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THE PHARMA SECTOR UNDER SCRUTINY:
FIRST INDICATIONS FROM THE EUROPEAN COMMISSION'S SECTOR INQUIRY

International Teleconference

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On January 15, 2009, EU and U.S. lawyers from Sidley's global antitrust practice hosted a seminar on the Preliminary Report of the European Commission's Pharmaceutical Sector Inquiry. Five main issues were addressed and perspectives given from both sides of the Atlantic. This note summarizes some of the key points raised.

ISSUE 1:

A critique of the Commission's suggestion that product life cycle management strategies may violate competition laws

The Preliminary Report evidences significant hostility to the introduction and marketing of "second generation products", launched *"shortly before loss of exclusivity of the first generation product [and] sometimes combined with the withdrawal of the initial product from the market."* Yet, we observe these same strategies in competitive markets, such as consumer products markets, and so they are presumptively pro-competitive. Why condemn presumptively pro-competitive conduct merely because it is engaged in by an alleged monopolist?

Three U.S. decisions address the antitrust issues raised by such life cycle management strategies:

Berkey Photo v. Eastman Kodak. The court (a) stated that *"any firm, even a monopolist, may generally bring its products to market whenever and however it chooses,"* (b) said that markets, not courts, should decide the relative merits of two products, but (c) suggested in *dicta* that a monopolist might be obligated to keep an old product on the market to avoid the charge that it had "compelled" customers to buy the new product.

Walgreens v. AstraZeneca. If the first generation pharmaceutical remains on the market, the introduction of a second generation product is not actionable because it does not eliminate consumer choice. Allegations that the second product is "no better" than the first or that the second product was heavily promoted do not change the result.

Abbott v. Teva. The introduction of a virtually identical second generation drug product, accompanied by the withdrawal of the earlier product to eliminate generic substitution, could give rise to a monopolization claim because the strategy restricted consumer choice.

The cases speak about the competitive effect of introducing new products, but the real question is: When does a monopolist have an obligation to keep an old product on the market? Regarding interoperable products, the law says that a monopolist may upgrade its product, even modestly, despite its effects on interoperable products, unless it (a) knows the new product is no better and (b) developed it solely to stifle competition. Thus, U.S. law suggests the following analyses, some of which conflict with the Commission's apparent generalized hostility toward life cycle management strategies:

1. Obtaining secondary patents, introducing new products, and promoting them are all inherently pro-competitive activities that should not give rise to liability.

2. The relative merits of first and second generation products should be determined by the market, not by the courts.

3. While the Commission should focus on the effects of product withdrawals, not introductions, there are many valid reasons to withdraw old products, such as avoiding consumer confusion, capturing cost savings, simplifying product lines, or building a brand.

4. Unless a product withdrawal blocks generic entry, there is no reason to condemn it. Further, in that case, the solution should be to tweak the regulatory scheme, not to impose antitrust liability on inherently pro-competitive conduct.

ISSUES 2 AND 3:

Does the Commission's Preliminary Report represent a divergence from U.S. law regarding so-called "pay-to-delay" patent settlement agreements between originator and generic pharmaceutical companies? Can U.S. law on that subject appropriately provide guidance to the Commission in light of different regulatory regimes governing generic entry?

The Commission's Preliminary Report presents myriad information in relation to patent settlement agreements among originator and generic pharmaceutical companies. Although the Commission draws no conclusions, the information it selects, and the language it uses, give strong hints as to the stance the Commission will adopt in its spring 2009 Final Report. Notwithstanding the multiple references to U.S. enforcement and jurisprudence in the Preliminary Report, it seems the Commission's Final Report risks being at odds with the more recent judgments of the higher U.S. courts. Any such EU/U.S. divergence would be of grave

concern to the pharmaceutical sector as a whole and to the innovative pharmaceutical sector in particular. A number of points emerge from the Commission's Preliminary Report.

First, the Commission appears to be paving the way for the examination in an antitrust context of the strength of patents at issue in settlement agreements. The Commission Task Force has been at pains to deny this but it is difficult to see any other interpretation for the statistics presented on generic companies' success rates in patent suits and the comparison of originator and generic companies' motivations in agreeing to settle disputes. Detailed assessment of the strength of a patent-in-suit risks undermining the effect of patent approval and risks rendering originators exposed to multiple antitrust challenges when looking to settle litigation with generic rivals.

If the Commission were to insist on an examination in an antitrust context of the strength of patents in settlement cases, this would constitute a significant divergence from the recent jurisprudence of the U.S. Courts. While the DOJ has advocated some limited form of *ex ante* assessment of the strength of patents-in-suit in assessing whether settlement agreements violate U.S. antitrust rules, the higher U.S. Courts, including the Court of Appeals for the Federal Circuit in *Ciprofloxacin*, have taken a more rigorous approach, pointing out that approved patents must be presumed valid unless proven otherwise.

Second, the starting point for the Commission's antitrust analysis seems to be that agreements involving "reverse payments" are inherently suspect from an antitrust perspective. The Preliminary Report states that: *"The clearest limitation of generic entry is when the settlement agreement contains a clause explicitly stating that the generic company recognises the validity of the originator company's patent(s) and refrains from entering the market until the patent(s) have expired."* (Emphasis added.) There is good reason to disagree with this analysis. Where a generic accepts as valid an originator's patent, there is no "limitation" of that generic's entry unless it is assumed that the patent-in-suit is in fact invalid.

Given that approved patents are to be presumed valid, the better view would be that articulated by the U.S. Courts in cases such as *Ciprofloxacin*, namely, that an agreement preventing generic entry only within the *"exclusionary zone"* of the patent-in-suit is not restrictive of competition. Agreements might be restrictive of competition if they create "bottlenecks" to challenges from other generics, or go beyond the term or scope of the patent-in-suit but, absent such effects, there should be no restriction of competition. Again, any assumption on the part of the Commission that "reverse payments" are inherently suspect would risk creating significant divergence between EU enforcement and U.S. jurisprudence.

Third, the Commission appears to have been influenced in the preparation of its Preliminary Report more by the U.S. antitrust enforcement agencies than by the higher U.S. Courts. Given the current divergence between the leading judgments of the higher U.S. Courts and the FTC in particular, if the Commission were to adopt wholesale the views of the FTC, it would risk creating further divergence between EU enforcement and U.S. jurisprudence.

That the Commission appears to be siding with the FTC emerges in part from the approach taken in the sections of the Preliminary Report covering patent settlement agreements. The Commission deals in much greater detail with the views of the FTC (and the DOJ) than with the jurisprudence of the U.S. Courts and even chooses to title the relevant section of the Report *"Enforcement Practice in the USA – In Particular by the FTC"*. Given that the FTC's enforcement is subject to review by the higher U.S. Courts and given that the latter have overruled the FTC in recent cases in relation to patent settlement agreements, the Commission's reliance on the FTC's approach creates a clear risk of a more generalized divergence among enforcers and the courts in this area.

Stepping back, however, is it useful or appropriate for the Commission to look to U.S. law for guidance in this area? The Commission suggests that elements of the U.S. jurisprudence in this area are influenced by, or specific to, the Hatch-Waxman Act regime. The references to "bottlenecks" to challenges from other generics may be one such example. However, the arguments for seeking U.S. guidance in this area seem more persuasive. The exact same issues have been the subject of significant agency enforcement and much litigation before the U.S. Courts. There is a great deal of U.S. learning not only on the workings of patent settlement agreements themselves but also on the overall balance between antitrust enforcement and the respect of the patent system.

Two particular findings of the U.S. Courts seem capable of providing particularly clear guidance to stakeholders and to enforcement agencies on both sides of the Atlantic: (i) the refusal to examine in an antitrust context the strength of the patent-in-suit; and (ii) the presumption that, absent restrictions going beyond the exclusionary scope of the patent, there is no restriction of competition. It remains to be seen, however, to what extent the Commission adopts these, and other, U.S. approaches in its Final Report.

ISSUE 4:

Does the Commission's Preliminary Report suggest hostility, or an attempt to displace, traditional intellectual property principles?

To give the Commission's Preliminary Report credit, it notes the consensus among the Commission, originators and generic companies that a Community Patent and a Community Patent Judiciary would already solve many of the current problems.

The Report's hostility to traditional intellectual property principles appears in its assessment of originator patenting strategies, and in particular: patent clustering, described as a tool for delaying generic entry; and defensive patenting, described as mainly aimed at limiting innovation by other originators. But the Commission's comments on those strategies must be seen in light of the longstanding principle that EU competition law cannot call into question the existence of patents but can apply to limit their exercise.

The Report does not indicate the Commission's future intentions regarding patent clustering and defensive patenting, but there are two fundamental possibilities. First, it may try to prohibit them from the outset. Using EU competition law for this purpose would call into question the patents' existence, which in principle the Commission cannot do without modifying the balance between competition law and patent law and challenging a fundamental tenet of EU law. Second, and more likely, the Commission may try to penalize originators when they exercise their patent rights. If the exercise of patent rights results in an agreement (licensing, settlement) or concerted practice that deters or limits generic entry (patent clustering) or innovation (defensive patenting), Article 81 EC could apply. In contrast, if there is no agreement or concerted practice, Article 82 EC could apply to the unilateral exercise of patent rights, but only if the originator occupies a dominant position in a relevant antitrust market. However, the mere fact of having patents does not give rise to a dominant position. It has to result from the particular structure and dynamics of the relevant antitrust market and the relative positions of the originator, its competitors and customers in that market.

The Commission also appears to target patent litigation strategies. Some indication of the Commission's possible approach in this regard can be found in a prior case in which the Commission rejected a complaint accusing Belgium's dominant telephone services provider of abusing its dominant position by bringing a lawsuit against a contractual partner. In upholding the Commission's rejection of the complaint, the European Court of First Instance stressed that

the ability to assert rights through the courts is the expression of a general principle of law and can amount to an abuse only in "wholly exceptional circumstances".

The test applied by the Commission, and implicitly upheld by the Court, was that a dominant company's bringing a lawsuit could exceptionally amount to an abuse violating Article 82 EC if it is: (i) frivolous (not reasonably an attempt to establish the dominant company's rights); (ii) vexatious (can only serve to harass the opponent); and (iii) exclusionary (part of a plan whose goal is to eliminate competition).

The foregoing test seems consistent with U.S. case-law on the circumstances in which starting litigation may violate Sherman Act § 2: the lawsuit would have to be "objectively baseless" and the fact of the lawsuit would have to create a deterrent to entry.

In principle, a requirement on a competent agency to find that litigation is frivolous should present a high threshold. Oftentimes, it would appear to hinge on the validity of the patents in question. If a patent office has granted the patents, there should in principle be a presumption of validity and any action to enforce or defend presumptively valid patents should not readily be deemed frivolous by an antitrust agency. However, the emphasis in the Preliminary Report on the relative weakness of many secondary patents may suggest that the Commission considers itself, and the EU's national competition authorities, competent to assess the relative strength or weakness of the patents-in-suit, when investigating whether a lawsuit is frivolous in the context of Article 82 EC. Naturally, this would be a concerning development for originators whose business models depend in large part on the effective protection of their intellectual property.

ISSUE 5:

Are there tensions between the Commission's suspicions regarding collaboration between drug companies and the perception in the pharmaceutical industry of greater market risk?

The Commission's Preliminary Report is not only suspicious of patent settlement agreements between originators and generic companies; it also expresses suspicion of agreements for the launch of an originator's 'authorized generic' before the originator loses exclusivity on its patented product. The report gives a very strong hint (¶ 683) that the Commission thinks those agreements have the purpose and effect of delaying generic market entry. According to the Report, an originator has no incentive to share its profits with another company during the exclusivity period. The Report seems to suggest that an authorized generic agreement only makes sense if the originator learns about another generic company's imminent market entry and cannot hold it at bay, for example because it cannot fully enforce its patent rights.

In the U.S., there is an apparent divergence in the views of the DOJ and the FTC on authorized generic agreements. The DOJ generally sees no anti-competitive effects and sees, instead, the potential for pro-competitive effects. In contrast, the FTC is suspicious, as it thinks such agreements may reduce the incentive for other generic companies to be the first to file for an Abbreviated New Drug Application (ANDA) and obtain the 180-day exclusivity period allowed under the Hatch-Waxman Act. As the EU does not provide for such an exclusivity period, however, it would be difficult to "read across" the FTC's apparent reasoning to the EU.

As regards collaboration agreements between originator companies, the Commission found more than 1,450 such agreements. Research and development collaboration accounted for around 10%, and joint R&D is generally likely to be welcomed because of its focus on innovation. The Commission's suspicion seems focused on the other 90%, consisting of

manufacturing, licensing, supply, distribution, co-promotion and co-marketing agreements – and especially the last three categories. The Commission is understood to have sent a further questionnaire to some companies raising questions about specific clauses in these kinds of agreement.

The Commission's suspicion is not really surprising, given that collaboration in this industry usually makes the most sense when the partners are doing similar things. For example, if a company wants to co-promote a product to neurologists, it will normally want its partner to be someone who also calls on neurologists. In these circumstances, the partners will in many if not most cases be actual or potential competitors, and agreements between competitors always attract the keen interest of antitrust authorities. Naturally, collaboration between competing originator companies should be seen in light of the enormous and growing risks involved in developing and marketing new pharmaceutical products and the need to share those risks. However, such collaboration is clearly in the Commission's sights, so careful self-assessment of antitrust risk is strongly advisable.

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