Federal Trade Commission

Patent Settlements, Patent Reform, and Mergers:
Recent Developments in Pharmaceutical Antitrust

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at the

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You've heard my views before in respect to the Federal Trade Commission's position on several issues relevant to the pharmaceutical industry.[1] This morning, I'm going to offer my own perspectives on some developments that have occurred since I voiced these views.

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* 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 advisors, Darren Tucker and Henry Su, for their invaluable assistance in preparing this paper.

[1] I've previously described my positions respecting these and other issues relevant to the pharmaceutical industry, and my remarks are posted on the Commission's website. *See* J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, The Role of Static and Dynamic Analysis in Pharmaceutical Antitrust, Remarks at the Fifth Annual In-House Counsel Forum on Pharmaceutical Antitrust (Feb. 18, 2010), *available at* http://www.ftc.gov/speeches/rosch/100218pharmaantitrust.pdf; J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Pay-for-Delay Settlements, Authorized Generics, and Follow-on Biologics: Thoughts on the How Competition Law Can Best Protect Consumer Welfare in the Pharmaceutical Context, Remarks at World Generic Medicine Congress, Washington, D.C. (Nov. 19, 2009), *available at* http://www.ftc.gov/speeches/rosch/091119worldgenerics.pdf.

Before I turn to the cases, the legislation, and the options respecting the pay-for-delay practice, let me give you some statistics from the Commission that are literally hot off the press. Chairman Leibowitz reported last week that deals delaying introduction of cheaper generics rose 63 percent in 2010—from 19 in 2009 to 31 in 2010.[2]

Pay For Delay – *Cipro* Case

On March 7, the Supreme Court denied certiorari in the *Cipro* case out of the Second Circuit. You will recall that this case involved a challenge to a "reverse payment" agreement between Bayer and Barr involving the blockbuster drug ciprofloxacin hydrochloride, known by its trade name as Cipro. The plaintiffs alleged that Bayer had paid hundreds of millions of dollars to the generics to stay off the market. The trial court granted summary judgment for the defendants, which a three-judge panel upheld on appeal.[3]

The three-judge panel held that it was bound by the *Tamoxifen* decision, which was a 2006 Second Circuit opinion upholding a similar patent settlement.[4] *Tamoxifen* held that patent settlements are presumptively lawful unless the patent holder procured the patent by fraud on the PTO or brought a baseless infringement lawsuit. The *Cipro* court explained that "[s]ince *Tamoxifen* rejected antitrust challenges to reverse payments as a matter of law, we are bound to review the *Cipro* court's rulings under the standard adopted in *Tamoxifen*."[5] Under that standard, the *Cipro* defendants were entitled to summary judgment.

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[2] *See* Press Release, Fed. Trade Comm'n, FTC Staff Report Finds 60 Percent Increase in Pharmaceutical Industry Deals That Delay Consumers' Access to Lower-Cost Generic Drugs (May 3, 2011), http://www.ftc.gov/opa/2011/05/mmareport.shtm.

[3] Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re* Ciprofloxacin Hydrochloride Antitrust Litig.) [hereinafter, Cipro], 604 F.3d 98 (2d Cir. 2010), *cert. denied*, 79 U.S.L.W. 3513, 2011 U.S. LEXIS 2090 (Mar. 7, 2011).

[4] In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006).

[5] *Cipro*, 604 F.3d at 106.

Nevertheless, the *Cipro* panel described the anticompetitive effects of reverse payment settlements, and invited the parties to submit a petition to rehear the case *en banc*. The plaintiffs did so. The FTC and DOJ filed amicus briefs in support of the en banc petition and urged the full court to apply an "inherently suspect" standard to patent settlement agreements.[6] Under this standard, these agreements would be considered presumptively unlawful, but could nevertheless be proven by the defendants to be procompetitive. On September 7, 2010, much to our disappointment, the Second Circuit denied plaintiffs' petition for rehearing *en banc*, with Judge Pooler writing a dissenting opinion.[7] Plaintiffs then petitioned for a writ of certiorari, which the Supreme Court denied.[8]

Although it may sound counterintuitive, I'm pleased that the Supreme Court denied cert in the *Cipro* case. That is because Justices Sotomayor and Kagan recused themselves from the case. Challengers to pay-for-delay agreements would likely have a far better chance at the highest court if all nine Justices were available to hear the case. There will undoubtedly be other opportunities for our highest court to address pay-for-delay settlements. There are other challenges to these settlements wending their way through the courts. The Commission alone

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[6] *See* Brief for the United States at 21-23, Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. Jul. 6, 2009) (No. 05-2851), *available at* http://www.justice.gov/atr/cases/f247700/247708.pdf; Brief for the Federal Trade Commission, Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. May 20, 2010) (No. 05-2851), *available at* http://www.ftc.gov/os/2010/05/051202amicuscarpentershealth.pdf.

[7] Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re* Ciprofloxacin Hydrochloride Antitrust Litig.) [hereinafter, Cipro II], 625 F.3d 779 (2d Cir. 2010) (denying petition for rehearing *en banc*).

[8] Ark. Carpenters Health & Welfare Fund v. Bayer AG, 79 U.S.L.W. 3513, 2011 U.S. LEXIS 2090 (Mar. 7, 2011).

has cases in the Third and Eleventh Circuits, which I'll discuss in a moment. There are also private cases, in particular, the K-Dur case in the Third Circuit.[9]

Pay-For-Delay – The AndroGel and Cephalon Cases

Oral argument will be held on May 13 before the Eleventh Circuit in the AndroGel case, which you may know as *FTC v. Watson Pharmaceuticals*.[10] As I've said before, in my view the AndroGel case is and should be winnable, notwithstanding the popularly held view that the Commission's chances are slim because of the Eleventh Circuit's decisions in *Schering-Plough*[11] and *Valley Drug.*[12]

More specifically, I don't see *Valley Drug* and *Schering* as obstacles; rather, I view them as supplying the tools needed for the Commission to survive a motion to dismiss in the Eleventh Circuit. Particularly in light of the Rule 12(b)(6) posture, our chances are probably better in the Eleventh Circuit than they would be at this stage in either the Second or Federal Circuits. The procedural posture in AndroGel is identical to the Eleventh Circuit's lesser-known, but most recent pay-for-delay decision in *Andrx*,[13] where the court sided with the private plaintiffs and reversed the district court's decision granting the motion to dismiss. In so holding, the Eleventh Circuit was clear that the plaintiffs' claims might fail on the merits (as in *Schering* and *Valley Drug*),[14] but observed that because "antitrust cases are 'fact-intensive' . . ., require appropriate market analysis, and therefore are typically inappropriate for a Rule 12 dismissal in the absence

[9] *In re* K-Dur Antitrust Litig., Nos. 10-2077, -2078, -2079, -4571 (3d Cir. first notice of appeal filed Apr. 30, 2010).

[10] FTC v. Watson Pharms., Inc., No. 10-12729-DD (11th Cir.).

[11] Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

[12] Valley Drug Co. v. Geneva Pharms., 344 F.3d 1294 (11th Cir. 2003).

[13] Andrx Pharms. v. Elan Corp., 421 F.3d 1227 (11th Cir. 2005).

[14] *Id.* at 1236 ("Our conclusion as to the sufficiency of the complaint does not preclude, however, Andrx's claims from being challenged at the summary judgment stage.").

of an applicable immunity doctrine," the case should be remanded for fact-finding.[15] I expect the same result in AndroGel.

The other pay-for-delay case that the Commission is prosecuting is the *Cephalon* litigation in the Eastern District of Pennsylvania.[16] As I also said last year, the district court sided with the Commission and the private plaintiffs and denied the defendants' motion to dismiss. The court concluded that, among other things, plaintiffs' allegations of fraud and misrepresentation to the PTO, non-infringement, and patent invalidity, were all sufficient to plead an antitrust violation under the "scope of the patent" test.[17]

Judge Goldberg has not yet set a trial date, but discovery will close on August 12 and summary judgment motions are due by September 9. In a related case filed by Apotex, Judge Goldberg recently held a hearing on the validity of Cephalon's '516 patent. The court's decision, which we hope will come soon, could have implications for the FTC's case.

Pay-For-Delay – Other Approaches

I'm optimistic about both of these cases. But because of the difficulties the Commission has faced challenging these settlements in the past, the agency has been urging Congress to adopt legislation that would address pay-for-delay settlements. On January 25, 2011, Senator Herb Kohl reintroduced the Preserve Access to Affordable Generics Act.[18] The bill would make an "agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product" presumptively unlawful if (a) "an ANDA filer receives anything of value" and (b) "the ANDA filer agrees to limit or forego research,

[15] *Id.* (citing *Schering*, 402 F.3d at 1065-66).

[16] King Drug Co. v. Cephalon, Inc., 702 F. Supp. 2d 514 (E.D. Pa. 2010).

[17] *Id.* at 533-34.

[18] S. 27, 112th Cong. (2011).

development, manufacturing, marketing, or sales of the ANDA product for any period of time."[19] However, this presumption can be overcome if the parties to the "agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement."[20] The bill also provides for the forfeiture of the 180-day exclusivity period for the marketing of a generic drug if there is a final decision of the Commission or a court holding that an agreement is illegal.

Where do I personally stand? In principle, I support the legislation that is pending on the Hill (with the possible exception of the "clear and convincing" standard). That is to say, I think the legislation's burden-shifting approach is correct and, given our track record in the courts, I believe a legislative fix may be the best way to eliminate these anticompetitive settlements. However, a legislative solution to this problem appears unlikely in the current Congress. While it's true that Congress came close to passing a reform measure in the last session, the mid-term elections have reshaped its makeup such that similar reform is less likely, particularly in the House.

So does the Commission have a "Plan C" if we continue to be unsuccessful before both the judiciary and Congress? At this point, the answer is no. But, as I've said, one possibility would be for the Commission to exercise its rulemaking authority under Section 6(g) of the FTC Act.[21] Under this provision, the Commission can "make rules and regulations for the purpose of

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[19] *Id.* § 28(a).

[20] *Id.* The Act also permits a resolution or settlement of a patent infringement claim if the only consideration granted by a new drug application holder to a filer of an abbreviated new drug application is the right to market the drug product in the United States prior to the expiration of any patent that is the basis for the patent infringement claim or any patent right that would prevent the marketing of such drug; a payment for reasonable litigation expenses not exceeding $7.5 million; and a covenant not to sue on any claim that the filer infringes a U.S. patent.

[21] 15 U.S.C. § 46(g); *see also* Nat'l Petroleum Refiners Ass'n v. FTC, 482 F.2d 672, 698 (D.C. Cir. 1973) ("[T]he Federal Trade Commission is authorized to promulgate rules defining

carrying out" the FTC Act. It strikes me that the agency could issue a rule that would deem pay-for-delay agreements as inherently suspect. The Commission would have the initial burden of production demonstrating the existence of a reverse payment settlement. At that point, the burden of production would shift to the parties to justify the practice. If they do so, the burden would shift back to the Commission, which would have to show under the full rule of reason that the agreement is anticompetitive. Because the burden of proof ultimately rests with the Commission, I think this approach would pass muster under the Administrative Procedures Act, which governs Section 6(g) rulemakings.[22]

The Ovation Case

In 2005, Lundbeck – the successor in interest to a company called Ovation – acquired a drug called Indocin IV, which at the time was the only drug available to treat a life-threatening heart condition called patent ductus arteriosis (PDA). About a year later, Lundbeck acquired NeoProfen, which was a drug awaiting FDA approval to treat PDA. Shortly after the transaction, Lundbeck raised the price of Indocin IV by almost 1,300 percent and introduced NeoProfen at a similar price. It also ceased promoting Indocin IV, seeking to move as many customers to NeoProfen.

The Commission and the State of Minnesota[23] brought suit in federal court alleging that Lundbeck's acquisition of NeoProfen violated the Sherman and Clayton Acts. A 7-day bench trial was held in December 2009. In its August 31, 2010 ruling, the district court held that the two drugs were not in the same relevant product market and that Lundbeck's acquisition

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the meaning of the statutory standards of the illegality the Commission is empowered to prevent.").

[22] Rulemaking under Section 6(g) follows the "informal" or "notice and comment" procedures of the APA. *See* 5 U.S.C. § 553.

[23] For convenience, I will refer to both plaintiffs as the Commission.

therefore did not violate the law.[24] The court's conclusion regarding the product market appears to have been largely based on its finding that neonatologists choose a PDA drug based on their personal views of the drugs' relative merits, rather than on prices. In addition, the court was critical of the Commission for not offering an opinion on the specific cross-elasticity between the two drugs, which the court seemed to view as necessary to define a relevant market. The court refused to credit Lundbeck's contemporaneous marketing documents, which showed price and non-price competition between the two drugs.

The Commission filed an appeal making several points. First, the district court's reliance on the lack of current price competition between the two products was legal error because the court failed to account for its own findings of fact that the acquisition was the very cause of this lack of competition. More specifically, the district court found that Lundbeck stopped marketing Indocin IV, priced NeoProfen to eliminate price as a competitive variable as much as possible, and refused to negotiate with group purchasing organizations.[25] Thus, the transaction eliminated competition that would have existed between the two products had they remained in independent hands.[26]

The court's own findings of fact that the post-acquisition market environment was controlled solely by Lundbeck also cast doubt on the reliability of the neonatologist testimony. The preferences of these physicians were formed in the post-acquisition world in which Lundbeck had eliminated the possibility of any price or non-price competition between the two

[24] FTC v. Lundbeck, Inc., Civil Nos. 08-6379, 08-6381 (JNE/JJG), 2010 WL 3810015 (D. Minn. Aug. 31, 2010). In March 2009, H. Lundbeck A/S acquired Ovation Pharmaceuticals and renamed it Lundbeck, Inc.

[25] *Id.*, Findings 81, 82, 90.

[26] The district court found that "when launching NeoProfen, an independent owner would not have disregarded Indocin's price." *Id.*, Finding 63.

drugs. Thus, neonatologists' testimony did not address the likely competition in the PDA drug marketplace absent Lundbeck's preemption of competition. For example, the neonatologists did not offer testimony on how they (through their hospitals) would have purchased PDA drugs if an independent company had owned Indocin IV and had actually promoted it.

The second error was the court's failure to follow clear Supreme Court and Eighth Circuit precedent holding that product markets need *not* be determined only on the basis of cross-price elasticity. Particularly where a quantitative assessment of the elasticity is not possible, product markets can be determined by the reasonable interchangeability of use.[27]

Applying the proper legal standards to the district court's findings established that Indocin IV and NeoProfen are in the same product market. According to the district court's findings of fact, the two drugs treat the exact same medical condition, are equally efficacious, are sold to the same customers, and are similarly distributed.[28] The court's findings of fact also show that if the two drugs had been owned by independent companies, those rivals would have competed on non-price factors and that buyers would have had the ability to obtain price concessions and shift their purchases between the products.[29] So the court's own findings of fact established that the two drugs were in the same market under the Supreme Court's *Brown Shoe* test, the Eighth Circuit's standards, and under the Merger Guidelines.

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[27] *See* United States v. Continental Can Co., 378 U.S. 441, 455 (1964) ("That there are price differentials … [is] relevant . . . but not determinative of the product market issue."); United States v. E.I. DuPont de Nemours & Co., 351 U.S. 377, 401 (1956) (same); Little Rock Cardiology Clinic v. Baptist Health, 591 F.3d 591, 596 (8th Cir. 2009) ("The relevant product market should include products that have reasonable interchangeability for the purpose for which they are produced.") (internal quotations omitted); HDC Medical, Inc. v. Minntech Corp., 474 F.3d 543, 547 (8th Cir. 2007) ("The boundaries of the product market can be determined by the reasonable interchangeability or cross-elasticity of demand between the product itself and possible substitutes for it.").

[28] *Lundbeck*, 2010 WL 3810015, Findings 14, 21, 78, 88, 90, 94.

[29] *Id*. Findings 58, 60, 63, 65, 81-84, 89, 90.

Third, the court was required to consider whether there would have been so called "marginal customers" (that is, those not firmly committed to one of the products) who could have constrained pricing had there been competing sellers. The Eighth Circuit has repeatedly emphasized the need to examine the extent to which customers are able and willing to choose alternatives for a product.[30] Although the district court's own findings demonstrated the existence of a significant percentage of customers that were willing to switch between the two drugs,[31] the district court ignored these findings.

Fourth, the court committed legal error by treating Lundbeck's contemporaneous, pre-litigation marketing documents as legally irrelevant to its product market analysis. These documents showed that Lundbeck made business decisions with the expectation of buyer substitution between the two drugs based on relative price changes.[32] Courts have long recognized that such documents can provide highly relevant and reliable evidence to aid in defining a relevant product market and showing likely competitive effects.[33] The district court's erroneous dismissal of these documents, which was based upon a misreading of a case from another circuit,[34] further compromised its product market analysis.

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[30] *See, e.g.*, H.J., Inc. v. Int'l Tel. & Tel. Corp., 867 F.2d 1531, 1538 (8th Cir. 1989).

[31] *Lundbeck*, 2010 WL 3810015, Findings 82-85.

[32] *Id.*, Findings 78-87.

[33] *See, e.g.*, Spirit Airlines, Inc. v. Northwest Airlines, Inc., 431 F.3d 917, 934-35 (6th Cir. 2005); United States v. Waste Mgmt., Inc., 743 F.2d 976, 980 (2d Cir. 1984); Meijer, Inc. v. Barr Pharms., Inc., 572 F. Supp. 2d 38, 60 (D.D.C. 2008); Cmty. Publ'rs, Inc. v. Donrey Corp., 892 F. Supp. 1146, 1155 (W.D. Ark. 1995), *aff'd*, 139 F.3d 1180 (8th Cir. 1998); FTC v. Staples, Inc., 970 F. Supp. 1066, 1079 (D.D.C. 1997). *Cf.* United States v. United States Gypsum Co., 333 U.S. 364, 395-96 (1948) (recognizing reliability of contemporaneous documents).

[34] Kentucky Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc., 588 F.3d 908, 919 (6th Cir. 2009).

Although our appeal is limited to the issue of market definition, a successful appeal for the Commission will almost certainly result in the conclusion that Lundbeck has violated the antitrust laws. That is because in the market alleged by the Commission, the transaction caused a merger to monopoly, a clear violation of the Sherman and Clayton Acts.[35] That means that the remand after a successful appeal is likely to focus on the remedy.

Briefing on the appeal has been completed, but the Eighth Circuit has not yet scheduled oral argument.

The FTC Patent Report

As you may have seen or read, in March of this year the Commission issued a report entitled "The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition."[36] For those of you who are keeping count, this is the *third* report that the Commission has issued on topics relating to the United States patent system and its impact on innovation and competition;[37] the first report came out in 2003[38] and the second report, issued

[35] United States v. El Paso Natural Gas Co., 376 U.S. 651, 660-62 (1964). Further, an acquisition by a monopolist that cuts off entry into the relevant market is patently exclusionary because it stops the competitive process in its tracks. *See* Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 488 (1992); III PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 701b (3d ed. 2008).

[36] FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION (Mar. 2011) [hereinafter, PATENT REPORT], *available at* http://www.ftc.gov/os/2011/03/110307patentreport.pdf. *See* Press Release, Fed. Trade Comm'n, FTC Report Recommends Improvements in Patent System to Promote Innovation and Benefit Consumers (Mar. 7, 2011), http://www.ftc.gov/opa/2011/03/patentreport.shtm.

[37] The Commission issues reports pursuant to its authority under Section 6(f) of the FTC Act. 15 U.S.C. § 46(f) (2009) ("To make public from time to time such portions of the information obtained by it hereunder as are in the public interest; and to make annual and special reports to the Congress and to submit therewith recommendations for additional legislation; and to provide for the publication of its reports and decisions in such form and manner as may be best adapted for public information and use:").

jointly with the Justice Department, came out in 2007.[39] (For the sake of brevity and clarity, I am going to refer to the latest Report as the Patent Report.)

Today I would like to share with you my own views regarding the one of the issues discussed in the Patent Report. Before I do, I would emphasize that, unlike the other two reports, which made a broader sweep of various issues, principles and reforms under the patent and antitrust laws, the Patent Report focuses on two specific sets of issues: first, how well our patent system gives notice to the public of the existence, scope and extent of patent rights,[40] and second, the standards under which our judicial system awards remedies in the form of monetary damages and injunctive relief.[41]

The Patent Report considers these sets of issues in the context of an "evolving patent marketplace," a secondary market in which patent rights are sold, bartered and auctioned among business entities, including entities that have no intention of practicing the patented inventions themselves and acquire patent rights for the sole purpose of asserting them against others.[42] Instead of referring to this latter group as non-practicing entities (NPEs) or "patent trolls,"[43] the

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[38] FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (Oct. 2003) [hereinafter, INNOVATION REPORT], *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

[39] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION (Apr. 2007) [hereinafter, ANTITRUST REPORT], *available at* http://www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf.

[40] PATENT REPORT, *supra* note 36, ch. 3.

[41] *ID.*, chs. 4-8.

[42] *ID.*, ch. 2.

[43] I have previously spoken about the problem of patent trolls. *See* J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, *Patent Trolls: Broad Brush Definitions and Enforcement Ideas*, Remarks Before the Newport Summit on Antitrust Law and Economics (May 31, 2008), *available at* http://www.ftc.gov/speeches/rosch/080531roschlecg.pdf.

Patent Report calls them "patent assertion entities" (PAEs).[44] The question I want to raise today is whether it is reasonable and practicable, from the standpoint of patent doctrine and policy, to differentiate among business entities that in general do not practice the patented inventions and seek only to license the patent rights to others, based upon the relative "pureness" of their business motives or objectives.[45]

The Patent Report focuses on issues relating to patent notice and patent remedies because these issues are arguably most directly tied to the problem of patent "hold-up"—a situation in which a putative infringer of a patent has sunk certain investments into developing and producing a particular good or service accused of infringement, and therefore would have to incur some amount of "switching costs" to avoid infringement.[46] Specifically, more effective

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[44] PATENT REPORT, *supra* note 36, at 8 n.5, 50 n.2, 60 & n.47, 162 n.10 & 220 n.21.

[45] *See ID.* at 60-61:

> The literal definition of non-practicing entity is broad enough to encompass the start-ups, universities, and design houses discussed in Chapter 1. But the term NPE also commonly refers to firms that obtain nearly all of their patents through acquisition or purchase in order to assert them against manufacturers. Such firms are sometimes called "trolls" by detractors. For clarity, this report refers to these firms as patent assertion entities (PAEs). For the most part, PAEs purchase patents, and then sell or license them as assets whose values are based on the amount of licensing fees that can be extracted from operating companies already using and marketing the technology, or they facilitate others who make the assertions. PAEs can also include patentees that "have turned their focus away from the active development or practice of their patents and have moved towards patent enforcement." Some commentators describe business strategies built around "being infringed," while others identify businesses that operate as "opportunistic litigation mills" and do not innovate. . . .

(Footnotes omitted.)

[46] *ID.* at 22 ("The ability of patentees to demand and obtain royalty payments based on the infringer's switching costs is commonly called 'hold-up.'"). *See also ID.* at 191 n.61 ("'Hold-up' is used throughout this report to describe a patentee's ability to extract a higher licensing fee after an accused infringer has sunk costs into implementing the patented technology than the patentee could have obtained at the time of design decisions, when the patented technology competed with alternatives.").

and reliable patent notice might help companies avoid a hold-up problem in the first place, before they have sunk investments into development and production.[47] Furthermore, changes in the way infringement damages based on lost profits or a reasonable royalty are calculated and awarded, and the circumstances under which permanent injunctions are issued, might minimize the "hold-up value" that companies have to pay for patents being asserted against them in litigation.[48]

The Patent Report urges careful consideration of how lost profit damages and reasonable royalties are recognized, calculated and awarded, and under what circumstances should permanent injunctions be granted, with the common theme being to avoid overcompensation to patent owners based on the hold-up value of a patent.[49] In general, the issues relating to lost profit damages and reasonable royalties involve ensuring that the theories and models of financial harm adopted in an infringement case are backed by the rigor of economic analysis and supported by solid factual and legal bases.[50] As a trial lawyer who has defended numerous

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[47] *See ID.* at 10 ("Notice is more beneficial to third parties when they are still planning their R&D strategies and before they make sunk investments that may expose them to hold-up.").

[48] *See ID.* at 22 ("Switching costs may be prohibitively high when an industry becomes locked into using standardized technology. Were patentees able to obtain the hold-up value, this overcompensation could raise prices for consumers while undermining efficient choices made among technologies competing for inclusion in a standard.") & 26 ("An injunction's ability to cause patent hold-up can support withholding injunctive relief in some situations. A manufacturer's high switching costs combined with the threat of an injunction can allow a patent owner to obtain payments unrelated to the economic value of its invention.").

[49] *ID.* at 144 ("In that case, the patentee can use the threat of an injunction to obtain royalties covering not only the value of its invention compared to alternatives, but also a portion of the costs that the infringer would incur if it were enjoined and had to switch. This higher royalty based on switching costs is called the 'hold-up' value of the patent.") & 193 ("Panelists recognized that the law of reasonable royalty damages has a significant effect on the ability of patentees to obtain hold-up value.").

[50] *See ID.* at 152-53 (need for flexibility in applying the "but for" test for lost profits), 156 & 211 (problems with applying the "entire market value" rule to lost profits and reasonable royalty), 157 (duplicative or overlapping awards for lost profits and reasonable royalty), 176 &

companies in antitrust cases, I can appreciate the Patent Report's push for stricter adherence to the rules of evidence with respect to proving infringement damages, including the admissibility of expert opinions. Where I disagree with the Patent Report's recommendations is—as I alluded to earlier—its proposed treatment of non-practicing entities (NPEs) with respect to the grant of injunctive relief for infringement.

Rather than recommending that injunctive relief be denied to NPEs altogether, the Patent Report turns the focus of the injunction inquiry on a putative subset of NPEs termed "patent assertion entities" (PAEs)—firms that "purchase patents, and then sell or license them as assets whose values are based on the amount of licensing fees that can be extracted from operating companies already using and marketing the technology" or that "have turned their focus away from the active development or practice of their patents and have moved towards patent enforcement."[51] In my view, such an inquiry would put the courts in the unwarranted business of making subjective judgments about what is or is not a legitimate business model or strategy, or what is or is not a good business motive. I highly doubt that the American public wants to see the judiciary intrude upon and regulate capitalism and free enterprise in this fashion.

More importantly, the fundamental concern in the injunction context is *not* whether a firm should or could be classified as a PAE; rather, it is whether the issuance of an injunction to *any NPE* will more than likely create a patent hold-up situation, a concern that the Patent Report

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184 (hypothetical negotiation framework and willing licensor/licensee model for reasonable royalty award), 189 (next-best alternative to licensing the patented invention), 191 (timing of hypothetical negotiation to avoid overcompensation based on switching costs), 194 (hypothetical negotiation framework in the standard setting context), 199 & 202 (application of *Daubert* principles to expert testimony on damages), 212 (choice of an appropriate royalty base).

[51] *ID.* at 60-61.

repeatedly underscores in its recommendations.[52] To my way of thinking, this concern *invariably arises* whenever an NPE comes into court seeking injunctive relief. Why?

We have a legal system that holds a defendant strictly liable for patent infringement, which means that a plaintiff patentee does *not* have to identify and stop infringing conduct in its incipiency. As a result, more often than not, a plaintiff sues for damages and injunctive relief *ex post*—that is to say, it demands a judicial remedy for infringement only *after* a defendant has already undertaken the accused activities.[53] If the defendant is found to have infringed, it will then have to incur some amount of switching costs in order to avoid future infringement and escape the judicial hammer of an injunction—assuming a switch from the patented technology or process is even practicable at that point.

If the plaintiff suing for ex post remedies is an NPE, then its principal reason for seeking an injunction is to gain additional leverage that will force a defendant to compensate it for the hold-up value of the patent.[54] After all, the NPE gets *no money* from the defendant if a

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[52] *See ID.* at 232 ("Courts should consider the hardship of an infringer facing hold-up under [the balance of equities and hardship] prong."), 233 ("When warranted by the facts, courts should consider the public's interest in avoiding patent hold-up, which can increase costs and deter innovation."), 235 ("Courts should give careful consideration under each of *eBay's* four factors to the consequences of issuing an injunction prohibiting use of patented technology incorporated into an industry standard."), 238 ("The Commission recommends that to fully compensate patentees but avoid creating hold-up, courts base awards of ongoing royalties following denial of an injunction on the willing licensor/willing licensee model, assuming the patent is valid and infringed."), & 243 ("The FTC also recommends that the ITC incorporate concerns about patent hold-up, especially of standards, into the decision of whether to grant an exclusion order in accordance with the public interest elements of Section 337.").

[53] Only rarely do the patentee and the would-be infringer actually get together and discuss whether a patent claim would cover future activity, i.e., before it has been undertaken by the would-be infringer. That is why the standard approach for determining a reasonable royalty calls for a *hypothetical negotiation* framework that examines *what would have happened* had the parties been able to get together. *See* PATENT REPORT, *supra* note 36, at 166-67. Moreover, the only cases in which relief might be sought *ex ante* would be those involving claims for declaratory relief, made by either the patentee or the would-be infringer.

[54] *See* PATENT REPORT, *supra* note 36, at 22 & 144.

permanent injunction is granted, insofar as future infringement is concerned.[55] And since the NPE does not practice the patent-in-suit to make its own goods or services, an injunction provides no immediate financial benefit unless the defendant is forced to pay up. So the NPE's determined hope is that the defendant, faced with the prospect of an injunction, will accede to its demands and settle the case for an amount that captures the hold-up value of the patent. Such a settlement would of course result in a windfall to the NPE and an attendant loss of consumer welfare.

It is hard enough to ask a trier of fact to determine whether and to what extent the damages being sought by an NPE includes an increment of hold-up value.[56] Yet, the Patent Report makes clear that a permanent injunction invites hold-up to a greater extent than the denial of such relief would.[57] If we are concerned about overcompensating an NPE for the hold-up value of an asserted patent, then we should limit an NPE to monetary relief, in a reasonable amount to be determined by the trier of fact, and avoid giving it additional leverage to bargain for a higher amount from the defendant. For this reason, I would favor denying injunctive relief to any NPE seeking ex post remedies, regardless of its business model or strategy, or business motives.

I recognize that my view runs counter to the principal teaching of *eBay Inc. v. MercExchange, LLC,*[58] under which "traditional principles of equity" may not be displaced by

[55] An NPE may be able to obtain an award of damages for past infringement, and it may be able to use the fact of the injunction as a bargaining chip in licensing negotiations with other infringers.

[56] PATENT REPORT, *supra* note 36, at 191 & 237-38.

[57] *ID.* at 225-27.

[58] 547 U.S. 388 (2006).

"categorical rules" for granting or denying injunctive relief in "a broad swath of cases."[59] Although this was indeed the view of a unanimous Court, a plurality of four Justices (Kennedy, Stevens, Souter and Breyer)[60] expressed the *additional view* that the courts, in exercising their equitable discretion over injunctions, have "to adapt to the rapid technological and legal developments in the patent system," which includes recognizing that "an injunction, and the potentially serious sanctions arising from its violation, can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent."[61] In other words, "[w]hen the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest."[62] In my view, overcompensating an NPE for the hold-up value of a patent, and allowing it to use the threat of an injunction as a bargaining chip to obtain the hold-up value, both disserve the public interest, which is, of course, one of the factors under the *eBay* test.

Patent Reform Legislation

We can debate the wisdom of a rule, or at least a "public interest" perspective, that weighs against granting permanent injunctions to NPEs seeking ex post remedies. Ultimately, however, any policy choice of this nature, and any "fix" of the problem, would probably be best

[59] *Id.* at 392-94.

[60] If one is counting Justices, there were only three Justices (Roberts, Scalia and Ginsburg) who signed on to the other concurring opinion, with the other two Justices (Thomas, Alito) signing on to neither concurrence.

[61] *Id.* at 396 (citing FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 3, at 38-39 (Oct. 2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf) & 397 (Kennedy, J., concurring).

[62] *Id.* 396-97 (Kennedy, J., concurring).

accomplished by reforming the patent laws. After all, the Constitution has put the Congress in charge of establishing our patent system,[63] which includes the current statute empowering the federal courts to "grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable."[64] The Congress can therefore overrule *eBay*—by replacing "the principles of equity" with some other injunction standard—if it sees fit to do so.

Currently pending in both houses of the Congress are two similar bills dubbed the "America Invents Act." The Senate version, S. 23, was introduced by Senate Judiciary Committee Chairman Patrick Leahy on January 25, 2011, and overwhelmingly passed by a bipartisan Senate with a vote of 95 to 5 on March 8, 2011.[65] Its House counterpart, H.R. 1249, was introduced by House Judiciary Committee Chairman Lamar Smith on March 30, 2011, and was voted out of the Committee, 32 to 3, on April 14, 2011.[66] I understand, based on press releases issued by the Biotechnology Industry Organization (BIO) and the Pharmaceutical Research and Manufacturers of America (PhRMA), that there is general industry support among

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[63] U.S. CONST. art. I, § 8, cl. 8.

[64] 35 U.S.C. § 283 (2009).

[65] America Invents Act, S. 23, 112th Cong. (2011) (as passed by Senate, Mar. 8, 2011). *See* Press Release, Senate Judiciary Committee Chmn. Patrick J. Leahy, Senate Passes Historic America Invents Act (Mar. 8, 2011), http://leahy.senate.gov/press/press_releases/release/?id=2a5e65f2-240e-4a01-b075-110aaa0613b0.

[66] America Invents Act, H.R. 1249, 112th Cong. (2011) (as reported by H. Comm. on the Judiciary, Apr. 14, 2011). *See* Angus Loten, *House Takes Up Patent Reform*, WALL ST. J. BLOG (IN CHARGE) (Apr. 1, 2011, 12:09 PM), http://blogs.wsj.com/in-charge/2011/04/01/house-takes-up-patent-reform/?mod=google_news_blog.

members of this audience for the bill that was passed by the Senate and for a similar version introduced in the House.[67]

Unfortunately, neither version of the bill includes provisions relating to the reform of damages or injunctive relief.[68] But there are other provisions in the bills that have garnered much attention from the press, one of which is the proposed replacement of the current first-to-invent system with a first-to-file system, used by other jurisdictions around the world.[69] Although harmonization of legal systems is generally regarded as a positive step, public controversy surrounds whether this system disadvantages small businesses, which may not have the resources at the disposal of large corporations to rush out and file patent applications based on new invention disclosures.[70] To monitor the impact of the first-to-file system on small

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[67] *See* Press Release, Biotech. Indus. Org. President & CEO Jim Greenwood, BIO Commends Launch of House Patent Reform Process (Mar. 31, 2011) ("BIO praises House Judiciary Committee Chairman Lamar Smith (R-TX) for his introduction of a comprehensive patent reform bill similar to the bill adopted by the U.S. Senate earlier this month by a nearly unanimous vote."), http://bio.org/news/pressreleases/newsitem.asp?id=2011_0331_02; Press Release, Pharm. Research & Mfrs. Am. President & CEO John Castellani, PhRMA Statement on Patent Reform (Mar. 9, 2011) ("We congratulate Senator Leahy and other Congressional leaders who supported the America Invents Act, including the members of the Senate Judiciary Committee, who previously came together for a bipartisan and unanimous committee vote. Today's Senate passage sends a clear message: that these leaders are willing to take steps toward creating an environment in America that will support innovation and, with it, the jobs that it provides."), http://www.phrma.org/media/releases/phrma-statement-patent-reform-0.

[68] The Senate bill, as introduced and reported, did include a provision that would have spelled out a federal court's role as a "judicial gatekeeper" in identifying, for any given case, "the methodologies and factors that are relevant to the determination of damages" and in allowing the trier of fact to consider only such evidence that is relevant to such "methodologies and factors." America Invents Act, S. 23, 112th Cong. § 4 (2011) (as reported by S. Comm. on the Judiciary, Feb. 3, 2011). But the damages reform provision was struck by an amendment made on the Senate floor.

[69] America Invents Act, S. 23, 112th Cong. § 2 (2011) (as passed by Senate, Mar. 8, 2011); America Invents Act, H.R. 1249, 112th Cong. § 2 (2011) (as introduced by H. Comm. on the Judiciary, Mar. 30, 2011).

[70] *See, e.g.*, Alex Philippidis, *Patent Reform Likely to Benefit Industry Giants More Than Start-Ups,* GENETIC ENG'G & BIOTECH. NEWS: Analysis and Insight, Mar. 9, 2011 ("In practice,

businesses, the America Invents Act includes a provision calling for the Small Business Administration, in consultation with the Patent and Trademark Office, to "conduct a study of the effects of eliminating the use of dates of invention in determining whether an applicant is entitled to a patent" on small businesses, and to submit a report regarding the results of the study to the Congress within one year after the enactment of the Act.[71]

Another provision that has generated a fair amount of controversy, especially in the biotechnology and pharmaceutical industries, is the establishment of a procedure for supplemental examination "to consider, reconsider, or correct information believed to be relevant to the patent."[72] If a patent survives the supplemental examination process, it is then immune to any inequitable conduct challenge based on information that "was considered, reconsidered, or corrected during a supplemental examination of the patent," and the fact that the patentee made a

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biotech and pharma giants can afford staffs of lawyers specializing in rushing patent applications, while start-up CEOs must juggle IP management with duties ranging from basic science to fundraising to facility oversight and commercialization."), http://www.genengnews.com/analysis-and-insight/patent-reform-likely-to-benefit-industry-giants-more-than-start-ups/77899369/. *But see* Press Release, Senate Judiciary Committee Chmn. Patrick J. Leahy, Leahy: Small Businesses Will Benefit from America Invents Act (Mar. 16, 2011) (observing that the transition to a first-to-file system will replace costly interference proceedings that are "almost always won by larger corporations" with simpler derivation proceedings that do not "require meticulous notes by the inventor, which gives large corporations an advantage, because the key date is the date of application"), http://leahy.senate.gov/press/press_releases/release/?id=95502316-a3bd-436a-a826-ed613f5485e2.

[71] America Invents Act, S. 23, 112th Cong. § 2(m) (2011) (as passed by Senate, Mar. 8, 2011); America Invents Act, H.R. 1249, 112th Cong. § 2(*l*) (2011) (as introduced by H. Comm. on the Judiciary, Mar. 30, 2011).

[72] America Invents Act, S. 23, 112th Cong. § 10(a) (2011) (as passed by Senate, Mar. 8, 2011) (proposed 35 U.S.C. § 257(a)); America Invents Act, H.R. 1249, 112th Cong. § 11(a) (2011) (as introduced by H. Comm. on the Judiciary, Mar. 30, 2011) (proposed 35 U.S.C. § 257(a)).

request for supplemental examination in response to an allegation of inequitable conduct "shall not be relevant to enforceability of the patent under section 282."[73]

The concern, as articulated by the Generic Pharmaceutical Association, is that this provision "will significantly weaken the inequitable conduct defense, compromise the integrity of the current patent process, add unnecessary workload to the PTO, impact the ability of generic manufacturers to bring lower-cost generic drugs to the market, and will cost the American people hundreds of millions of dollars."[74] At the Commission, we take very seriously claims that invalid or unenforceable patents will be used to delay or deter generic entry. That said, I note the bills provide an exception to the grant of inequitable conduct immunity for allegations of inequitable conduct that have been pled *with particularity*, or set forth *with particularity* in a Paragraph IV notice letter to the patent owner[75] before the date of the supplemental examination request concerning information that forms the basis of the allegations.[76] This provision would appear to provide some protection for generic entry based on a defense of inequitable conduct.

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[73] America Invents Act, S. 23, 112th Cong. § 10(a) (2011) (as passed by Senate, Mar. 8, 2011) (proposed 35 U.S.C. § 257(c)(1)); America Invents Act, H.R. 1249, 112th Cong. § 11(a) (2011) (as introduced by H. Comm. on the Judiciary, Mar. 30, 2011) (proposed 35 U.S.C. § 257(c)(1)).

[74] Press Release, Generic Pharm. Ass'n, GPhA Submits Written Statement to House Judiciary Subcommittee on Intellectual Property, Competition, and the Internet Concerning "The America Invents Act" (Mar. 31, 2011), http://www.gphaonline.org/media/press-releases/2011/gpha-submits-written-statement-house-judiciary-subcommittee-intellectual-p.

[75] *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II) ("A notice required under this subparagraph shall—include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."); 21 C.F.R. §§ 314.94(a)(12)(i)(A)(*4*) & 314.95(c)(6) (2010) (making clear that a Paragraph IV certification may include an asserted defense of unenforceability addition to the invalidity and noninfringement defenses stated in 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).

[76] America Invents Act, S. 23, 112th Cong. § 10(a) (2011) (as passed by Senate, Mar. 8, 2011) (proposed 35 U.S.C. § 257(c)(2)(A)); America Invents Act, H.R. 1249, 112th Cong. § 11(a) (2011) (as introduced by H. Comm. on the Judiciary, Mar. 30, 2011) (proposed 35 U.S.C. § 257(c)(2)(A)).

The proposed supplemental examination provision also clarifies that it is not to be construed "to preclude the imposition of sanctions based upon criminal or antitrust laws (including section 1001(a) of title 18, the first section of the Clayton Act, and section 5 of the Federal Trade Commission Act to the extent that section relates to unfair methods of competition)."[77] As I interpret this subsection, a supplemental examination would not insulate the owner of an asserted patent from investigation and enforcement by the Antitrust Division (hence the reference to "sanctions") in a federal district court or by the Commission under Section 5 of the FTC Act, whether under a Sherman Act Section 2 theory (for example, *Walker Process* monopolization) or on a standalone basis. Whether these provisions would be sufficient to adequately protect generics from loss of the inequitable conduct defense remains to be seen.

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Thank you for your time and attention today. I look forward to your questions.

[77] America Invents Act, S. 23, 112th Cong. § 10(a) (2011) (as passed by Senate, Mar. 8, 2011) (proposed 35 U.S.C. § 257(e)(1)); America Invents Act, H.R. 1249, 112th Cong. § 11(a) (2011) (as introduced by H. Comm. on the Judiciary, Mar. 30, 2011) (proposed 35 U.S.C. § 257(e)(1)).