



Federal Trade Commission

The Antitrust/Intellectual Property Interface: Thoughts on How To Best Wade Through the Thicket in the Pharmaceutical Context

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Forty-five years ago, in what has to remain one of the few antitrust cases from that era that is still held in high esteem, Justice Harlan issued an insightful concurrence to the majority's opinion in *Walker Process*.¹ As you all may know, *Walker Process* concerned the standard that applies to determine whether fraud on the patent office constitutes an antitrust violation. As I will discuss a bit later, the majority held that in limited circumstances it could. In his concurrence, however, Justice Harlan offered a doctrinal framework to more generally guide the analysis of how to judge whether a

* 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 in preparing this paper.

¹ *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179-80 (1965) (Harlan, J., concurring).

patent holder's conduct violates the antitrust laws. To briefly summarize, Justice Harlan opined that rather than trying to apply a per se or rule of reason approach to conduct by a patent holder, the correct approach was to evaluate the patent holder's conduct in light of the aims of the patent laws (which seek to foster innovation) and the antitrust laws (which seek to foster competition). If the patent holder's conduct did not further either of those objectives, he concluded that application of the antitrust laws to the patent holder would not undermine the patent laws because, quite simply, the patent holder's conduct was already inconsistent with those laws.

Although that standard may seem patently obvious (no pun intended), you would be surprised how often the federal courts and the antitrust agencies appear all too willing to tie themselves in knots about what the proper standard should be for assessing whether a patent holder should be subject to antitrust liability. With Justice Harlan's theoretical construct in mind, I'd like to discuss three important areas at the intersection of patent and antitrust law: pay-for-delay settlements, strategies by brand firms to extend the life cycles of their products, and authorized generics.

I.

On the litigation side of the pay-for-delay debate, there have been three major developments in the last year. The first is that the FTC filed its appellate brief in the Eleventh Circuit in the Androgel litigation (which you may know as *FTC v. Watson Pharmaceuticals*). In my view, the Androgel case is and should be winnable, not withstanding the popularly-held view that the FTC's chances are slim because of the Eleventh Circuit's decisions in *Schering-Plough*² and *Valley Drug*,³ as well as the

² *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

unfavorable case law in the Second and Federal Circuits. How do I reach that conclusion? It's actually quite straightforward and were I arguing the case, I'd make three points.

First, the appeal comes to the Eleventh Circuit following a decision granting a motion to dismiss. Both *Schering* (an appeal from a Commission Part 3 decision following an ALJ trial) and *Valley Drug* (an appeal from a summary judgment ruling) had extensive factual records. And, more importantly, in assessing the anticompetitive nature of the pay-for-delay settlements in those cases, the Eleventh Circuit parsed those records very carefully, evaluating all of the evidence. In both cases, the record mattered. In contrast, the Androgel appeal follows a district court decision that granted a motion to dismiss. The procedural posture is identical to the Eleventh Circuit's lesser-known, but most recent pay-for-delay decision in *Andrx*,⁴ 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*),⁵ but observed that because "antitrust cases are 'fact-intensive' . . . , require appropriate market analysis [citing *Schering*], and therefore are typically inappropriate for a Rule 12 dismissal in the absence of an applicable immunity doctrine," the case should be remanded for fact-finding.⁶ The same result should be obtained in Androgel.

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

⁴ *Andrx Pharms. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005).

⁵ *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.").

⁶ *Id.*

Second, the district court’s application of *Schering* and *Valley Drug* was wrong as a matter of law. In *Androgel*, the district court construed both cases as holding that, so long as a settlement is within the “scope of the exclusionary potential of the patent,” it is per se legal.⁷ That statement, however, turns entirely on how one construes the patent’s scope and, in so doing, the district court plainly erred. In an oversimplified (and incorrect) reading of *Schering* and *Valley Drug*, the district court concluded that the patent’s scope was solely a function of the patent’s text and its duration. *Schering* and *Valley Drug*, however, do not so hold. To the contrary, both cases make clear (consistent with *Walker Process*), that the patent’s exclusionary potential is a function of whether the patent holder employs the patent in ways that are inconsistent with the objectives of the patent and antitrust laws—and not simply a function of the patent’s text and duration.⁸

⁷ *In re AndroGel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1377 (N.D.Ga. 2010).

⁸ *See, e.g., Valley Drug Co.*, 344 F.3d at 1311 (stating that antitrust liability for a settlement agreement should turn on “an analysis of the effects of antitrust liability on the innovation and disclosure incentives created by the patent regime, with the aim of ‘achieving a suitable accommodation between the differing policies’” (quoting *Walker Process*, 382 U.S. at 179) (Harlan, J., concurring)); *id.* at 1304 (the antitrust analysis hinges on whether subjecting agreements that implicate a patent’s exclusionary power would undermine the patent system’s “incentive to induce investment in innovation and the public disclosure of inventions”); *id.* at 1307 (discussing *Walker Process* and noting that “Justice Harlan’s concurrence explained that the effect of antitrust liability on the incentives for innovation and disclosure created by the patent regime must be taken into account when a court considers whether a patentee is stripped of its immunity from the antitrust laws”); *id.* (“A suitable accommodation between antitrust law’s free competition requirement and the patent regime’s incentive system is required by the complementary objectives of the two....”); *id.* at 1311 n. 27 (emphasizing that “what is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects,” *quoted in Schering-Plough*, 402 F.3d at 1066); *Schering-Plough*, 402 F.3d at 1076 (the “law in our Circuit” is that an antitrust violation cannot lie “[s]imply because a brand . . . holding a patent paid its generic competitor money”; that “cannot be the sole basis for a violation of antitrust law”; instead the court must “evaluate the strength of the patent”(emphasis added)).

Both cases also underscore that this analysis is a fact-intensive inquiry.⁹ Any doubt on that score is born out by *Valley Drug*'s reliance on Justice Harlan's concurrence in *Walker Process* (and *Schering*'s reliance on *Valley Drug*), which emphasized that "the effect of antitrust liability on the incentives for innovation and disclosure created by the patent regime must be taken into account when a court considers whether a patentee is stripped of its immunity from the antitrust laws."¹⁰ That analysis inherently requires looking at the patent holder's conduct in the context of the patent system's incentives for innovation. *Valley Drug* and *Schering* do not and cannot be read as imposing the bright-line rule of per se legality that the district court applied.

Third, applying the analysis required by *Valley Drug* and *Schering*, defendants' motion to dismiss must be denied. Here, the Commission pled that the defendants (1) entered into a pay-for-delay settlement, and (2) that the settlement undermined the incentives created by the Hatch-Waxman Act, which include incentivizing innovation¹¹

⁹ See, e.g., *Valley Drug Co.*, 344 F.3d at 1308 (holding that a court must look at the "reasonableness" of the settlement at the time it was entered into against the antitrust and patent laws' distinct objectives); *id.* ("[W]e conclude that exposing settling parties to antitrust liability for the exclusionary effects of a settlement *reasonably within the scope of the patent* merely because the patent is subsequently declared invalid *would undermine the patent incentives.*" (emphases added)); *id.* ("There may be circumstances under which the *unreasonableness of a settlement agreement* regarding a subsequently-invalidated or unenforceable patent would be sufficiently apparent *that antitrust liability would not undermine the encouragement of genuine invention and disclosure.*" (emphases added)); *Schering-Plough*, 402 F.3d at 1068 (criticizing the FTC for neither alleging that the underlying patent was invalid and for going out of its way to avoid ruling on that issue); *id.* (concluding that "the proper analysis now turns to whether there is *substantial evidence* to support the Commission's conclusion that the challenged agreements restrict competition beyond the exclusionary effects of the '743 patent" (emphasis added)).

¹⁰ *Walker Process*, 382 U.S. at 179-80 (Harlan, J., concurring).

¹¹ See, e.g., Second Amended Complaint, *FTC v. Watson Pharms.*, Docket No. 09-CV-00955 (N.D. Ga. May 28, 2009) at ¶ 17 (noting the Hatch Waxman Act "establishes procedures designed to facilitate competition from lower-priced generic drugs, while

by eliminating the opportunity for the generic firms to show that the brand firm's patent was invalid or not infringed.¹² Under the *Valley Drug/Schering* paradigm, these allegations were sufficient to plead (1) that the parties entered into an agreement which exceeded the scope of the patent's exclusionary potential (which, of course, is limited to conduct that is consistent with the aims of the patent laws), and (2) that that agreement had anticompetitive effects.¹³

I march through this detailed analysis because, while our brief to the Eleventh Circuit makes all of these points at one point or another, I'm not convinced they are made (and will be made during oral argument) with the clarity needed to walk the panel down what I remain convinced is a very clear path to victory. Put differently, I do not see *Valley Drug* and *Schering* as obstacles (as they are conventionally perceived as doing by those who look at these cases very superficially); rather, I view them as supplying the tools needed for the FTC to survive a motion to dismiss in the Eleventh Circuit. We shall see what happens next.

maintaining incentives for pharmaceutical companies to invest in developing new drugs”), ¶100 (“Exclusion payment settlements, including Defendants’, distort the careful balance achieved by the Hatch-Waxman Act by eliminating generic companies’ incentives to compete.”).

¹² See, e.g., *id.* at ¶ 30 (noting that “empirical studies have shown that when pharmaceutical patent infringement claims are tested in the courts, the alleged infringer prevails in the majority of cases” and discussing statistics), ¶ 86 (noting the generic firms prior to settlement “developed persuasive arguments and amassed substantial evidence that their generic products did not infringe the formulation patent and that the patent was invalid and/or unenforceable” and that “Solvay was not likely to prevail in each of its patent lawsuits to prevent competition to AndroGel”), ¶ 88 (noting that the generic firms “argued that the formulation patent was invalid”).

¹³ *Schering-Plough*, 402 F.3d at 1066 (noting that an analysis of whether a patent settlement agreement violates the antitrust laws requires an analysis of “(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects”).

The second pay-for-delay case that I would like to discuss is the Eastern District of Pennsylvania’s decision earlier this year in the *Cephalon* litigation.¹⁴ In that case, the district court got it right when it sided with the FTC and the private plaintiffs and denied the defendants’ motion to dismiss. Citing *Valley Drug* favorably, the district court aptly noted that “[a]dopting the scope of patent framework takes into account . . . patent principles” but “[a]t the same time, to the extent that the agreements in question improperly afford more rights than those granted under the patent, antitrust principles may apply.”¹⁵ The court then observed that “[t]his approach appears to strike the proper balance between competing patent and antitrust principles.”¹⁶ As a result, the court concluded that, among other things, plaintiffs’ allegations of fraud and misrepresentation to the PTO, non-infringement, and patent invalidity, were all independently sufficient to plead an antitrust violation under the scope of the patent test.¹⁷ *Cephalon* is currently proceeding to trial. Incidentally, I have no idea why the Commission did not cite the very helpful *Cephalon* case in our brief to the Eleventh Circuit in *Androgel*. Hopefully the Eleventh Circuit will find it on its own.

Third, I would be remiss in not mentioning the developments in the Second Circuit *Cipro* pay-for-delay litigation. In April of this year, the Second Circuit affirmed the district court’s grant of summary judgment to the defendants in a pay-for-delay

¹⁴ *King Drug Co. v. Cephalon, Inc.*, 702 F. Supp.2d 514 (E.D. Pa. 2010).

¹⁵ *Id.* at 529.

¹⁶ *Id.*

¹⁷ *Id.* at 533-34.

case.¹⁸ The Second Circuit’s decision to follow the narrow, defendant-friendly test that it applied in *Tamoxifen*¹⁹ (and that the Federal Circuit applied in a companion case)²⁰ was not surprising. What was remarkable, however, was the panel’s call for the Second Circuit to essentially reconsider the *Tamoxifen* standard en banc, along with the Second Circuit’s request that the Department of Justice weigh in—neither the FTC nor the DOJ was a party to the litigation. As you can imagine, these developments gave those of us in the government hope. The DOJ and FTC both filed amicus briefs, which I would encourage you to read, in which we advocated that the Second Circuit should grant rehearing en banc and apply an “inherently suspect” standard to pay-for-delay settlements, under which they would be considered presumptively unlawful, but could nevertheless be proven to be procompetitive.²¹ Much to our disappointment, however, the Second Circuit denied the petition for rehearing en banc. It remains to be seen, however, whether the *Cipro* plaintiffs will petition for certiorari with the Supreme Court, in which case the final chapter has not yet been written.

On the legislative side of the pay-for-delay debate, where the FTC has been actively seeking a legislative fix to this problem, things have quieted down after the FTC made considerable inroads this summer. In July 2010, the House passed legislation that

¹⁸ *Ark. Carpenter Health & Welfare Fund v. Bayer AG (Cipro)*, 604 F.3d 98 (2d Cir. 2010).

¹⁹ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

²⁰ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed Cir. 2008).

²¹ See Brief for the United States at 21-23 *Cipro*, 604 F.3d (2d Cir. Jul. 6, 2009) (No. 05-2851), available at <http://www.justice.gov/atr/cases/f247700/247708.pdf>; Brief for the FTC, *Cipro*, 604 F.3d (2d Cir. May 20, 2010) (No. 05-2851), available at <http://www.ftc.gov/os/2010/05/051202amicuscarpentershealth.pdf>.

would give the FTC authority to initiate proceedings against any party that enters into a pay-for-delay deal, which the legislation defines as a circumstance in which the filer of an abbreviated new drug application challenging the validity of a patent for a brand-name drug agrees to “anything of value” in exchange for forgoing research, development, manufacturing, marketing or selling the new generic alternative. The legislation would not ban pay-for-delay settlements, but would make them presumptively anti-competitive. The parties could then overcome that presumption by demonstrating by “clear and convincing evidence” that the procompetitive benefits of the deal outweigh any potential anticompetitive effects. The House legislation was added to offset war and education spending in H.R. 4899, the Supplemental Appropriations Act of 2010, which passed the House by a vote of 239-175.

On the Senate side, things have been a bit of a rollercoaster. On July 29th, the Senate Appropriations Committee passed the Affordable Access to Generics Act as part of the Financial Services and General Government Appropriations bill reported out of that Committee. That legislation is the same as the legislation passed in the House. The Senate Appropriations Committee’s actions, however, only came after the Senate passed the war funding bill in the previous week after deciding to drop the House pay-for-delay provision at the last minute. So that’s where things currently stand on the Hill.

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 somewhat abysmal track record in the courts, I believe a legislative fix is likely the only way to eliminate these anticompetitive settlements. Nevertheless, where I depart from

the Chairman and perhaps the rest of the Commission (although I can't say for sure) is on process. In my view, the legislation should rise or fall on its own merit; put differently, I think tacking it on to the war funding bill is a terrible idea. If the goal is to put money back in consumers' pockets, then that is what we should be doing – not funding the war. Some may say that is an unrealistic, idealistic view of government, but I have tried very hard in my five years at the Commission not to let politics or, to be more blunt, vote trading infect our competition mission and I don't plan on changing my tune here.

II.

Next I would like to discuss ways in which the law has helped or hindered efforts by pharmaceutical companies to extend the life cycles of their existing products. This is an area of significant interest to the Commission because, while we support the patent system and its importance in incentivizing innovation, our competition mission requires that we be cognizant of the fact that firms will sometimes seek to use patents in ways that expand their scope—be it by covering additional products, obtaining large damage awards that deter competition, or deterring challenges to design arounds. In this regard, I would encourage you to take a look at the Commission's recent amicus brief in the Federal Circuit's *TiVo v. EchoStar* litigation, where the Commission (consistent with Justice Harlan's *Walker Process* concurrence) urged the Federal Circuit to balance the purposes of the patent system with the need to incentivize competition for design arounds.²² The themes that run through the Commission's *TiVo* brief are much like those

²² See Brief for the FTC, *TiVo, Inc. v. EchoStar Corp.*, No. 2009-1374 (Fed. Cir. Aug. 2, 2010) (argued Nov. 9 2010, en banc), available at <http://www.ftc.gov/os/2010/08/100802tivoechostarbrief.pdf>.

that you will find running through many of the pharmaceutical patent cases that concern strategies for extending product life cycles.

For example, one category of cases that has been particularly hot over the last few years is the category of cases concerning Orange Book fraud. In Orange Book fraud cases, the brand companies improperly list patents in the Orange Book and then file infringement actions against ANDA applicants. As a result, the brand companies are able to obtain 30-month stays of the ANDA approval. In 2002 and 2003, the FTC entered into consent agreements with two companies engaged in this practice, resolving the FTC's concerns.²³ Those consents, however, have not more generally resolved the legal issues surrounding this practice.

In 2001, in *Mylan Pharm. v. Thompson*,²⁴ the Federal Circuit held that generic drug manufacturers could not sue to correct inaccurate Orange Book listings. Congress responded by amending the Hatch-Waxman Act through the Medicare Modernization Act of 2003 to give ANDA applicants who have been sued for patent infringement the statutory right to file a counterclaim seeking the delisting of the patent from the Orange Book.²⁵ Specifically, the provision allows an ANDA applicant who is defending against a patent infringement suit brought by the holder of the NDA, to assert a counterclaim to correct or delete Orange Book "patent information submitted" on the ground that the

²³ *In re Biovail Corp.*, FTC Docket No. C-4060 (Oct. 2, 2002) (consent order), available at <http://www.ftc.gov/os/2002/10/biovaildo.pdf>; *In re Bristol-Myers Squibb Co.*, FTC Docket No. C-4076 (Apr. 14, 2003) (consent order), available at <http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf>. Congress also addressed this abuse by passing the Medicare Prescription Drug Improvement and Modernization Act of 1993, which precludes successive 30-month stays in most circumstances. See 21 U.S.C. § 355(j)(5)(B).

²⁴ 268 F.3d 1323 (Fed. Cir. 2001).

²⁵ 21 U.S.C. 355(j)(5)(C)(ii).

patent does not claim “the drug for which the application was approved” or “an approved method of using the drug.”²⁶

In *Novo Nordisk v. Caraco Pharmaceutical Labs.*, the Federal Circuit recently provided an important clarification on the scope of that statutory right.²⁷ The issue in the *Novo Nordisk* litigation concerned the fact that, as you may know, some New Drug Applications (NDAs) cover uses of a drug that are patented as well as uses that are not patented. Novo Nordisk had obtained the ‘358 patent on which its drug Prandin was based for one specified use. Caraco also desired to market a generic version of Prandin, but for a different use. Caraco’s ANDA application contained a Paragraph IV certification and a statement that declared that Caraco was not seeking approval to use the drug for the FDA-approved uses. The purpose of this statement was to bring Caraco within the statutory provision that allowed an ANDA applicant to assert a counterclaim on the ground that the patent did not claim an “approved method of using the drug.” Because it found there was no overlap, the FDA accepted Caraco’s proposed carve-out label which specified a different use and approved the drug for the new use.

Thereafter, Novo Nordisk changed the use code for the ‘358 patent. The new use code covered all of the approved uses for Prandin (including Caraco’s uses), even though the ‘358 patent only covered one approved use. This meant that Caraco’s carve-out label now overlapped with the use code and the FDA therefore retracted its approval of Caraco’s proposed label. Caraco’s proposed label now infringed claim 4 of the ‘358 patent. This caused Caraco to file a counterclaim to the infringement charge seeking an

²⁶ *Id.*

²⁷ 601 F.3d 1359 (Fed. Cir. 2010).

order that would direct Novo Nordisk to replace the use code with the former listing. The Eastern District of Michigan agreed and granted Caraco an injunction.²⁸

In a 2-1 decision, however, the Federal Circuit reversed and vacated the injunction.²⁹ The majority reasoned that the statutory language in the MMA was clear on its face: “an approved method of using the drug” means “*any* approved method” (as Novo urged) rather than “*all* approved methods” (as Caraco argued). Further, according to the majority, its decision to vacate the injunction was consistent with the legislative intent: the counterclaim provision in the 2003 Act “sought to correct the specific issue raised in [*Mylan v. Thompson* (Fed. Cir. 2002)], i.e., to deter pioneering manufacturers from listing patents *that were not related at all* to the patented product or method.”³⁰ In addition, the majority concluded that “the patent information” referred to in the counterclaim provision meant “the patent number and the expiration date”—*not the use code narrative*. In a 21-page dissent, Judge Dyk strongly disagreed with the majority and took a view that was more consistent with promoting competition than broad patent rights. He stated that “Congress enacted the counterclaim provision of the Hatch-Waxman Act in order to prevent manipulative practices by patent holders with respect to the Orange Book listings. These practices were designed to delay the onset of competition from generic drug manufacturers.”³¹ He concluded that, “[i]n my view, the majority, in reversing the district court, now construes the statute contrary to its manifest purpose and allows the same manipulative practices to continue in the context of method

²⁸ No. 05-40188, 2010 U.S. Dist. LEXIS 56752 (E.D. Mich. Jun. 9, 2010).

²⁹ 601 F.3d 1359.

³⁰ *Id.* at 1365 (emphasis added).

³¹ *Id.* at 1368 (Dyk, J., dissenting).

patents.”³² The Federal Circuit recently denied en banc review (with Judges Gajarsa and Dyk dissenting)³³ so, absent further clarification from Congress, the *Novo Nordisk* gloss on the counterclaim provision remains the law.

A second, related category of conduct that we see brand firms use to extend their products’ life cycles is “product hopping” or “product switching.” This is the practice of brand firms introducing new patented products with minor or no substantive improvements in the hopes of preventing substitution to lower-priced generics.³⁴ The practice is most likely to arise when generic entry is imminent. Of course, the antitrust laws don’t seek to discourage the introduction of new products or product line extensions.³⁵ Here the concern is that the new product is, in a sense, a sham whose only purpose is to delay generic competition without any consumer benefits.

Product hopping concerns are relatively recent and, as a result, there are few litigated cases and enforcement actions in this area. In 2005, the FTC filed a complaint in federal district court alleging that Warner Chilcott had entered into an agreement with

³² *Id.*

³³ 615 F.3d 1364 (Fed. Cir. 2010) (denying en banc review).

³⁴ Mark A. Lemley, *Ignoring Patents*, 2008 MICH. STATE L. REV. 19, 30 (product hopping involves “[p]atent owners . . . changing the product they sell and restarting the regulatory clock once their patent on the existing product expires or is invalidated”).

³⁵ Many courts are reluctant to find that product improvements by themselves violate Section 2, even if done by a monopolist and competitors are harmed as a result. *See, e.g., Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 1000 (9th Cir. 2010) (“Absent some form of coercive conduct by the monopolist, the ultimate worth of a genuine product improvement can be adequately judged only by the market itself.”).

Barr to forestall generic entry for the birth control product Ovcon.³⁶ While the case was pending in court, the FTC learned that Warner Chilcott intended to launch a new, chewable version of Ovcon and stop selling the tablet version of Ovcon in order to convert consumers to the new product. Such a strategy would have essentially destroyed the market for generic Ovcon because if regular Ovcon were unavailable, generic substitution at the pharmacy would be unavailable. To prevent that development, the FTC filed for a preliminary injunction to require Warner Chilcott to continue to make tablet Ovcon. The day that the FTC filed its motion, Warner Chilcott waived the provision in its agreement with Barr that prevented Barr from marketing its generic version of Ovcon, and Barr then announced its intention to start selling a generic version of the product. The Commission and Warner Chilcott subsequently entered into a final order requiring Warner Chilcott to take steps to preserve the market for the tablet form of Ovcon providing Barr the opportunity to compete with its generic version.³⁷

In *Abbott Labs. v. Teva Pharmaceuticals U.S.A., Inc.*,³⁸ Teva alleged that Abbott had “responded to the threat of generic entry . . . by changing the formulation of TriCor, not to improve the product but simply to prevent generic formulations from becoming AB-rated for substitution with TriCor.”³⁹ The district court denied Abbott’s motion to dismiss, explaining that “an antitrust inquiry into the benefits provided by Defendants’

³⁶ Complaint for Injunctive and Other Equitable Relief, *FTC v. Warner Chilcott Holdings Co. III*, No. 1:05-cv-02179-CKK (D.D.C. Nov. 7, 2005), available at <http://www.ftc.gov/os/caselist/0410034/051107comp0410034%20.pdf>.

³⁷ Final Order and Stipulated Permanent Injunction, *FTC v. Warner Chilcott Holdings Co. III*, No. 1:05-cv-02179-CKK (D.D.C. Oct. 23, 2006), available at <http://www.ftc.gov/os/caselist/0410034/finalorder.pdf>.

³⁸ 432 F. Supp. 2d 408 (D. Del. 2006).

³⁹ *Id.* at 415.

product changes is appropriate.”⁴⁰ Relying on the balancing test from the D.C. Circuit’s *Microsoft* decision, the court explained that “if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants.”⁴¹ Applying this test, the court found that plaintiffs had adequately alleged anticompetitive harm because Abbott had allegedly barred competitors from the most cost-efficient means of distribution. (In January of this year, 24 states reached a \$22.5 million settlement with Abbott and Fournier to resolve their own claims involving TriCor product hopping.)⁴²

A different result occurred in *Walgreen Co. v. AstraZeneca Pharm.*,⁴³ where a federal district court granted defendant’s motion to dismiss a “product hopping” claim. Plaintiffs alleged that as the branded drug Prilosec was about to lose patent protection, AstraZeneca introduced Nexium, a drug that was “virtually identical” to Prilosec but offered no incremental medical benefits. However, unlike the situation in *Abbott Labs. v. Teva*, the case did not involve the withdrawal of a product from the market. The court

⁴⁰ *Id.* at 422.

⁴¹ *Id.*

⁴² Press Release, California Dep’t of Justice, California and 23 States Reach \$22.5 Million Settlement Against Pharmaceutical Companies that Blocked Generic Drugs (Jan. 7, 2010), available at <http://www.ag.ca.gov/newsalerts/release.php?id=1844>. The states alleged that Abbott and Fournier forced customers to convert to new formulations of TriCor before generic entry by “reformulating TriCor with only minor changes to a form and dosage strength, which did not provide any significant new clinical benefit” and by “removing the old TriCor formulation from the market, so as to make it commercially unavailable by the time a generic competitor could enter the market.” First Amended Complaint ¶ 4, *Florida v. Abbott Labs.*, Case No. 08-155 (SLR) (D. Del. Apr. 18, 2008).

⁴³ 534 F. Supp. 2d 146 (D.D.C. 2008).

found this distinction to be significant.⁴⁴ The court stressed that AstraZeneca had not limited consumer choice by withdrawing any product from the market. To the contrary, the court found that AstraZeneca had *added* choices.

The European Commission (EC) has taken a more aggressive approach to regulating efforts by brand firms to extend their products' life cycles. On July 1, 2010, the European General Court upheld the EC's decision that AstraZeneca had abused its dominant position in violation of Article 102 by blocking or delaying market access for generic versions of Prilosec (called "Losec" in Europe).⁴⁵ The General Court found that AstraZeneca had impermissibly made misrepresentations to national patent offices in order to obtain supplementary protection certificates for Losec, which had the effect of extending Losec's lifecycle. From a U.S. perspective, perhaps the most interesting aspect of the General Court's *AstraZeneca* decision is the extent to which it departs from U.S. law. Under U.S. case law—and specifically the Supreme Court's decision in *Walker Process*—in order to prove that fraud on the patent office constitutes a violation of our monopolization law (Section 2 of the Sherman Act), the plaintiff must show that the patent holder made a misrepresentation of a material fact that was intended to deceive the

⁴⁴ *Id.* at 151 ("The elimination of choice was a critical factor in the court's decision to deny Abbott [sic] motion to dismiss the complaint."). In *Abbott v. Teva*, the court also noted the importance of this distinction. 432 F. Supp. 2d at 421 ("[W]hen the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate."); *id.* at 422 ("But here, according to Plaintiffs, consumers were not presented with a choice between fenofibrate formulations. Instead, Defendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations.").

⁴⁵ Case T-321/05, *AstraZeneca v. Comm'n* (July 1, 2010), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:221:0033:0034:EN:PDF>.

patent office.⁴⁶ The Federal Circuit has reiterated that a finding of *Walker Process* fraud requires a finding of “but for” materiality—that the patent holder could not have obtained the patent “but for” the intentional fraud.⁴⁷

In its briefs to the General Court, AstraZeneca emphasized that U.S. law required intentional misrepresentations. The General Court, however, dismissed this argument out of hand, finding that a mere “lack of transparency” on the part of the dominant company was sufficient to ground a finding of abuse.⁴⁸ In so holding the General Court cited the very general standard that a dominant company has a “special responsibility not to allow its conduct to impair genuine undistorted competition on the market.”⁴⁹ Although it is too soon to say, the commentary following the *AstraZeneca* decision suggests that the General Court appears to identify a new category of abuse of dominance based on “lack of transparency” when dealing with a regulator.⁵⁰ Suffice it to say that brand firms practicing overseas need to be particularly careful when dealing with patent offices since an intent to commit fraud appears not to be an element of an abuse of dominance claim.

A third and final practice that I would like to discuss that brand firms allegedly use to extend their product life cycles is the improper filing of citizen petitions to delay

⁴⁶ *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

⁴⁷ *Nobelpharma Ab v. Implant Innovations*, 141 F.3d 1059, 1069-70 (Fed. Cir. 1998) (citing *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1170, 211).

⁴⁸ *AstraZeneca*, ¶ 368 (“with respect to [AstraZeneca’s] arguments based on United States law, suffice it to note that the position adopted by the latter cannot take precedence over that adopted by European Union law”).

⁴⁹ *Id.* (citing Case 322/81 *Nederlandshe banden-Industrie-Michelin v. Commission* [1983] ECR 3461, ¶ 57).

⁵⁰ Kristina Nordlander & Patrick Harrison, *General Court’s AstraZeneca Judgment Set to Embolden Commission*, 9 CPI ANTITRUST CHRON. (September 2010, Issue 2).

the FDA's approval of ANDAs.⁵¹ Citizen petitions are submissions designed to alert the FDA to possible scientific and safety issues related to regulated products or agency procedures.⁵² Generic pharmaceutical companies have alleged that brand companies have improperly used citizen petitions to block or delay their entry by raising frivolous or untimely concerns about ANDA filings.

In a 2002 report, the FTC recognized the potential for misuse of citizen petitions, but concluded that no actual anticompetitive effects had resulted.⁵³ In particular, the report found that citizen petitions did not affect the timing of generic entry. To date the FTC has not brought an enforcement proceeding on these grounds, and private plaintiffs have generally not fared well in court.⁵⁴

⁵¹ For a more detailed review of this issue, see Darren S. Tucker, *FDA Citizen Petitions: A New Means of Delaying Generic Entry?*, 20 ANTITRUST HEALTH CARE CHRON. 10 (Nov. 2006), abstract available at <http://ssrn.com/abstract=1531776>.

⁵² 21 C.F.R. § 10.30; see also section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355.

⁵³ FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* at 65-68 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. In March 2000, the FTC submitted comments to the FDA explaining how the cost of filing an improper citizen petition is negligible compared to the value of securing a delay of a rival's entry. See Comment of the Staff of the Bureau of Competition and the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration, FDA Docket No. 99N-2497 (Mar. 2, 2000), available at <http://www.ftc.gov/be/v000005.pdf>; see also Commissioner Jon Leibowitz, Fed. Trade Comm'n, Remarks at the Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust (Apr. 24, 2006) at 2, available at <http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf> (noting that that citizen petitions are low cost to file in comparison to the "value of securing even a brief delay in a rival's entry").

⁵⁴ See, e.g., *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, Case Nos. 5:03-00887-MRP (PLA) and 5:04-00333-MRP (PLA) (C.D. Cal. Feb. 17, 2009) (unpublished opinion dismissing antitrust counterclaim that Aventis filed a materially false citizen petition delaying generic entry; court ruled that plaintiff failed to show that conduct was beyond the protection of *Noerr*); *Louisiana Wholesale Drug Co. v. Sanofi-Aventis*, No. 07-cv-07343 (S.D.N.Y. Nov. 21, 2008) (jury verdict in favor of Sanofi on the ground that its

III.

The final issue that I would like to discuss is Authorized Generics and, more specifically, whether the entry of Authorized Generics during the 180-day exclusivity period created by Hatch-Waxman is anti- or pro-competitive. As you know, Authorized Generics are prescription drugs that are produced by brand pharmaceutical companies but are marketed under a private (generic) label at generic prices. Over the past few years, generic manufacturers have argued to the FDA and the courts that the Hatch-Waxman Act bars Authorized Generics from entering the market during the 180-day exclusivity period that starts running when a generic manufacturer makes a Paragraph IV ANDA filing. The FDA has taken the position that it lacks authority to delay entry of Authorized Generics during the 180-day period and has noted that, even if it did have authority, the marketing of Authorized Generics “appears to promote competition in the pharmaceutical marketplace, in furtherance of a fundamental objective of the Hatch-Waxman amendments.”⁵⁵ In 2005, the United States Court of Appeals for the D.C. Circuit agreed

citizen petition was not baseless under *Noerr*). *But see In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009) (reversing dismissal of antitrust claim on the basis that allegations in the complaint “indicate the plaintiffs could plausibly show the citizen petition to have been a sham” and noting “the possibility that the sham petition caused a delay in generic competition”); *Roxane Labs., Inc. v. Smithkline Beecham Corp.*, No. 09-CV-1638, 2010 WL 331704 (E.D. Pa. Jan. 26, 2010) (generic company had antitrust standing to challenge citizen petitions allegedly intended to delay FDA approval of its ANDA filing).

⁵⁵ Letter from William K. Hubbard, Assoc. Comm’r for Policy and Planning, Dep’t of Health & Human Servs., to Stuart A. Williams, Chief Legal Officer, Mylan Pharm. Inc., and James N. Czaban, Heller Ehrman White & McAuliffe LLP (July 2, 2004) at 2, available at http://www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04_p-0261-pdn0001.pdf.

with the FDA that nothing in the Hatch-Waxman Act prohibits brands from marketing Authorized Generics during the 180-day exclusivity period.⁵⁶

In March 2006, in response to a request from Congress,⁵⁷ the Commission announced that it would study what effects, if any, Authorized Generics have on pharmaceutical competition.⁵⁸ The Commission issued an Interim Report last summer summarizing its findings to date⁵⁹ As the Commission's Interim Report and the statements that Chairman Leibowitz and I separately issued⁶⁰ suggest, where one comes out on the debate over the competitive benefit or harm caused by Authorized Generics has boiled down to two issues. First, how and to what extent should the Commission consider whether the entry of Authorized Generics during the 180-day exclusivity period decreases the incentives for generics to bring Paragraph IV challenges under Hatch-Waxman? The generic pharmaceutical lobby of course claims that the entry of

⁵⁶ *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005); *see also Mylan Pharm. Inc. v. FDA*, 454 F.3d 270, 271 (4th Cir. 2006) (concluding that the Hatch-Waxman Act “does not grant the FDA the power to prohibit the marketing of authorized generics during the 180-day exclusivity period”).

⁵⁷ *See* Press Release, Office of U.S. Senator Patrick Leahy, “Grassley, Leahy, Rockefeller Request Study on Impact of ‘Authorized’ Generics” (May 12, 2005), *available at* http://leahy.senate.gov/old_site/press/200505/051205b.html (reprinting Letter to Chairman Deborah Platt Majoras, May 9, 2005).

⁵⁸ Press Release, FTC Proposes Study of Competitive Impacts of Authorized Generic Drugs (Mar. 29, 2006), *available at* <http://www.ftc.gov/opa/2006/03/authgenerics.shtm>; FTC Comment Request, 71 Fed. Reg. 16779, 16780 (Apr. 4, 2006).

⁵⁹ FED. TRADE COMM'N, AUTHORIZED GENERICS: AN INTERIM REPORT (June 2009), *available at* <http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf>.

⁶⁰ *See* Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics (June 2009), *available at* <http://www.ftc.gov/os/2009/06/P062105authgenstatementLeibowitz.pdf>; Concurring Statement of Commissioner J. Thomas Rosch on the Release of the Commission's Interim Report on Authorized Generics (June 2009), *available at* <http://www.ftc.gov/os/2009/06/P062105authgenconcurringrosch.pdf>.

Authorized Generics during this period decreases the incentives for generics to bring Paragraph IV challenges, while advocates of Authorized Generics claim that an Authorized Generic's entry lowers prices and is therefore good for consumers.⁶¹ Second, to what extent should the fact that Authorized Generics are sometimes used as a pawn in pay-for-delay settlements cause the Commission to limit (or support legislative limitations on) their availability? As I made clear in my concurring statement, I believe the answers to these questions from a competition standpoint are straightforward.

First, as to whether Authorized Generics should be allowed to enter during the 180-day period, I believe that the Commission's main focus—as an antitrust agency—should be on whether Authorized Generics are good or bad for consumers. Consumer welfare, in turn, is judged in this context by whether the introduction of Authorized Generics causes prices to increase or overall output to decrease. Thus far, I have seen no evidence of either effect. To the contrary, every bit of data that I have seen so far shows that when Authorized Generics enter the market during the 180-day exclusivity period, prices for generic drugs go down. That, of course, is not surprising: when one generic enters the market during the 180-day exclusivity period, it may bring the brand's price down slightly, but it still has a “monopoly” so-to-speak over those purchasers interested in buying a generic product. The introduction of an Authorized Generic, of course,

⁶¹ *Compare* Letter from Kathleen Jaeger, President & CEO, Generic Pharm. Ass'n, to Office of the Sec'y, Fed. Trade Comm'n 3 (June 27, 2006), *available at* <http://www.ftc.gov/os/comments/genericdrugstudy3/062806gpha.pdf> (arguing that the sale of authorized generics during the exclusivity period “reduces the value of the 180-day exclusivity” and diminishes the incentives for generic entry), *with* Richard E. Coe and M. Howard Morse, “Authorized Generics are Good for You: Competition from Drug Pioneers Shouldn't Trouble the FTC,” *Legal Times* (Apr. 10, 2006), at 37 (“There is little doubt that authorized generics benefit consumers by driving down prices for generic drugs. They are legal under the current regulatory scheme, and the suggestion that their introduction somehow violates antitrust law is baseless.”).

upsets that monopoly by creating competition for purchasers of generic drugs and, in turn, further depresses prices for generic drugs. Likewise, from a consumer welfare standpoint, I have not seen evidence suggesting that the entry of Authorized Generics during the 180-day exclusivity period somehow decreases the *total* output of the particular generic drug at issue (i.e., the *total* quantity of that generic drug – authorized or not – that comes to market). Indeed, the Interim Report made no attempt to analyze that issue.

As to the second issue, from an antitrust perspective, I believe that evaluating whether Authorized Generics are, in some absolute sense, “good” or “bad” based on whether they create additional incentives for parties to enter into pay-for-delay settlements asks the wrong question. Any analysis that simply assumes (as the Interim Report did) that, because pay-for-delay settlements are bad for consumers, all of the subjects employed in those settlements—including promises to launch or not launch Authorized Generics—are bad, puts the cart before the horse. As I said in my concurring statement, if pay-for-delay settlements that implicate Authorized Generics are a problem, the way to remedy that problem is not to ban Authorized Generics from marketing their products during the 180-day exclusivity period.⁶² Instead, it is (at most) to analyze the legality of those agreements under the truncated rule of reason and provide that a brand’s promises not to manufacture Authorized Generics will be presumptively illegal, absent proof adduced by the parties to the agreement to justify their agreement.⁶³

I should note, however, that all of this disagreement happened at the Commission more than a year ago. Since then, President Obama has added Commissioners Edith

⁶² *Id.* at 3.

⁶³ *Id.*

Ramirez and Julie Brill to the Commission. To be honest, I have no idea where they would come out on this issue. Stay tuned for more developments in this area.

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In conclusion, at first glance, many of the issues that arise at the intersection of antitrust and intellectual property are anything but easy. On the one hand, innovation must be encouraged but, on the other hand, innovation must not drown out competition. This tension between the two legal regimes perhaps explains why there is so much discord over what the right answers in these various contexts should be. Nevertheless, over the years, I have found that returning to Justice Harlan's first principles ultimately supplies a succinct analysis—one that ensures that, whatever the context, we at the FTC are encouraging the courts and Congress to both promote innovation and competition.