# Federal Trade Commission

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## 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

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.

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

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[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.

development, manufacturing, marketing, or sale 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 the agreement is illegal.

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 12, 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 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 price. 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

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[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

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, on 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

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[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); IIIA PHILIP 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, ¶ 701b (3d ed. 2008m98 0 048 123.36 9.48 158.7 8 90 21(M12

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 so, 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

and reliable patent notice might help companies avoid a hold-up problem in the first place, before they have sunk investments in development and production.[47] Furthermore, changes in the way infringement damages based on lost profits or 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 when 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. Where 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

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 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 cost 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

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 is invited 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, 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

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[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.

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"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."

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 override 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 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 Business 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 a corporations" with sio0 ust juggle wd2e2 d2e2 d2e0

request for supplemental examination in response to an allegation of inequitable conduct “shall not be relevant to enforceability

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 such 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)).