The EC's Pharmaceutical Sector Inquiry Preliminary Report—Wading Into The Thicket of The Antitrust/Intellectual Property Law Overlap

position in that industry.[3] James Langenfeld, on the other hand, has suggested that, without exception, "[p]atents and other intellectual property rights are critical in stimulating innovation and ensuring dynamic competition" and "must be protected."[4] His view presumably would apply directly to the pharmaceutical industry.

The dispute about the general virtue of patent innovation is a debate for another day. Today, I would like to discuss the EC's recent sectoral study from my perspective on the U.S. Federal Trade Commission ("FTC") and place it in a comparative light. First, I will discuss the benefits that, from a prosecutorial, law-making, and regulatory standpoint the EC gains from doing these sectoral studies. I will then discuss the facts surrounding the recent sectoral study as well as the main conclusions that the EC drew in its Preliminary Report. Second, I will discuss how U.S. law has (or, in some cases, has not) addressed the anticompetitive practices in the pharmaceutical industry that the Preliminary Report identifies. I will explain

business, conduct, practices, management, and relation to other corporations, partnerships, and individuals" of the entities to whom the inquiry is addressed.[5] The FTC's § 6(b) authority thus enables it to conduct wide-ranging economic studies that do not have a specific law enforcement purpose. But the FTC's § 6(b) authority has its limits—including, foremost, limitations on the number of subpoenas that the FTC can issue without seeking approval from the Government Accountability Office (which can be a lengthy process and dramatically slow an investigation) and the ability of parties to move to quash requests for information.[6] The EC's ability to conduct sectoral studies has no similar limits.

From my perspective at the FTC, the EC gains at least three benefits from its far-reaching power to conduct sectoral inquiries. First, by analyzing a particular industry on a market-wide basis—as opposed to the conduct of a handful of key players in that market or a specific agreement—the sectoral inquiry enables the EC to proactively identify widespread patterns of anticompetitive conduct and develop a comprehensive enforcement strategy.[7] Second, a sector inquiry allows the EC to proceed at its own pace

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5 15 U.S.C. § 46(b).

6 *See* Gregory Olsen & Bryony Roy,

without the time pressures that attend subjecting a specific party to a targeted investigation or inevitably result from litigation. Third, as a practical matter, a sector inquiry framework is largely unconstrained as to both the structure of the EC's investigation and the substance of the issues that the EC may address.[8] Thus, while the law does constrain the EC from using the information it obtains through the sectoral study in investigations of specific firm conduct under Articles 81 or 82,[9] a sectoral study has the practical benefit of giving the EC a head start on any such investigation by providing it with a preview of the anticompetitive practices that may be at work.

Such a head start may be enormously beneficial to the EC in deciding how to best challenge and regulate anticompetitive conduct in the pharmaceutical realm. That said, the pharmaceutical industry presents unique challenges when it comes to competition law. Both intellectual property and antitrust law share to some extent the goal of promoting innovation which, in turn, enhances consumer welfare.[10] The two bodies of

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competition. We have initiated a string of

law, however, don't always easily co-exist. A brand firm is permitted to patent its original ideas. At what point, if ever, can antitrust laws regulate the conduct of a brand firm in conjunction with its abuse of a patent when that patent confers a form of legal monopoly power? Moreover, after how many patents have been obtained on the same product, do patents stop serving as mechanisms that promote innovation and become mechanisms that prohibit it? When, if ever, in the spirit of competition law, can the law prohibit a firm from accessing the court to protect its patent rights? The recent EC Pharmaceutical Sector Inquiry raises these and other questions that we have been considering in the U.S.

As you probably know, the EC launched this sectoral inquiry with dawn raids on January 16, 2008 in response to complaints that fewer new medicines were coming to market and that the entry of generic medicines into the market was often delayed.[11] On that date, Commissioner Kroes announced, "if innovation products are not being produced, and cheaper alternatives . . . delayed, then we need to find out why and, if necessary, take action."[12] Following the dawn raids, the EC sent questionnaires to more than 200 participants, including innovators and generics regarding everything from their litigation practices to the volume of patents they held on various products.[13]

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http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/49&format=HTML&aged=0&language=EN&guiLanguage=en.

11 *Id.*

12 *Id.*

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On November 28, 2008, the EC released its Preliminary Report summarizing the initial results of its inquiry. A final report is due out later this year. As Janusz Ordover pointed out at an ABA Antitrust Section conference earlier this month on intellectual property and antitrust issues, the EC's Preliminary Report focuses on a certain class of tactics—which the EC collectively refers to as a "tool-box"—that brand firms use to extend the life of their patents at the expense of competition from generic firms. Although the EC identifies several "tools," for the purposes of my speech today, I would like to focus on three such tactics.

First, the EC found that pharmaceutical companies create "patent clusters" or "patent thickets" that consist of multiple—and in many cases hundreds—of patents covering the same drug.[14] The Preliminary Report noted that these patent thickets not only have the effect of expanding the breadth and duration of the brand firm's monopoly over a successful medicine, but also, as a practical matter, deter generics from entering a particular market because of uncertainty over when a generic can enter a market without breaching the originator's patent.[15] The Preliminary Report noted that in one instance a pharmaceutical company had secured 1300 patents to protect the same medicine.[16] Moreover, the Preliminary Report observed that pharmaceutical companies often make these additional patent filings late in the life cycle of a particular medicine.[17]

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questionnaires to producers of originator and/or generic materials and other stakeholders).

[14] European Commission, DG Competition Staff Working Paper, "Pharmaceutical Sector Inquiry Preliminary Report" ("Report") at 9 (Nov. 28, 2008), *available at* http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf.

[15] *Id.* at 9-10.

[16] *Id.* at 9.

[17] *Id.*

Second, the EC concluded that pharmaceutical companies bring meritless lawsuits against generic drug companies to deter generics from entering their markets. The EC reported that there was a four-fold increase in patent litigation between 2000 and 2007 and that, although 91 percent of those cases were brought by pharmaceutical companies, in those cases that went to final judgment, the generic companies won 62 percent of the time.[18]

Third, the EC observed that patent litigation settlements between pharmaceutical companies and their generic counterparts cause the generic company to either delay or forego entry into the market.[19] The substance of these settlements run the gamut from reverse payments from the company with the patent to the generic competitor to agreements in which a generic receives licensing or distribution rights in exchange for abandoning challenges against the patent.[20] Although the Preliminary Report acknowledged that patent settlements are, in many cases, laudable, the Preliminary Report expressed concern that these payments and other agreements were not necessary to settle disputes over the patent's validity, but, instead, were simply quid pro quo payments designed to keep generics off the market. The Preliminary Report noted that the size of many of the payments in the settlement agreements that the EC reviewed were well in excess of the likely litigation costs and therefore could not simply be explained away as litigation cost savings by the licensor.

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18 *Id.* at 10.

19 *Id.* at 214.

20 *Id.* at 225-241 (describing different kinds of patent settlement agreements).

II.

licensee could bring infringement actions against Japanese competitors violated Section 1.[23] A few years later, in *Zenith Radio Corp. v. Hazeltine*, the Supreme Court held that a patent pool violated section 1 of the Sherman Act because the pool's "chief purpose" was to exclude competition and it was effective in doing so.[24]

The Federal Trade Commission has likewise sought in some cases to prosecute firms that use patent thickets to deter innovation by their competitors. In 1975, in conjunction with the *Rank-Xerox* merger, the FTC alleged that Xerox violated Section 5 of the FTC Act by creating and preserving a noncompetitive market structure in the market for plain paper copiers by, among other things, developing an extensive patent portfolio through acquisition of control over Rank Xerox (a joint venture in which Xerox had previously held a non-majority stake).[25] Because Xerox had acquired patents to all of the technologies needed to engage in xerography, the FTC alleged that Xerox was eliminating the competition in the development and creation of office copiers. The FTC settled the *Xerox* suit in 1975 with a consent decree that required Xerox to permit the use

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[23] *United States v. Singer Manufacturing Co.*, 374 U.S. 174, 176 (1963).

[24] *Zenith Radio Corp. v. Hazeltine*, 395 U.S. 100 (1969). *Hazeltine* involved several Canadian manufacturers of televisions and radios who had transferred patents to a holding company which refused licenses to any importer who did not manufacture in Canada (and comply with other rules). In holding that the pool, acting in conspiracy with American patent holders, violated section 1, the Court found that "[t]he chief purpose of the pool was to protect the manufacturing members and licensees from competition by American and other foreign companies seeking to export their products into Canada." *Id*. at 115. The pool aggressively acted to prevent importation by U.S. firms, policing the

of any three of its dry paper copier patents on a royalty-free basis and to desist in pursuing certain of its infringement suits.[26]

More recently, the Commission addressed this issue on December 23, 2008 in *In re Inverness Medical Innovations*. There it announced the filing of a proposed complaint and consent order against Inverness Medical Innovations.[27] Inverness is the dominant firm in the market for home pregnancy tests and retains a 70 % market share.[28] The Commission brought a post-acquisition challenge to Inverness's acquisition of competing technology from ACON Laboratories—a chief competitor—on the grounds that the acquisition gave Inverness exclusive control over the intellectual property that ACON developed relating to digital home pregnancy tests.[29] In a January 27, 2009, consent order, Inverness agreed to disclaim any intellectual property rights over the digital technology, thereby preventing Inverness from having a lock on the intellectual property associated with new developments in the home pregnancy market.[30]

B. Repetitive Meritless Patent Challenges

Turning to the second tactic in the toolbox, efforts to limit meritless patent infringement challenges have been met with mixed results in the U.S. Under U.S. law,

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[26] *Id.* Subsequently, in *SCM Corp. v. Xerox Corp*., 645 F.2d 1195 (2d Cir. 1981) the Second Circuit held that the same acquisitions did not violate either Section 7 or Section 2 because, inter alia, the acquisitions were made many years before there was a plain paper copier market.

[27] *See* Analysis of Agreement Containing Consent Order to Aid Public Comment, *In re Inverness Medical Innovations, Inc.*, File No. 061-0123 (FTC Dec. 23, 2008), *available at* http://www.ftc.gov/os/caselist/0610123/081223invernessanal.pdf.

[28] *Id.* at 2.

[29] *Id.* at 2-3.

[30] *See* Decision and Order, *In re Inverness Medical Innovations, Inc.*, File No. 061-0123 (FTC Jan. 27, 2009), *available at* http://www.ftc.gov/os/caselist/0610123/090127invernessdo.pdf.

allegations that a patentee is liable under the antitrust laws for engaging in litigation to enforce its patent rights are subject to a very high threshold. In a series of cases, the Supreme Court has held that conduct that qualifies as petitioning the government—be it seeking legislative or regulatory action or the filing of a lawsuit—is protected conduct under our First Amendment to the United States Constitution. As a result, under the so-called *Noerr-Pennington* doctrine,[31] parties that engage in such protected conduct are generally immune from antitrust liability.

To be sure, *Noerr Pennington* immunity is not without its limits. In a trio of cases, culminating with its decision in *Professional Real Estate Investors v. Columbia Pictures Industry* (what I will call "*PRE*"), the Supreme Court has recognized that *Noerr-Pennington* immunity does not extend to those cases where the defendant uses the governmental process itself (including the tool of litigation)—as opposed to the outcome of that process—as an anticompetitive weapon.[32]

drug company) can obtain a favorable result

15 of the defendants' 29 lawsuits had proven successful, the Ninth Circuit rejected plaintiff's claim that defendants' conduct rose to the level of a sham.[37]

By contrast, in *Primetime 24 Joint Venture v. National Broadcasting Co.*, our Second Circuit Court of Appeals found that the sham exception did apply where the plaintiff alleged a conspiracy among the four major television networks to simultaneously file with the Federal Communications Commission thousands of objections to the plaintiff's competing service, knowing that most of the objections lacked merit.

an agreement in conjunction with the brand company's suit. At the FTC, we have brought a series of challenges against parties that engage in these agreements on the grounds that, because the agreements keep generics out of the market, they eliminate competition with the brand firm and therefore deprive customers of competitive prices. Our results have been, at best, mixed.

Initially, courts divided over whether reverse payment agreements were per se illegal. In 2003 in the *Cardizem* litigation, our Sixth Circuit Court of Appeals rejected the brand patentee's argument that reverse payment agreements were presumptively procompetitive and good for innovation and held that the reverse payments there were per se illegal because the agreement between the brand and the generic "was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade."[43] A few months later, however, Judge Posner, sitting as a district court judge, rejected this view in dicta in his *Asahi Glass* decision. There he reasoned that "a ban on reverse payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought as anticompetitive."[44]

More recently, federal appellate courts addressing the legality of reverse payment agreements have held that the agreements under review did not violate the antitrust laws because the agreements were within the scope of the brand firm's patent and therefore did not have anticompetitive effects beyond the monopoly power conferred by that patent.

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[43] *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

[44] *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. Oct. 30, 2003).

The leading case on this issue is the U.S. Court of Appeals for the Eleventh Circuit's decision in *Schering-Plough*.[45] There, the court rejected the FTC's claim that the settlement agreement failed under the rule of reason because the brand firm's payment to the generic constituted a quid pro quo for the generic's agreement to defer entry into the market and therefore had anticompetitive effects because it eliminated competition.[46] The Eleventh Circuit reasoned that the traditional rule of reason analysis, under which courts analyze whether the defendant's conduct had anticompetitive effects, was not "appropriate in this context" because "[b]y their nature, patents create an environment of exclusion, and, consequently, cripple competition."[47] As a result, the Eleventh Circuit reasoned, the proper analysis was to examine "the extent to which antitrust liability might undermine the encouragement of innovation and disclosure."[48] The court held that the legality of the settlement agreement rested on (1) the patent's potential exclusionary scope; (2) the extent to which the settlement agreement created exclusions beyond that scope; and (3) the resulting anticompetitive effects.[49] Because it held that the settlement in *Schering* did not have anticompetitive effects that were beyond the scope of the patent's exclusionary effect, the Eleventh Circuit refused to find liability under the antitrust laws.

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45 *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005).

46 *Id.* at 1065.

47 *Id.* at 1065-66.

48 *Id.* at 1066.

49 *Id.*

In the wake of the Eleventh Circuit's 2005 decision in *Schering*, both the U.S. Court of Appeals for the Second Circuit in its 2006 decision in *Tamoxifen,*[50] and the U.S. Court of Appeals for the Federal Circuit in its decision last fall in *Cipro*[51] have followed the Eleventh Circuit's lead and applied this same doctrinal framework. In each case, the court started from the presumption that the patent was valid and then went on to analyze whether the settlement was beyond the patent's scope.[52] Assuming that these cases remain good law, the next question is, under what circumstances could the Government or a private plaintiff nevertheless prevail in an antitrust challenge to a reverse payment agreement under U.S. law? As I read the cases, there are at least two such circumstances.

First, returning to the standards that I discussed earlier in the context of meritless lawsuits, a party contesting a reverse payment agreement can prevail if it can show that the brand firm's infringement lawsuit qualifies as a sham under *PRE* or rests on a patent that was obtained through fraud on the PTO. In *Tamoxifen*, for example, the Second Circuit held that, because a patent holder has a right to protect its monopoly, an agreement that is within the scope of the patent is lawful, unless the patent holder's infringement suit "was objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits."[53] Likewise, in *Cipro*, the Federal Circuit observed that, because a patent is presumed va

validity in the antitrust analysis of a settlement agreement involving a reverse payment absent "evidence of fraud before the PTO or sham litigation."[54]

Second, I also continue to believe that based on the Eleventh Circuit's decision in *Schering* and Judge Posner's decision in *Asahi Glass* that, at least outside of the Federal Circuit, a party contesting a reverse payment agreement can prevail if it can show that it is highly unlikely that the patent is valid or that it is likely that the generic firm did not infringe the patent.[55] Put another way, the validity or scope of the brand's patent does not need to be taken at face value—*Schering* does not create an *irrebuttable presumption* that the brand firm's patent is valid and/or that it will be infringed by the generic.

The tougher question—and the one that courts have yet to really grapple with—is what must the party challenging the reverse payment prove in order to show that validity and/or infringement are sufficiently unlikely? One option would be for the parties to engage in the battle of experts that often occurs in patent litigation and essentially resolve the validity or infringement claim on the merits. That would of course be expensive and would require either in-house or outside expertise. A second option would be for the party challenging the reverse payment agreement to prove that validity is highly unlikely or infringement is unlikely through direct evidence such as internal statements or

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[54] *Cipro*, 544 F.3d at 1336.

[55] In *Schering*, for example, the court noted that "there has been no allegation that the'743 patent itself is invalid" and that "*in the absence of any evidence to the contrary*, there is a presumption that the '743 patent is a valid one, which gives Schering the ability to exclude those who infringe on the patent." *Schering*, 402 F.3d at 1068 (emphasis added). Similarly, in *Asahi Glass*, Judge Posner noted that if "a seller obtain[ed] a patent that it knows is almost certainly invalid" and then settled infringement litigation by requiring that the generic competitor not sell the patented products for less than the price specified in the license, "the patent, the suit, and the settlement would be devices—masks—for fixing prices, in violation of antitrust law." *Asahi Glass*, 289 F. Supp. 2d at 991. *But see Cipro*, 544 F.3d at 1337 ("We disagree that analysis of patent validity is appropriate in the absence of fraud or sham litigation.")

evaluations by the brand and generic firms. The problem with dire

A second consideration that we have at the Commission and that itself has been the subject of much debate is how we should proceed to litigate these cases going forward. Much of this debate boils down two fundamental questions: what should the law should be and how should we get there? Should reverse payment settlements be per se illegal in certain circumstances as the *Cardizem* court found? If so, should we engage in rulemaking to that effect? Or should we seek an Act of Congress to make that the law? Proponents of the Hatch-Waxman Act recently introduced such a bill in the Senate.

Should we seek to re-orient the law away from the *Schering* analysis that essentially disclaims a reliance on the rule of reason simply because patents are presumptively anticompetitive? If so, one approach might be for the FTC to use our administrative trial process (which we term "Part 3"). If the FTC proceeded down that path and filed an administrative complaint against parties to a reverse payment agreement, a decision by the ALJ (regardless of the outcome) would almost invariably be appealed to the whole 5-person Commission. At that point, the FTC itself could weigh in through a written opinion. Although the FTC's decision would be subject to appeal to a federal appellate court, this process would nevertheless allow the FTC to clearly articulate its views of what the legal standard should be.

A second strategy is to pursue cases where we include specific allegations that the reverse payment reflects a quid pro quo for an agreement to divide the market coupled with specific allegations that the brand firm's infringement claim is weak. The FTC has recently done just that twice in cases filed in the federal district court in Pennsylvania and

the federal district court in California.[59] The FTC's specific allegations of market division and weak infringement claims distinguish these cases from *Schering*, *Tamoxifen*, and *Cipro* and my hope is that they will yield a different result.

As a third and final strategy, to avoid the unfavorable law that has developed in the last few years, the FTC could altogether side-step claims that these agreements are collusive horizontal agreements in violation of Section 1 of the Sherman Act and challenge these practices under Section 5 of the Federal Trade Commission Act which gives us broad (and largely undefined) authority to challenge "unfair methods of competition" [60] but which does not provide an escape from the *Noerr-Pennington* doctrine.

At the end of the day, there is of course the question of whether any one of these strategies is the best approach. Perhaps we should simultaneously pursue all of these strategies in an effort to foster more critical thinking on this topic and increase our likelihood of success.

III. CONCLUSION

In closing, the EC's Preliminary Report raises a whole host of issues that are at the heart of the complicated interface between the antitrust and intellectual property laws. In the U.S., we have been grappling with these issues for some time, and, as you can see, finding the right answers is not easy. With the change of Administration, we now have a new Assistant Attorney General for the DOJ's Antitrust Division and we will soon also have a new FTC Chairman. Based on initial press reports, it appears that the EC intends

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[59] *See FTC v. Cephalon, Inc.*, No. 08-cv-2141-RBS (E.D. Pa.); *FTC v. Watson Pharmaceuticals, Inc.*, No. CV 09-00598 (C.D. Cal.)

[60] 15 U.S.C. § 45(a)(1).

to commence a period of more aggressive antitrust enforcement in the pharmaceutical sector as a result of its findings. It will be interesting to see how these issues simultaneously play out in the U.S. and at the EC and whether and to what extent we are able to reach a consensus on the right ways to prosecute anticompetitive conduct in the pharmaceutical industry. The answers are rarely obvious, but the issues are fascinating.