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# Comment on the EC's Pharmaceutical Dawn Raids

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### Introduction

The pharmaceutical industry remains under close examination by antitrust enforcers on both sides of the Atlantic. The U.S. Federal Trade Commission's (FTC) enforcement activities—challenging both unilateral and concerted action undertaken by pharmaceutical firms—have been ongoing for more than a decade. Just this week, the FTC brought a suit challenging the settlement of patent litigation by brand firm Cephalon with four generic firms. The suit concerns Cephalon's US\$800 million drug Provigil. The FTC alleges that Cephalon monopolized the Provigil market “not through the strength of its patent, but by paying its potential competitors to accept [an] April 2012 entry date.”<sup>1</sup>

Similar concerns regarding anticompetitive conduct by pharmaceutical firms in Europe contributed to the European Community's (EC) decision several weeks ago to commence a broad probe into the pharmaceutical industry. The stated purpose of this “sector inquiry” is to determine whether anticompetitive conduct is responsible for either the sharp decline in the launch of new drugs in Europe or the relative hesitancy of generic drug manufacturers to enter the market with cheaper bio-equivalent alternatives to

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<sup>1</sup> FTC Complaint for Injunctive Relief, U.S. Federal Trade Commission v. Cephalon, Inc, Civil Action No. pending (Feb. 13, 2008), at 2, *available at* <http://www.ftc.gov/os/caselist/0610182/080213complaint.pdf>.

branded drugs that are still on patent.<sup>2</sup> The EC expects to release an interim report of its findings in the fall of 2008, with a final report scheduled for the spring of 2009.

That the EC has a keen interest in understanding the competitive dynamics of the pharmaceutical industry is hardly exceptional. Indeed, the FTC also has authored several studies in the pharmaceutical industry based on similar concerns. The EC's inquiry is unique, however, because it commenced with the seizure of documents and data through targeted dawn raids, without a publicly acknowledged reason to suspect ongoing cartel activity or other exigent circumstances.<sup>3</sup> Naturally, this has left many wondering why the need for the EC to undertake such extreme measures.

### **Analogy to FTC Investigative Processes**

Much like the EC, the FTC has made substantial use of sector inquiries to advance its knowledge base and improve its ability to safeguard the competitive process. Under Section 6(b) of the FTC Act,<sup>4</sup> the FTC has authority to issue document subpoenas, depose company executives, and convene broader hearings for the purpose of better understanding the competitive dynamics in a given industry. Traditionally, the FTC has enjoyed great success with this approach, and it has enabled it to secure the necessary information and generate a comprehensive report in a relatively short timeframe. Of course, when an investigation gives rise to a strong inference of anticompetitive activity,

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<sup>2</sup> Press Release IP/08/49, European Commission, Commission launches sector inquiry into pharmaceuticals with unannounced inspections (Jan. 16, 2008), *available at* <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/49&format=HTML&aged=0&language=EN&guiLanguage=en>; *see also* MEMO/08/20, European Commission, Sector Inquiry into Pharmaceuticals—Frequently Asked Questions (Jan. 16, 2008), *available at* <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/08/20&format=HTML&aged=0&language=EN&guiLanguage=en>.

<sup>3</sup> *See supra* note 2.

<sup>4</sup> U.S. Federal Trade Commission Act, 15 U.S.C. § 46(b).

the FTC can partner with the U.S. Department of Justice (DOJ) for purposes of commencing a criminal investigation, which is frequently precipitated by document seizures and grand jury testimony, not entirely unlike those recently conducted by the EC. But outside of these rare circumstances, compulsory process, as opposed to a seizure of documents, is the norm.

As one might expect, the process of studying competition through sector inquiries (and the expected deterrent effect on would-be antitrust violators) is only one of the tools available to the antitrust agencies. In instances where investigations have revealed particularly egregious instances of abuse, the FTC has moved quickly to eradicate the conduct, typically resulting in consent decrees that help to establish the boundaries of permissible conduct in a particular industry or with regard to a particular practice. For the more delicate issues that require sophisticated antitrust counseling, the FTC typically reveals its thinking with regard to potential competitive harm through the issuance of interim reports, economic findings, policy announcements, and congressional reporting. Finally, where the legality and competitive impact of an inherently suspect practice remains in dispute with private parties, the FTC has relied on administrative adjudication to develop the exhaustive record needed to eliminate competitive harm and reveal its analytical framework.

The FTC followed this process in the pharmaceutical industry several years ago, beginning with the release of 2002 study of *Generic Drug Entry Prior to Patent Expiration*,<sup>5</sup> moving to its pursuit of a cease and desist order against the practice of

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<sup>5</sup> U.S. FEDERAL TRADE COMMISSION, GENERAL DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (Jul. 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

“reverse payments” at issue in the *Schering-Plough* matter,<sup>6</sup> and most recently, with the announcement of a study regarding authorized generic drugs.<sup>7</sup>

Nonetheless, differences between the underlying regulatory structures of the EU and U.S., with regard to the pharmaceutical industry, make it difficult for the EC to borrow meaningfully from the FTC’s experience in the industry. Likewise, these differences make it difficult for practitioners to project whether the EC will seek to forge a new direction in how it regulates issues that implicate the intersection of antitrust and intellectual property (IP).

### **Fundamental Distinctions between U.S. and EU Patent Regimes for Pharmaceuticals**

The Hatch-Waxman Act<sup>8</sup> is a unique feature of the U.S. pharmaceutical industry landscape that has fundamentally altered the manner in which branded and generic manufacturers compete.<sup>9</sup> The Act was intended to facilitate the rapid entry of low-cost generic drugs, without compromising existing incentives that drive branded manufacturers to invest substantially in the research and development of new drugs.<sup>10</sup> To achieve this balance, the Hatch-Waxman Act employs three basic mechanisms.

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<sup>6</sup> In re Schering-Plough Corp., No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003), vacated, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11<sup>th</sup> Cir. 2005), cert. denied (Jun. 26, 2006).

<sup>7</sup> See Press Release, U.S. Federal Trade Commission, FTC Proposes Study of Competitive Impacts of Authorized Generic Drugs (Mar. 29, 2006), available at <http://www.ftc.gov/opa/2006/03/authgenerics.htm>.

<sup>8</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§301-397 (2001)) [hereinafter “Hatch-Waxman Act”].

<sup>9</sup> See generally Prepared Statement of the Federal Trade Commission, before the Special Committee on Aging of the United States Senate, Barriers to Generic Entry (Jul. 20, 2006), available at <http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf>.

<sup>10</sup> H.R. REP. No. 98-857(I), at 14(1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647.

First, the Act provides six months of market exclusivity to the first generic manufacturer that files notice that it intends to enter with a bio-equivalent drug that does not infringe any valid patent rights of the branded drug.<sup>11</sup> As history has revealed, market exclusivity provides a compelling profit incentive, allowing a generic manufacturer to almost immediately recoup costs and gain a strong market position. Second, the Act allows the generic manufacturer to challenge any alleged blocking positions of the branded drug prior to entry—through what is effectively a declaratory judgment process—thus eliminating the risk of a debilitating damage award.<sup>12</sup> Finally, branded manufacturers are permitted to invoke an automatic 30-month stay of the approval process for any allegedly infringing generic drugs, without having to satisfy the substantial burdens of injunctive relief, in exchange for agreeing to litigate the merits of the underlying IP dispute in advance of generic entry.<sup>13</sup> In combination, these mechanisms have encouraged generic manufacturers either to identify blocking positions that are vulnerable to challenge or invest in a work-around solution (e.g., invest in new formulation or mode of action).

Certainly, the United States now enjoys a vibrant market for generic drugs, which has grown as a result of the Hatch-Waxman Act regime.<sup>14</sup> Nonetheless, competitive concerns remain. Of particular concern to the FTC are the efforts of drug manufacturers

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<sup>11</sup> See 21 U.S.C. §355(j)(2)(A)(iv) (allowing generic manufacturers to “piggy back” on the clinical trials of the branded manufacturers, provided they can demonstrate “bio-equivalence” of the branded drug).

<sup>12</sup> *Id.* at §355(j)(2)(B)(iv).

<sup>13</sup> *Id.* at §355(j)(5)(B)(iii).

<sup>14</sup> See Jon Leibowitz, Remarks at the FTC’s Second Annual In-House Counsel’s Forum on Pharmaceutical Antitrust, Exclusion payments to Settle Pharmaceutical Patent Cases: They’re B-a-a-a-ck! (Apr. 24, 2006), available at <http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf>.

(both branded and generic) to game the market-exclusivity provision in a manner that allows both parties to share in monopoly profits by agreeing to extend the effective life of the branded manufacturer's blocking IP position for a period longer than they believe is justified.

As has been well-documented, the FTC has advocated that parties to a patent dispute should be permitted to settle their claims by agreeing to a date certain by which a generic drug is permitted to enter the market (in advance of patent expiration), which presumably reflects the risk-adjusted assessment of the infringement claims at issue.<sup>15</sup> The FTC continues to take issue, however, with the practice of making substantial "reverse payments" for the sole purpose of pushing back the agreed upon entry date.<sup>16</sup> Without question, there is a wide array of informed opinions on whether, and under what circumstances, reverse payments violate the antitrust laws. I do not seek to revisit or add to that debate here. But suffice it to say, in the absence of an analogous regulatory regime, the EC is unlikely to encounter a reverse payments scenario that is not more appropriately characterized as a naked market allocation, subject to per se condemnation.

### **Conclusion: We Are Only at the Beginning of the Story**

Moving forward, most commentators anticipate that the EC's primary focus will remain on the efforts of dominant firms to unilaterally harm generic competition through

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<sup>15</sup> See *supra* notes 6 & 9.

<sup>16</sup> See Complaint filed in *FTC v. Warner Chilcott*, No. 1:05-cv-02179-CKK (D.D.C. Nov. 7, 2005), at <http://www.ftc.gov/os/caselist/0410034/051107comp0410034%20.pdf>; see also Complaint filed in *FTC v. Cephalon*, 1:08-cv-00244 (D.D.C. Feb. 13, 2008), available at <http://www.ftc.gov/os/caselist/0610182/index.shtm>.

exclusionary tactics, such as patent misuse, fraud on the patent authorities, and sham litigation, as evidenced, for example by the EC's recent decision in *AstraZeneca*.<sup>17</sup>

As we continue to follow the comparative development of antitrust jurisprudence in the United States and European Union, it will be interesting to see whether the EC's recent sector inquiry leads it to pursue industry investigations that focus on dominant firm behavior or instead on collusive arrangements. And while the use of dawn raids in this instance is an unusual step—particularly in light of the fact that the EC did not publicly declare that there was evidence of collusive behavior or potential for document destruction that usually justifies such a process (e.g., in conjunction with supposed cartel-like behavior)—the bigger picture question of whether the EC will engage in a broader inquiry into the practices of pharmaceutical companies as the FTC has done recently will be of tremendous importance to the pharmaceutical industry and antitrust practitioners going forward.

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<sup>17</sup> Commission Decision 2006/857/EC, Re: AstraZeneca Plc, 2006 O.J. (L 332) 24 (on appeal).