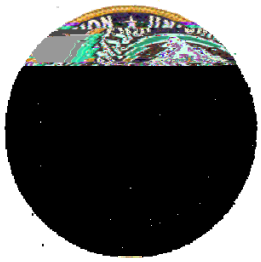

Pay-for-Delay Settlements, Authorized

the biologic context while ensuring the production of less-expensive biosimilars? Running through all of these issues is the debate about how and to what extent the law should strike a balance between creating the right incentives for brand firms to innovate and develop groundbreaking drugs while still ensuring that generic firms have the incentives to enter the market.

All of these overlapping issues have been the subject of much discussion at the Commission over the last year a

Application ("ANDA") with the FDA asserting that the brand's patents are invalid or not infringed by the generic drug may enter the market without going through FDA approval and obtains an exclusive right to market a generic version of the drug for 180 days which creates a duopoly during that 180-day period.[1] In response to the ANDA, the brand firm may file a patent infringement suit to establish validity and infringement.

It is the settlement that arguably creates the antitrust problem because, once the generic firm that has obtained the rights to that 180-day exclusivity period under Hatch Waxman agrees in exchange for payment from the brand firm to stay off the market, there is no competition. For nearly the last decade, the FTC has challenged these agreements on the grounds that, by keeping generics out of the market, they eliminate competition with the brand firm and therefore deprive customers of competitive prices. At the courts, we have generally not had much success.

Initially, courts divided over whether pay-for-delay settlement agreements were per se illegal. In 2003 in the *Cardizem* litigation (a private lawsuit), the Sixth Circuit rejected the brand patentee's argument that the pay-for-delay agreements were presumptively procompetitive and good for innovation and held that the payments there were per se illegal because the agreement between the brand and the generic "was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade."[2] A few months later, however, Judge Persky, sitting as a district court judge,

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[1] In some cases, multiple generic firms file ANDAs on the same day and therefore share the right to 180-days of exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv).

[2] *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

rejected this view in dicta in his Asahi Glass decision.[3] There he reasoned that "a ban on reverse payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought as anticompetitive."[4]

In the next wave of cases, federal appellate courts addressing pay-for-delay settlement agreements held that the agreements under review did not violate the antitrust laws because the agreements were within the scope of the brand firm's patent and therefore did not have anticompetitive effects beyond the monopoly power conferred by that patent. The Eleventh Circuit was the first appellate court to so hold in Schering-Plough.[5] There, the court rejected the FTC's claim that the settlement agreement failed under the rule of reason because the brand's payment to the generic constituted a quid pro quo for the generic's agreement to defer entry into the market and therefore had anticompetitive effects because it eliminated competition.[6] The Eleventh Circuit reasoned that the traditional rule of reason analysis – under which courts analyze whether the defendant's conduct had anticompetitive effects – was not "appropriate in this context" because "[b]y their nature, patents create an environment of exclusion, and, consequently, cripple competition."[7] As a result, the Eleventh Circuit reasoned, the proper analysis was to examine "the extent to which antitrust liability might undermine

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[3] Asahi Glass Co., Ltd. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill.

the encouragement of innovation and disclosure."[8] The court held that the settlement agreement's legality rested on (1) the patent's potential exclusionary scope; (2) the extent

> litigation in order to succeed in establishing that a settlement has provided defendants "with benefits exceeding the scope of the tamoxifen patent." Whether there is fraud or baseless litigation may be relevant to the inquiry, but it is hardly, we think, 'the…standard,' as the dissent posits in order to take issue with it."

Two years later, however, In re Ciprofloxacin Hydrochloride Antitrust Litigation,[12] the Federal Circuit went further and rejected the distinction that the Second Circuit crafted in *Tamoxifen*, and held that pay-for-delay settlement agreements were essentially per se legal. The court held that those agreements were legal unless the plaintiffs could prove (1) that the brand's patent infringement lawsuit fell within the "sham" exception to the *Noerr-Pennington* doctrine set out in the Supreme Court's decision in *PRE*, or (2) that the settlement terms were outside the scope of the brand's patent. In June, the Supreme Court refused to consider the Federal Circuit's decision when it denied the *Cipro* plaintiffs' petition for certiorari.[13]

More recently, however, two developments suggest that there is reason to believe that the tide may be turning again – this time in the Commission's favor. First, in a companion case to the Federal Circuit's *Cipro* case,[14] the Second Circuit appears to be revisiting whether it applied the correct standard in *Tamoxifen*. Over the summer, the Second Circuit requested the Justice Department's views on the correct standard for analyzing the validity of reverse payments. Judge Pooler, who dissented from the Second Circuit's *Tamoxifen* decision,[15] is on the *Cipro* panel – a fact that provides further fodder to suggest that the Second Circuit is, indeed, revisiting its test. In response to the Second

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[12] In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed Cir. 2008).

[13] Id., cert. denied, 129 S. Ct. 2828 (June 22, 2009) (No. 08-1194).

[14] In re Ciprofloxacin Hydrochloride Antitrust Litig. (2d Cir.) (No. 05-2851).

[15] In re Tamoxifen Citrate Antirust Litig., 466 F.3d at 221 (Pooler, J., dissenting).

if the Commission finds such agreements to be for the benefit of consumers. That bill passed the House as part of the health care reform legislation.

In the Senate, the Judiciary Committee last month passed S. 369 with an amendment that would create a presumption that pay-for-delay agreements are illegal, but allow parties to overcome that presumption by establishing by clear and convincing evidence that the agreement's procompetitive benefits outweigh its anticompetitive effects. Unlike the House provision, which amends the Food, Drug, and Cosmetic Act, the Senate proposal amends the FTC Act and contains a provision allowing for the assessment of civil penalties. Like the House version, the Senate proposal would permit the FTC, by rule, to except additional pay-for-delay agreements from the bill's coverage. We'll have to wait and see what happens to these proposals in the upcoming months.

In light of all these legal standards, where do I come out? In my current view, the optimum standard is not that such agreements should be per se illegal. Instead, paralleling the DOJ's brief in the Second Circuit, I believe that the Commission and courts should evaluate antitrust liability in reverse payments cases under the "truncated rule of reason" standard embraced by the Supreme Court in

infringement of the patent) when the parties also agree on when the generic company can enter the market without infringement. Since the agreement is "inherently suspect," under the truncated rule of reason analysis adopted by the D.C. Circuit in Polygram Holding[23] and the Fifth Circuit in North Texas Specialty Physicians,[24] the burden shifts to the defendant to justify the payment.

At that point in my view – and I depart from the DOJ's brief in Cipro at this juncture – I believe that the defendants should be able to defend the settlement by introducing evidence of the strength of the patent. Indeed, although the DOJ has since

evaluate the correct legal standard[26]

brand's patent does not need to be taken at face value. Schering does not create an irrebuttable presumption that the brand firm's patent is valid and/or that it will be infringed by the generic.

A second and tougher open question – and one that courts have yet to really grapple with – is what must the party challenging the reverse payment prove in order to show that validity and/or infringement are sufficiently unlikely. One option would be for the parties to engage in the type of experts that often occurs in patent litigation and essentially resolve the validity or infringement claim on the merits. That would of course be expensive and would require either in-house or outside expertise. A second option would be for the party challenging the reverse payment agreement to prove that validity is highly unlikely or infringement is unlikely through direct evidence such as internal statements or evaluations by the brand and generic firms. The problem with direct evidence, however, is that it rarely actually exists. A third and more viable option would be for the party challenging the reverse payment agreement to prove that validity is highly unlikely or that infringement is unlikely by relying on circumstantial evidence, including the parties' positions at the time of the settlement, projections from the firms about the patent's validity or the likeli

reverse payment equals or exceeds the generic's potential profits if it wins (taking into account the remaining life of the patent and the lower profit margins if there is competition), buttressed by other evidence (for example, that the payment was made despite the presumption of validity or evidence from an ex-employee or because the parties' documents show the payment was made because it was believed the brands' patent was invalid) might be sufficient to create an inference that the patent is in fact invalid.[29]

A third question that remains to be answered is whether the courts are simply wrong in looking at pay-for-delay settlement agreements in the vacuum of the antitrust laws. As I discussed at the outset, U.S. firms and courts operate against the backdrop of not only federal antitrust and intellectual property laws, but also the Hatch-Waxman Act, which regulates the introduction of generic drugs into the marketplace. Professor Scott Hemphill has argued that courts should give the Hatch-Waxman Act independent relevance in considering the legality of reverse payment settlements.[30] His argument is that, because the Hatch-Waxman Act reflects a congressional judgment, it deliberately

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payment should not dictate the availability of the settlement remedy." Id. Thus, under Schering, the circumstantial evidence of invalidity or non-infringement cannot consist solely of the existence of a reverse payment; nor can the size of the payment, standing alone, dictate findings of invalidity or non-infringement.

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

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

As a third and final strategy, to avoid the unfavorable law that has developed in

II.

A second issue that the Commission has tackled this year concerns whether Authorized Generics – and more specifically, the entry of Authorized Generics during the 180-day exclusivity period created by Hatch-Waxman – are 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 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."[33] 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.[34]

[33] Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, Department of Health & Human Services, to Stuart A. Williams, Chief Legal Officer, Mylan Pharmaceuticals Inc., and James Cleaban, 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.

[34] Teva Pharm. Indus., Ltd. v. Crawford, 410 F.3d 51 (D.C. Cir. 2005); see also Mylan Pharmaceuticals, 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").

In March 2006, in response to a request from Senators Grassley, Leahy, and Rockefeller,[35] the Commission announced that it would study what effects, if any,

consumers.[39] 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,[40] 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 consumer welfare. Consumer welfare, in tern, 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

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. Analysis that simply assumes (as the Interim

III.

The final issue that I would like to discuss is the ongoing debate over the pathway to market for follow-on biologics. As most of you no doubt know, biologics are drugs manufactured using living tissues and microorganisms and are classified as "large molecule" drugs in comparison to their "small molecule," chemically-synthesized equivalents. Biologics are increasingly used to treat arthritis, cancer, diabetes, and other diseases. In theory, follow-on biologics are like generic drugs in that they provide a lower cost replica of the original large molecule biologic drug. However, because follow-on biologics are not "identical" (in the same way a small molecule generic drug is to its brand counterpart), follow-on biologics pose significant challenges from a regulatory standpoint. Currently, no regulatory pathway exists in the United States for such follow-on biologics to enter the market and compete with their pioneer counterparts.[43]

One year ago, the Commission held a roundtable to consider issues associated with creating a pathway for follow-on biologics, including the competitive effects of creating such a pathway. Following that roundtable, in June, the FTC released a report that concluded that providing the FDA with the authority to approve such FOBs would be

[43] In 2004, the European Union enacted the world's first regulatory system for follow-on biologics. See European Commission Directive 2003/63/EC, Art. 10 (2004). More recently, Canada has also established a pathway for follow-on biologics. See Minister of Health: Health Products, Food and Drug Branch, Draft Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (2008), available at http://www.hc-sc.gc.ca/dhp-mps/consult/therap/activit/consultation/seb-pbu/2008-1-eng.php

an efficient way to bring these lower-priced drugs to market.[44] The Report concluded that a 12- to 14-year regulatory exclusivity period was not to long to promote innovation by these firms, particularly since they likely will retain substantial market share after FOB entry. The Report also concluded that special procedures to resolve patent issues between pioneer and FOB manufacturers before FDA approval, which are not needed, could undermine patent incentives and harm consumers. Finally, the Report concluded that FOB manufacturers are unlikely to need additional incentives – such as a 180-day marketing exclusivity period – to develop interchangeable FOB products.

As a threshold matter, I believe that we need to make sure that we are providing sufficient incentives for pioneer firms to spend the time and money to develop pioneer drugs. My understanding is that the process to develop such drugs takes approximately 8 years. In developing those incentives, there are two issues in my view. First, are the incentives that the Hill is currently debating the right ones? Under the current proposed legislation, a firm developing a pioneer drug will receive patent protection plus an addition period of exclusivity for 12 years. That legislation is contrary to the recommendation that the FTC made in June in its follow-on biologics report, where the FTC concluded that innovative products should not receive additional market exclusivity beyond the term of their patent. It is not clear to me why pioneer firms need more exclusivity than what is already conferred by the patent laws. Moreover, it is inexplicable to me why any statutory exclusivity period should be conferred on drugs

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[44] See FTC, Press Release, "FTC Releases Report on Follow-on Biologic Drug Competition" (June 10, 2009), available at http://www.ftc.gov/opa/2009/06/biologics.shtm; Emerging Health Care Issues: Follow-on Biologic Drug Competition: A Federal Trade Commission Report (June 2009), available at http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf

whose patentability is suspect (either because there is no prospect of infringement or because the patent is invalid).

Second, will the fixes that the Hill is debating create disincentives for generics to enter the market at all? Under the current bill, the generic firm would be required to share with the pioneer all of its information regarding its own developments ostensibly to ensure that they do not infringe on the pioneer's patent. That seems like an empty premise if the bill also provides statutory exclusivity on top of the patent. Moreover, that disclosure requirement will chill generic firm development in the first place because all of the trade secretes flowing from development will have to be disclosed.

* * *

In conclusion, although the answers are not always immediately crystal clear, the Commission has sought to determine what conduct will best facilitate competition (and therefore protect consumer welfare) in each of these three contexts. To be sure, however, the answer that leads to the best competitive framework will not always make the brand lobby happy or the generic lobby happy. Thankfully, however, as an independent Commissioner, I am not beholden to either party of any lobby. That may not always make the Hill or various interest groups happy, but it does mean that I will always listen to both sides carefully and that when I provide you with an opinion about what practices will best facilitate competition, you can be sure that I am bringing my antitrust experience to bear in the interests of consumers.