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THE ONLINE MAGAZINE FOR GLOBAL COMPETITION POLICY

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### **I. INTRODUCTION**

Following its unprecedented January 2008 dawn raids of pharmaceutical companies throughout Europe, the European Commission (EC) published its *Pharmaceutical Sector Inquiry: Preliminary Report* (the "Report") on November 28, 2008.<sup>1</sup> The Report is noteworthy for the speed at which it was prepared, and the breadth of its observations on pharmaceutical industry conduct. While the Report does not attribute anticompetitive conduct to any specific pharmaceutical companies, the Report "confirms" the EC's premise regarding the "decline of new chemical entities reaching the market and the delay of generic market entry," and it "highlights some of the possible causes." Following a review of public comments on the Report, the EC intends to issue a final report this spring.

The Report adopts a skeptical tone regarding the propriety of a broad variety of conduct undertaken by pharmaceutical industry participants. This may not be surprising

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<sup>1</sup>The Report and related materials are *available at* <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>.

to many antitrust observers, as the EC often has taken more aggressive stances on antitrust enforcement (particularly regarding single-firm conduct) than its U.S. counterparts, and a number of the types of conduct identified in the EC Report have been the subject of enforcement actions during the past decade by the U.S. Federal Trade Commission (“FTC”). The Report nonetheless raises competition concerns with other types of conduct that have not (at least not yet) been challenged by the FTC.

This commentary explores the potential impact of the Report in Europe, and evaluates whether the EC’s posture regarding pharmaceutical conduct identified in the Report may ultimately go beyond FTC enforcement regarding that conduct. In doing so, we discuss many of the key findings of the Report regarding the “causes” of delayed generic entry, and consider how those findings compare to antitrust enforcement undertaken in the United States.

## **II. REVIEW OF EC’S PRELIMINARY FINDINGS**

The Report discusses in detail what it refers to as a *toolbox* (“toolbox”) of instruments used by pharmaceutical industry participants to ensure continued revenue streams for their products. This toolbox includes “patent clusters,” pursuit of patent litigation, patent settlement agreements, “interventions” with regulatory authorities, and certain life-cycle management strategies. Each of these areas of conduct is reviewed in turn below.

### ***A. Brand-Generic Patent Settlements***

The EC Report surveys patent settlements in Europe between brand and generic

firms. It finds that in more than half of the settlements, the brand firm did not impose any restriction on generic entry. In 48 percent of the settlement agreements, however, the Report finds that the generic firm's ability to market its product was restricted. In a "significant portion" of those settlements, a "value transfer" from the brand firm to the generic company occurred in the form of a direct payment or a side-deal (e.g., license, distribution agreement). The direct payments in these settlements exceeded 200 million Euros in total. The Report further notes that the FTC has "scrutinised" such settlements where a payment is made by the brand firm to the generic firm combined with a restriction on the generic firm's marketing its own product.

As the Report observes, such "reverse-payment" settlements (as the FTC calls them) have been a major focus of the FTC. Over the past decade, the FTC has: obtained consents regarding three settlements; it has litigated and lost one case on appeal; and it is currently litigating two additional cases in federal court. Thus, this is potentially an area where the EC may follow the lead of the FTC in evaluating the prevalence and potential effects of such conduct within the borders of Europe.

### ***B. Regulatory Interventions***

The EC Report also highlights "interventions" by brand firms with national regulatory authorities. It describes brand firms intervening with such authorities when generic firms apply for marketing authorization and pricing/reimbursement status for their drugs. These interventions generally involve claims that the generic products are less safe and/or effective, and that obtaining marketing authority could violate the brand

firm's patent rights.

According to the Report, brand firms generally have had a low success record on the merits with respect to their intervention claims. At the same time, it found that “interfering in administrative proceedings can lead to delays to generic market entry.” The Report observes that market authorizations occurred four months later in cases in which an intervention took place, and that brand firms believe they have generated significant additional revenues as a result of such practices. The EC highlighted the use of “interventions” in its 2006 action against AstraZeneca resulting in a 60 million Euro fine.<sup>2</sup>

The FTC has long been concerned with conduct that it believes may manipulate the pharmaceutical regulatory system and potentially delays generic entry. The FTC's investigations earlier this decade into the Orange Book patent-listing system, where the FTC alleged that brand firms had falsely listed patents with the Food and Drug Administration (FDA) to obtain additional stays of generic approvals, resulted in a major consent against Bristol-Myers, and it ultimately led Congress to adopt legislation to reform the Orange Book listing system. The FTC has also consistently expressed concerns regarding other conduct that might “game” the regulatory system, such as brand firms filing “citizen petitions” with the FDA for the purpose of delaying generic approval. Thus, this type of conduct appears to be of considerable concern and attention by the antitrust authorities on both sides of the Atlantic.

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<sup>2</sup>Commission Decision 2006/857/EC, Re: AstraZeneca Plc, 2006 O.J. (L 332) 24 (on appeal).

### *C. Life Cycle Management*

The Report discusses the prevalence of brand firms pursuing “second generation” or “follow-on” drug products. It finds that 40 percent of the drugs surveyed that lost exclusivity between 2000 and 2007 launched follow-on products, and that such launches took place, on average, one year and five months before the loss of exclusivity for the first generation product. The Report then describes marketing efforts undertaken “with the aim of switching a substantial number of the patients to the new medicine prior to market entry of a generic version of the first generation product.” It adds that patents relating to second generation products are sometimes criticized as “weak” as they only show a “marginal (if any) improvement or additional benefit to the patients.”

The EC’s concern regarding the potential anticompetitive intent behind pursuing “follow-on” products—clearly evoked in these statements from the Report—is not a new revelation. Its 2006 action against AstraZeneca also focused on various measures undertaken by AstraZeneca to protect its Losec product through the introduction of a new tablet formulation.

The FTC likewise has expressed concerns regarding follow-on products being used as part of a broader strategy to delay or otherwise impede generic entry. Former FTC Chairman Deborah Majoras discussed such “product hopping” or “product switching” strategies in a 2007 speech, stating that “[w]e are following controversies and research in this area, so that we can better understand the market issues and whether there

is any role for antitrust law in addressing them.”<sup>3</sup>

In addition, in several recent FTC enforcement actions, “switching” strategies provided the backdrop for brand/generic agreements challenged by the FTC. For example, the FTC alleged that brand firms may have entered into these agreements to gain additional time to switch to a follow-on product.<sup>4</sup> Still, the FTC has not brought, to date, any enforcement actions specifically targeting such a “switch” strategy as anticompetitive. The EC Report may signal a stronger EC willingness to target and directly challenge such conduct.<sup>5</sup>

#### *D. Patent Strategies and Litigation*

The EC Report also presents its preliminary findings regarding brand companies’ patent filing and enforcement strategies. It observes that in recent years these companies have changed their patent strategies with the “aim to develop strategies to extend the breadth and duration of their patent protection.”

The Report specifically cites the formation of “patent clusters” or “patent thickets” by brand firms—i.e., filing numerous patents for the same drug product. The Report states that documents gathered by the EC “confirm that an important objective of this strategy is to delay or block the market entry of generic medicines.” It further notes that individual blockbuster drugs are protected by up to 1,300 patents and/or pending

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<sup>3</sup>Deborah Majoras, Keynote Address, ABA Antitrust Section Fall Forum (Nov. 15, 2007), available at <http://www.ftc.gov/speeches/majoras/071115fall.pdf>.

<sup>4</sup>See, e.g., *FTC v. Cephalon, Inc.*, (compl. filed on Feb. 13, 2008), available at <http://www.ftc.gov/os/caselist/0610182/080213complaint.pdf>.

<sup>5</sup>Private litigants and the various state attorneys general, however, have challenged such conduct in federal court. See *Abbott Labs. v. Teva Pharm.*, 432 F. Supp 2d 408 (D. Del. 2006) (denying defendant’s motion to dismiss regarding brand firm’s introduction of follow-on products). The two generic firm plaintiffs in this matter recently settled the litigation, while various state attorneys general continue to litigate the matter.

patent applications EU-wide, and that such patent filings occur late in the life cycle of a drug.

With regard to enforcing patent rights, the Report observes that enforcement of such rights in court is generally legitimate. However, it adds that the preliminary findings indicate that litigation can be an efficient means of “creating obstacles in particular for smaller generic companies” and that brand companies may consider litigation “not so much on its merits, but rather as a signal to deter generic entrants.”

The Report’s observations concerning patent strategies (e.g., patent clustering) and the enforcement of patent rights suggest EC skepticism regarding the intellectual property practices of brand firms. These statements appear to go beyond conduct that the U.S. antitrust laws would reach, and that the FTC would be likely to challenge. In particular, prior FTC actions have focused more narrowly on abuse of patents in regulatory contexts (e.g., fraudulent Orange Book listings) and extreme litigation conduct (e.g., sham litigation or patents obtained by fraud). Enforcement of pharmaceutical patent rights and the resulting Hatch-Waxman patent litigation are, in fact, a by-product of the Hatch-Waxman system itself, which was designed to encourage generic firms to challenge patents while providing brand firms the ability to litigate such cases while generic entry is stayed for 30 months. Thus, the EC’s preliminary views expressed in the Report regarding abuse of patent rights appear to extend beyond practices that the FTC and U.S. antitrust law likely would find unlawful.



### **III. CONCLUSIONS**

The EC's Report sets forth substantial concern or skepticism regarding several types of conduct undertaken by pharmaceutical companies. The manner in which the EC is pursuing this sector inquiry—first, by seizing documents through dawn raids and second, by releasing its preliminary findings less than a year later—demonstrates the seriousness and significant resources placed behind this endeavor by the EC.

As discussed above, many of the EC's findings reflect concerns that parallel prior or current FTC enforcement activities regarding potentially anticompetitive conduct by pharmaceutical firms. The prime examples are patent settlements and regulatory interventions. At the same time, the EC's findings regarding life cycle management practices may indicate a willingness by the EC to target conduct that the FTC has not (at least, not yet) challenged. In particular, the EC's findings regarding patent strategies and patent litigation clearly extend beyond the FTC's enforcement efforts to date, and may go beyond the scope of U.S. antitrust law.

The EC's final report is expected to be released later this year after the EC considers comments filed by industry participants. It will be interesting to see whether the views expressed in such comments—many of which will likely express strong opposition to the preliminary findings (particularly with regard to patent rights)—will moderate the positions adopted in the final report. Ultimately, assuming the EC maintains some of its more aggressive positions in the final report, the EC will need to determine whether to test those theories through actual enforcements efforts.