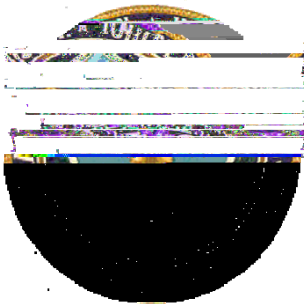

Federal Trade Commission

The Antitrust/Intellectual Pr operty Interface: Thoughts on How To Best Wade Through the Thicket in the Ph9 0.000Wade

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 pretty obvious (no pun intended), you would be surprised how often the federal courts and 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 antirust 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 qu

by eliminating the opportunity for the generic firm 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 commonly 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.

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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 such 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

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

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[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

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 licensing 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 of 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 reported out , g2

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 engaging in this practice, resolving the FTC's concerns.[23] Those consents, however, have not 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

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[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.,[27] the Federal Circuit recently provided an important clarification on the scope of that statutory right. 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 a '358 patent on which its drug Prandin was based for one specified use. Caraco also desired to market a 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

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[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 Fed. Cir. 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

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[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 some 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

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[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

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.,

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

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

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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]

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[51] For a more detailed review of this issue, see Darren S. Tucker, FDA Citizen Petitions: A New Means of Delaying Generic Entry?, 22 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. 5D u N.Td .0005 Tw 0 0 7.98 9[illegible]

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

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, the Commission[57]

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,

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[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

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.