Federal Trade Commission

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

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My remarks this evening will focus on the EC's recent sectoral study into anticompetitive practices in the pharmaceutical industry and the extent to which U.S. law has regulated or prohibited similar practices.

There is disagreement over whether patents are generally critical to innovation, but not when it comes to the pharmaceutical industry. Professor Mike Scherer argues, for example, that patents have been relatively unimportant to the decision-making processes of large corporations in deciding when to innovate and, in some cases, have inhibited innovation.[2] However, Scherer describes the pharmaceutical industry as an exception: he says that there is a direct correlation between patent power and market

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[1] The views stated here are my own and do not necessarily reflect the views of the Commission or other Commissioners. I am grateful to my attorney advisor, Amanda Reeves, for her invaluable assistance preparing this paper.

[2] F.M. Scherer, *The Political Economy of Patent Policy Reform in the United States*, AEI Brookings Joint Center for Regulatory Studies (October 2006), *available at* http://aei-brookings.org/admin/authorpdfs/redirect-safely.php?fname=../pdffiles/WP06-22_topost.pdf.

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 how the law has evolved and the extent to which it remains unsettled and will discuss some of the decisions that we face in deciding how to litigate these issues at the intersection of intellectual property and antitrust law. Finally, I will offer some concluding remarks.

I. SECTORAL INQUIRIES

Sectoral inquiries are unique to the European Commission. In the U.S., the closest analog is Section 6(b) of the Federal Trade Commission Act, under which the FTC can require the filing of "annual or special . . . reports or answers in writing to specific questions" for the purpose of obtaining information about "the organization,

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[3] *Id.*

[4] James Langenfeld, *Antitrust: New Economy, New Regime*, 52 Case W. Res. 91, 96 (Fall 2001).

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, *The New World of Proactive EC Antitrust Enforcement? Sector Inquiries by the European Commission*, 21 Antitrust ABA 82, 84 (Summer 2007) ("[I]n relation to such a general, industry-wide investigation, it is interesting to note that the FTC must first seek clearance from an external body (the Government Accountability Office) if it wishes to send information requests to ten or more persons which are not under investigation. Requests for clearance are published in the *Federal Register*, and interested parties may submit written comments in relation to the request within the prescribed timeframe. There is no equivalent provision in the EC regime.").

7 *See Making Waves: Interview with EU Commissioner For Competition Neelie Kroes*, 22 Antitrust ABA 47, 55 (Spring 2008). As Commissioner Kroes has noted:

> "The energy sector inquiry gave us deep insights into the functioning of European gas and electricity markets, indentifying a number of key obstacles to

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 antitrust investigations to deal with these problems. Without the inquiry we would not have been able to develop such a comprehensive enforcement strategy." *Id*.

[8] *See* Olsen & Roy, 21 Antitrust ABA at 87 (noting that "there is no requirement that the Commission must establish its findings on the balance of probabilities or indeed any recognized standard of proof").

[9] *Id.* (citing Council Regulation (EC) No. 1/2003, art. 28).

[10] Indeed, the press release that the EC issued at the start of the inquiry into the pharmaceutical industry recognizes as much. The EC stated:

> Innovation in the pharmaceutical sector is driven by patents and other intellectual property rights, and the inquiry will be conducted taking into account those existing rights. The Commission's action will therefore complement, not challenge, intellectual property law, as both systems share the objectives of fostering innovation, and increasing consumer welfare.

Press Release IP/08/49, European Commission, "Commission launches sector inquiry into pharmaceuticals with unannounced inspections" (Jan. 16, 2008), *available at*

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*.

13 Thomas Cueni, The EC Pharmaceutical Inquiry: Behind the Headlines, What is the Real Story on Innovation and Generic Competition in Pharmaceuticals?, Global Competition Policy (Nov. 2008, Release 1), *available at* http://www.globalcompetitionpolicy.org/index.php?&id=1470&action=907. *See also* Index of files relating to EC's Pharmaceutical Sector Inquiry, *available at* http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html (summarizing

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. THE BRAND FIRMS' "TOOL-BOX" OF STRATEGIES

Let me now please discuss how U.S. law has addressed each of these three strategies identified by the EC as residing in the big pharmaceutical companies' "tool-box" for deterring competition from generic companies.

A. Patent Thickets

First, as to "patent thickets" or "patent clusters," the decision by innovators to erect patent walls or thickets as a means to blocking out entry into a particular market by a competitor is not new. Stretching back more than 50 years U.S. courts have recognized that the acquisition of multiple overlapping patents with the intent to exclude competition can constitute a violation of Section 1 or 2 of the Sherman Act, depending on whether a monopolist acts alone or multiple parties act in concert. In *Kobe, Inc. v. Dempsey Pump Co.*, for example—one of the earliest U.S. cases to recognize the illegality of patent thickets—the U.S. Court of Appeals for the Tenth Circuit found that "every important patent" in the hydraulic pump manufacturing field, even if never used, "found its way into the [pump manufacturers' patent] pool."[21] The court held that the pump manufacturers' conduct constituted unlawful monopolization in violation of Section 2 where the evidence revealed that the plaintiffs' purpose in aggregating the patents was to do "everything within [their] power to 'build up and maintain its patent monopoly,'" over the technology needed to manufacture hydraulic pumps.[22]

The U.S. Supreme Court has likewise so held. In *United States v. Singer Manufacturing Co.*, the Supreme Court held that, in the context of a broad monopolistic scheme, the transfer of a patent from a Swiss manufacturer to its U.S. licensee so that the

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21 *Kobe, Inc. v. Dempsey Pump Co.*, 198 F.2d 416, 423 (10th Cir. 1952).

22 *Id.*

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 markets, sent warning notices to distributors, dealers, and consumers, and initiated infringement suits and threats. *Id*.

25 *See* Complaint, Xerox Corp., Docket No. 8909, *reprinted in Xerox Corp.*, 86 F.T.C. 364, 364-68 (1975) (hereinafter "Complaint"), ¶¶14(a)-(c), 15. The *Xerox* case is discussed in detail in Willard K. Tom, *The 1975 Xerox Consent Decree: Ancient Artifacts and Current Tensions*, 68 Antitrust L. J. 967 (2001).

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] In these cases, the defendant's act of petitioning the government is considered a "sham." The "sham exception," however, as it was defined in *PRE*, is quite narrow and whether an antitrust plaintiff (such as a generic

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[31] *Eastern Railroad Presidents Conference v. Noerr Motor Freight Inc.*, 365 U.S. 127, 137-38 (1961) (establishing immunity from antitrust liability for conduct protected by the First Amendment and acknowledging that "there may be situations in which a publicity campaign, ostensible directed toward influencing governmental action, is a mere shame to cover what is actually nothing more than an attempt to interfere with the business relationships of a competitor, and the application of the Sherman Act would be justified"); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965) (holding that "[j]oint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition").

[32] *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972); *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380 (1991); *Professional Real Estate Investors v. Columbia Pictures Industry*, 508 U.S. 49, 60-61 (1993).

drug company) can obtain a favorable result by filing suit under the sham exception depends on the circumstances alleged.[33]

Under *PRE*, the sham exception extends to a claim that an antitrust defendant engaged in anticompetitive behavior by filing a single meritless lawsuit. To defeat a claim of immunity in these circumstances, however, a plaintiff must pass a high bar and show, first, that the lawsuit is objectively baseless (i.e., that no reasonable litigant could foreseeably expect a favorable result) and, second, that the defendant's subjective motivation in filing the alleged sham lawsuit was to use the adjudicatory process itself as an anticompetitive weapon.[34]

When the antitrust defendant's alleged anticompetitive behavior is the filing of a *series* of meritless lawsuits, the law is more ambiguous. In *USS-POSCO Industries*, for example, the plaintiff alleged that the defendants filed 29 frivolous lawsuits and administrative complaints for the purpose of harassment "without regard to and regardless of the merits of said petitions."[35] Our Ninth Circuit Court of Appeals rejected the plaintiff's suggestion that the *PRE* two-step analysis applied, instead holding that a court should look prospectively at whether the lawsuits were "part of a pattern or practice of successive filings undertak[en] essentially for purposes of harassment."[36] Finding that

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33 *von Bulow v. von Bulow*, 657 F. Supp. 1134, 1145 (S.D.N.Y. 1987) (describing the "sham" exception as "a narrow exception to the general principle that legitimate court action cannot give rise to antitrust liability").

34 *PRE*, 508 U.S. at 60-61.

35 *USS-POSCO Industries v. Contra Costa County Building & Construction Trades Council*, 31 F.3d 800, 810 (9th Cir. 1994).

36 *Id.* at 811.

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.[38] Following the Ninth Circuit, the Second Circuit held that the "relevant issue" in cases involving allegations of repetitious lawsuits "is whether the legal challenges 'are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival.'"[39] As several courts have since held, however, because *Primetime 24 Joint Venture* involved allegations that the defendants literally filed *thousands* of objections, its holding may not extend to those cases that involve a smaller number of alleged, meritless lawsuits.[40]

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37 *Id.*

38 *Primetime 24 Joint Venture v. National Broadcasting Co.*, 219 F.3d 92 (2d Cir. 2000).

39 *Id.* at 101 (quoting *USS-POSCO*, 31 F.3d at 811). The FTC has taken the position that the "pattern" exception to *Noerr Pennington* immunity should apply to any predatory pattern of invoking government process of any kind, and not simply to litigation. *See* Analysis to Aid Public Comment, *In re Bristol Myers Squibb Co.*, No. C-4076, at 11 (FTC Mar. 7, 2003), *available at* http://www.ftc.gov/os/2003/03/bristolmyersanalysis.htm ("Just as the repeated filing of lawsuits without regard to the merits . . . warrants rejection of *Noerr* immunity, so too" does the repeated filing of knowing and material misrepresentations to the PTO and FDA.).

40 *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1367 (S.D. Fla. 2004); *Marchan Eyewar v. Tura LP*, No. 98 CV 1932 (SJ), 2002 WL 31253199, at *8 (E.D.N.Y. Sept. 30, 2002).

A failure to meet the requirements of the sham exception, however, is not dispositive of a rival's ability to defeat a patentee's claim of *Noerr Pennington* immunity. In *Nobelpharma,* our Court of Appeals for the Federal Circuit held that the sham exception to *Noerr Pennington* immunity provides an "alternative legal grounds on which a patentee may be stripped of its immunity from the antitrust laws" and that a rival may also challenge a brand patentee's lawsuit under the *Walker Process* doctrine on the grounds that the defendant procured its patent through fraud on the Patent and Trademark Office.[41] The Federal Circuit held that "if the . . . elements of *Walker Process* fraud, as well as the other criteria for antitrust liability, are met, such liability can be imposed without the additional sham inquiry required under *PRE*."[42] A party in the U.S. can therefore challenge meritless litigation on the grounds that the litigation is a sham or that the brand firm procured the underlying patent through fraud.

C. Reverse Payment Settlements

Third, as the EC itself noted in its Preliminary Report, the legality of "reverse payment" settlement agreements has been a subject of widespread and ongoing debate in the U.S. As the pharmaceutical sector study points out, these are payments (or something else of value) made by a patent holder to the generic company as part of a settlement or

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41 *Nobelpharma AB v. Implant Innovations,* 141 F.3 1059, 1071 (Fed Cir. 1998). The *Walker Process* doctrine permits a patent infringement defendant to defend against an infringement claim (generally through a counterclaim or a declaratory judgment action) on the ground that the infringement suit constitutes unlawful monopolization or an unlawful attempt to monopolize. The patent infringement defendant must show (1) clear and convincing proof that the patentee engaged in a misrepresentation or omission of a material fact with the intent to deceive the patent examiner that causes the PTO to issue a patent that it would not have issued absent the fraudulent conduct, and (2) the elements of a Section 2 monopolization claim. *See Walker Process Equip. v. Food Mach. & Chem. Corp.,* 382 U.S. 172 (1965).

42 *Id.*

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 valid, the court need not consider the patent's

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50 *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

51 *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed Cir. 2008).

52 *See, e.g.*, *Tamoxifen*, 466 F.3d at 208-09 n. 22 (explaining presumption of validity).

53 *Id.* at 213 (quoting *PRE*, 508 U.S. at 60).

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 direct evidence, however, is that it rarely actually exists. A third and more viable option would be for the party challenging the reverse payment agreement to prove that validity is highly unlikely or that infringement is unlikely by relying on circumstantial evidence, including the parties' positions prior to settlement, projections from the firms about the patent's validity or the likelihood of infringement, or the existence of a demonstrably excessive "reverse payment."[56] Thus, for example, evidence that the reverse payment equals or exceeds the generic firm's potential profits if it wins (taking into account the remaining life of the patent and the lower profit margins if there is competition), buttressed by other evidence (for example, that the payment was made despite the presumption of validity or evidence from an ex-employee or because the parties' documents show the payment was made because it was believed the brands' patent was invalid) might be sufficient to create an inference that the patent is in fact invalid.[57]

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[56] *Schering* does not reject the use of circumstantial evidence to resolve the issues of validity and/or infringement. To be sure, *Schering* rejects as a sufficient basis for finding invalidity or non-infringement the existence of a reverse payment, standing alone. *Schering*, 402 F.3d at 1075 ("Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the *sole* basis for a violation of the antitrust law. . . "). Moreover, in *Schering* the court said that "the size of the payment should not *dictate* the availability of the settlement remedy." *Id.* Thus, under *Schering*, the circumstantial evidence of invalidity or non-infringement cannot consist *solely* of the existence of a reverse payment; nor can the size of the payment, standing alone, *dictate* findings of invalidity or non-infringement.

[57] This circumstantial evidence of course is not dispositive. The brand (and the generic) can introduce evidence to rebut the inference of invalidity and/or non-infringement created by the circumstantial evidence. For example, they may present expert testimony on these issues (which of course can be tested on cross-examination). However, circumstantial evidence of the sort described should be sufficient to create an *inference* of invalidity and/or non-infringement and hence make out a prima facie case. If not dispelled by contrary testimony (weighed in the light of cross-examination), the circumstantial evidence should also be sufficient to support conclusions of invalidity and/or non-infringement.

In the alternative, a party challenging a reverse payment agreement in the Sixth Circuit or in a jurisdiction that has not weighed in on this issue yet, can distance itself from these cases and argue that the strength of the patent (whether it is invalid or infringed) is not a threshold issue. Thus, as in *Cardizem*, the plaintiff may argue that the reverse payment is a flat out quid pro quo for an agreement by the generic firm not to compete, be it by dividing up the market or by simply staying out of the market.

Apart from these doctrinal arguments, there are other considerations that bear on the evolution of the law in the reverse payment context. For one, although a proper discussion of it is beyond the scope of my remarks here today, as the Preliminary Report itself notes, a major difference between U.S. law and EC law when it comes to reverse payments is that U.S. firms and courts operate against the backdrop of not only federal antitrust and intellectual property laws, but also the Hatch-Waxman Act, which regulates the introduction of generic drugs into the market place. Professor Scott Hemphill has argued that courts should give the Hatch-Waxman Act independent relevance in considering the legality of reverse payment settlements.[58] His argument is that, because the Hatch-Waxman Act reflects a congressional judgment, it deliberately favors litigated challenges to brand patents rather than settlement. That judgment, of course, is the polar opposite from the view expressed in *Schering, Tamoxifen,* and *Cipro* that courts should favor patent settlements over litigation. Put another way, it may be correct that, in a world without the Hatch-Waxman Act—as you have here—a policy that defaults in favor of settlement is arguably appropriate. But that is not the policy that we arguably have in the U.S. in the context of generic drugs.

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[58] *See* C. Scott Hemphill, *Paying For Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U.L. Rev. 1553 (Nov. 2006).

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.