatory reality (market authorization, price approval, reimbursement) at the "downstream" level of marketing activity.

Moreover, the Commission seems to have drawn the operational conclusion from this fact finding exercise that its antitrust enforcement policy should be highly selective. It even seems that in the short term, the priority will be to monitor just a few types of practices that have been under scrutiny the last year and a half—settlement agreements between an originator and a generic company being top of the list. In addition, the only pending case explicitly referred to not only involves originator companies but also generic companies. Remarkably, in all these cases, compliance with Art. 81 or Art. 82 EC appears to be a shared responsibility for originator and generic companies.

However, legal uncertainty remains since it is unclear against which standard of legality the Commission will assess the lawfulness of individual company behavior under Art. 81 and Art. 82 EC. Companies are expected to assess the legality of their market conduct for themselves. However, it is regrettable that this self-assessment will have to depend on how well they are capable of reading between the lines of the Final Report.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

Luc Gyselen
+32 (0)2 290 7831
Luc.Gyselen@aporter.com

Marleen Van Kerckhove
+32 (0)2 290 7817
Marleen.VanKerckhove@aporter.com

Tim Frazer
+ 44 (0)20 7786 6124
Tim.Frazer@aporter.com

Niels Ersbøell
+32 (0)2 290 7829
Niels.Ersboell@aporter.com

ENDNOTES

1. Cf. Press release IP/09/1098 and MEMO/09/328 with Frequently Asked Questions.
2. Unless otherwise specified, quotes have been taken from the Commission's Communication giving an executive summary of the Pharmaceutical Sector Inquiry Report.
3. O.J. C 45/7 of February 24, 2009.
4. Commission Staff Working Paper accompanying the Report on the functioning of Regulation 1/2003 (SEC (2009) 574 final, 29.4.2009), §§ 185 and 248.
5. Cf. Commission Notice on cooperation with the network of competition authorities, OJ C 101/43 of April 27, 2004.
6. *See:* Commission Staff Working Document on 'Market Monitoring: State of Play and Envisaged Follow-Up', at: http://ec.europa.eu/economy_finance/publications/publication13688_en.pdf (see in particular Section 4 par. 5 on monitoring the retail sector);
7. It refers to a Decision of the EPO Administrative Council from March 25, 2009 amending the Implementing Regulations to the European Patent Convention.
8. Decision of June 15, 2005 in case COMP/37507/F3.
9. Judgment of July 17, 1998 in case T-111/96, *ITT-Promedia* v. *Commission*, ECR II-2937.
10. Regulation 2659/2000 of November 29, 2000, OJ L 304/7 of December 5, 2000.