



Federal Trade Commission

Pay-for-Delay Settlements, Authorized Generics, and Follow-on Biologics: Thoughts on the How Competition Law Can Best Protect Consumer Welfare in the Pharmaceutical Context

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This year marks the 25th Anniversary of the Drug Price Competition and Patent Restoration Act of 1984, known to all of us as the Hatch-Waxman Act. That Act, of course, is credited with creating the modern regulatory framework that allows generic, lower-cost drugs to come to market. From an antitrust standpoint, however, the Hatch Waxman Act has also unleashed several challenging practical and theoretical questions at the intersection of competition law and patent policy. Should the law incentivize settlements of costly patent litigation that delay generic entry or, in certain cases, unilaterally ban those settlements? Can those settlements ever be held “reasonable”? To what extent does the entry of Authorized Generics during the Hatch Waxman 180-day exclusivity period into the marketplace ultimately help or harm consumers? What time frame of patent protection strikes the right balance between incentivizing innovation in

* 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 preparing this paper.

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 and today I would like to discuss their application in three different contexts. First, I will discuss the various legal standards that the Commission, the courts, and now Congress have offered for determining when pay-for-delay settlements are anticompetitive. Second, I will offer some thoughts on the debate over whether the entry of Authorized Generics during the 180-day exclusivity period is harmful to competition. Third and finally, I will discuss the ongoing debate over the proper pathway for follow-on biologics.

I.

I would like to begin by discussing “pay-for-delay” settlements. As you know, these are settlement agreements where a patent holder makes a payment (or provides something else of value) to the generic company to settle the generic company’s claim that the brand’s patent is invalid. As part of the agreement, the generic company typically agrees to stay off the market for a period of time that may or may not cover the life of the patent. Ironically, these agreements are a negative by-product of the Hatch Waxman Act which was intended to bring generics to market faster and creates an industry-specific scheme that regulates competition in the pharmaceutical markets. Under Hatch Waxman, the first generic firm (or firms) to file an Abbreviated New Drug

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 Posner, sitting as a district court judge,

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 firm’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

³ *Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).

⁴ *Id.* at 994.

⁵ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

⁶ *Id.* at 1065.

⁷ *Id.* at 1065-66.

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 to which the settlement agreement created exclusions beyond that scope; and (3) the resulting anticompetitive effects.⁹ Because it held that the settlement in *Schering* did not have anticompetitive effects that were beyond the scope of the patent’s potential exclusionary effect, the Eleventh Circuit refused to find liability under the antitrust laws. However, in my view, the court did not answer definitively the critical question of whether the merits of the patent could be litigated in order to determine whether the settlement was within the scope of the patent.

The next year in *In re Tamoxifen Citrate Antitrust Litigation*,¹⁰ the Second Circuit applied *Schering* and held that a plaintiff must show that the agreement’s exclusionary effects exceed the patent’s scope. However, in my view, the Court did not go so far – as some have suggested – as to require that a plaintiff show that the litigation initiated and settled by the brand was a sham under the Supreme Court’s decision in *Professional Real Estate Investors v. Columbia Pictures Industry* (which I will refer to as “*PRE*”).¹¹ Nor, in my judgment, did the *Tamoxifen* court require a showing that the litigation settled a claim involving a patent that the brand obtained through fraud on the PTO. To the contrary, it observed,

[W]e do not . . . think there is a “requirement” that “antitrust plaintiffs must show that the settled litigation was a sham, i.e. objectively baseless, before the settlement can be considered an antitrust violation. . . .” There is no such requirement. . . . A plaintiff need not allege or prove sham

⁸ *Id.* at 1066.

⁹ *Id.*

¹⁰ 466 F.3d 187 (2d Cir. 2006).

¹¹ *Prof'l Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49, 60-61 (1993).

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 *In re Ciprofloxacin Hydrochloride Antitrust Litigation*,¹² the Federal Circuit went further and, rejecting the distinction that the Second Circuit crafted in *Tamoxifen*, 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

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 Antitrust Litig.*, 446 F.3d at 221 (Pooler, J., dissenting).

Circuit’s request for the views of the United States, the Department of Justice filed a brief this summer and took the position that the court should essentially apply a truncated rule of reason.¹⁶ Under that analysis, if a plaintiff makes a prima facie showing that a reverse payment took place, it has proved an agreement that is “presumptively unlawful.”¹⁷ The DOJ argued that the defendants can then rebut that showing through a rule of reason analysis showing that the settlement agreement did not unreasonably restrain competition, such as by showing that the consideration paid was equivalent to the patent holder’s expected litigation costs.¹⁸ Under the DOJ’s analysis, if the settlement bans generic competition for the life of the patent, “defendants will be unable to carry their burden.”¹⁹ The DOJ’s position brought it largely into line with the FTC’s position in *Schering*. A decision from the Second Circuit could come any day.

The second development has been on the Hill, where the FTC has been urging Congress – with recent success – to adopt legislation that would address pay-for-delay settlements. In the House, a provision barring agreements that include both the generic filer’s receiving anything of value and agreeing to limit or forego production or marketing its generic drug, was incorporated into the health care reform bill, H.R. 3962, that passed the chamber on November 8th. Section 2573 of that bill amends the Federal Food, Drug, and Cosmetic Act to prohibit pay-for-delay agreements, with certain exceptions, but also to allow the FTC to promulgate rules exempting certain agreements

¹⁶ Brief for the United States, *In re Ciprofloxacin Antitrust Litig.*, 21-23 (2d Cir.) (No. 05-2851), available at <http://www.justice.gov/atr/cases/f247700/247708.htm>.

¹⁷ *Id.*

¹⁸ *Id.* at 27-32.

¹⁹ *Id.* at 29.

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 *NCAA v. Board of Regents*²⁰ and *FTC v. Indiana Federation of Dentists*.²¹ My thinking is as follows. Under the Supreme Court's decision in *Palmer v. BRG*,²² I believe a pay-for-delay settlement agreement is "inherently suspect" because it is a putative market division agreement between a competitor (the branded pharmaceutical company holding the patent) and a potential competitor (the generic pharmaceutical company challenging the validity of

²⁰ 468 U.S. 95, 109 (1984).

²¹ 476 U.S. 447 (1986).

²² *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990) (per curiam).

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 backpedaled from such a position, the Solicitor General advocated such a view before the Supreme Court when it urged the Court to take the *Tamoxifen* appeal.²⁵ A rule that purports to give defendants get an opportunity to defend their settlement, but then prohibits them from introducing evidence that could go to the core of why they settled the case (i.e., the merits of the original patent challenge) is not, in my view, fair because it unduly stacks the deck in the plaintiff’s favor.

But whether or not my views ultimately prevail is a debate for a different day. Looking ahead, history tells us that the Commission can only safely assume that the law will remain the status quo – the Supreme Court has repeatedly passed on opportunities to

²³ *Polygram Holding v. FTC*, 416 F.3d 29 (D.C. Cir. 2005).

²⁴ *North Texas Specialty Physicians v. FTC*, 528 F.3d 346 (5th Cir. 2008).

²⁵ See, e.g., Brief of United States at 13, *Joblove v. Barr Labs., Inc.* (“*In re Tamoxifen Antitrust Litig.*”), No. 06-380 (U.S. May 23, 2007). See also Brief for the United States, *In re Ciprofloxacin*, *supra* n. 16 at 26, n.9 (“We have suggested elsewhere that a court could conduct a limited evaluation of the claims in the settled patent litigation rather than conduct a full trial of those claims, U.S. *Joblove* Br. at 13, but as part of a rule of reason analysis, not as a single decisive determination, *id.* at 12-13. We acknowledge some tension between statements in our *Joblove* brief and our current views.”).

evaluate the correct legal standard²⁶ and I am not experienced enough in the ways of the Hill to make any guarantees about how things will end up in Congress. Assuming that to be so, there are several open questions on the horizon. I will opine on answers to just a few.

First, in the face of the existing federal appellate decisions, under what circumstances could the Government or a private plaintiff nevertheless prevail in an antitrust challenge to a pay-for-delay settlement agreement under current U.S. law? As I read the cases, there are at least two such circumstances. Under one scenario, a party contesting a pay-for-delay settlement agreement can prevail if it can show that the brand firm's infringement lawsuit qualifies as a sham under *PRE* or rests on a patent that was obtained through fraud on the PTO.

Under a second scenario, I also continue to believe that based on the Eleventh Circuit's decision in *Schering* and Judge Posner's decision in *Asahi Glass* that, at least outside of the Federal Circuit, a party contesting a reverse payment agreement can prevail if it can show that it is highly unlikely that the patent is valid or that it is likely that the generic firm did not infringe the patent.²⁷ Put another way, the validity or scope of the

²⁶ See, e.g., *In re Cardizem*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004); *Schering-Plough Corp.*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006); *In re Tamoxifen*, 429 F.3d 370 (2d Cir. 2005), *amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007); *In re Ciprofloxacin*, 544 F.3d 1323 (Fed Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (June 22, 2009).

²⁷ In *Schering*, for example, the court noted that “there has been no allegation that the ’743 patent itself is invalid” and that “*in the absence of any evidence to the contrary*, there is a presumption that the ’743 patent is a valid one, which gives Schering the ability to exclude those who infringe on the patent.” *Schering*, 402 F.3d at 1068 (emphasis added). Similarly, in *Asahi Glass*, Judge Posner noted that if “a seller obtain[ed] a patent that it knows is almost certainly invalid” and then settled infringement litigation by requiring that the generic competitor not sell the patented products for less than the price specified in the license, “the patent, the suit, and the settlement would be devices—

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 the 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 battle 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 likelihood of infringement, or the existence of a demonstrably excessive "reverse payment."²⁸ Thus, for example, evidence that the

masks—for fixing prices, in violation of antitrust law.” *Asahi Glass*, 289 F. Supp. 2d at 991. *But see Cipro*, 544 F.3d at 1337 (“We disagree that analysis of patent validity is appropriate in the absence of fraud or sham litigation.”).

²⁸ *Schering* does not reject the use of circumstantial evidence to resolve the issues of validity and/or infringement. To be sure, *Schering* rejects as a sufficient basis for finding invalidity or non-infringement the existence of a reverse payment, standing alone. *Schering*, 402 F.3d at 1075 (“Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the *sole* basis for a violation of the antitrust law. . .”). Moreover, in *Schering* the court said that “the size of the

reverse payment equals or exceeds the generic firm'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 market place. 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

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).

favors litigated challenges to brand patents rather than settlement. That judgment, of course, is the polar opposite from the view expressed in *Schering, Tamoxifen, and Cipro* that courts should favor patent settlements over litigation. Put another way, it may be correct that, in a world without the Hatch-Waxman Act, a policy that defaults in favor of settlement is arguably appropriate. But that is not the policy that we arguably have in the U.S. in the context of generic drugs where Congress has made a policy judgment in favor of litigated challenges.

A fourth question that the Commission may have to face is how, in the absence of a legislative fix, we should proceed to challenge these settlements going forward. Under one view, the FTC should use our administrative trial process (which we term “Part 3”). If the FTC proceeded down that path and filed an administrative complaint against parties to a reverse payment agreement, a decision by the ALJ (regardless of the outcome) would almost invariably be appealed to the entire Commission. At that point, the FTC itself could weigh in through a written opinion. Although the FTC’s decision would be subject to appeal to a federal appellate court, this process would nevertheless allow the FTC to clearly articulate its views of what the legal standard should be.

A second strategy is to pursue cases where we include specific allegations that the reverse payment reflects a quid pro quo for an agreement to divide the market coupled with specific allegations that the brand firm’s infringement claim is weak. The FTC has recently done just that twice in cases filed in the federal district court in Pennsylvania and the federal district court in California. The FTC’s specific allegations of market division and weak infringement claims distinguish these cases from *Schering, Tamoxifen, and Cipro* and my hope is that they will yield a different result.

As a third and final strategy, to avoid the unfavorable law that has developed in the last few years, the FTC could altogether side-step claims that these agreements are collusive horizontal agreements in violation of Section 1 of the Sherman Act and challenge these practices under Section 5 of the Federal Trade Commission Act which gives us broad (and largely undefined) authority to challenge “unfair methods of competition” but which does not provide an escape from the *Noerr-Pennington* doctrine. As I discussed in a speech last month,³¹ one proper use of Section 5 might be in those contexts where proceeding under Section 5 will have fewer collateral consequences than a challenge under Section 1 or Section 2.³² This is an especially important consideration when federal court private treble damage litigation involving the same conduct is pending or threatened. A plaintiff cannot rely on favorable Section 5 case law in a federal treble damage action. Neither can a federal district court rely on such a decision because the FTC alone can avail itself of Section 5 at the federal level. Thus, a fair argument can be made that, to the extent the FTC really wants to take full control over regulating pay-for-delay settlement agreements (as some in Congress have suggested would be advisable), suing under Section 5 – as opposed to Section 1 – would be a better course.

At the end of the day, there is of course the question of whether any one of these strategies is the best approach. Perhaps we should simultaneously pursue all of these strategies in an effort to foster more critical thinking on this topic and increase our likelihood of success.

³¹ See J. Thomas Rosch, “Wading Into Pandora’s Box: Thoughts On Unanswered Questions Concerning the Scope and Application of Section 2 & Some Further Observations on Section 5,” Remarks before the LECG Summit on Antitrust Law & Economics, Newport, RI (Oct. 3, 2009), *available at* <http://www.ftc.gov/speeches/rosch/091003roschlecgspeech.pdf>.

³² *Id.* at 25.

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 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.

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, Authorized Generics have on pharmaceutical competition.³⁶ The Commission issued an Interim Report over the summer summarizing its findings to date.³⁷ As the Commission's Interim Report and the statements that Chairman Leibowitz and I separately issued³⁸ 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 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

³⁵ See Press Release, Grassley, Leahy, Rockefeller Request Study on Impact of "Authorized" Generics (May 12, 2005), *available at* <http://leahy.senate.gov/press/200505/051205b.html> (reprinting Letter to Chairman Deborah Platt Majoras, May 9, 2005).

³⁶ 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>; Comment Request, 71 Fed. Reg. 16779, 16780 (Apr. 4, 2006).

³⁷ Federal Trade Commission, Authorized Generics: An Interim Report (June 2009), *available at* <http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf>.

³⁸ 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>.

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 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 AGs 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,

³⁹ *Compare* Letter from Kathleen Jaeger, President & CEO, Generic Pharmaceutical Association, to Office of the Secretary, Federal Trade Commission 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.”).

⁴⁰ 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>.

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.⁴¹ 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 AGs will be presumptively illegal, absent proof adduced by the parties to the agreement to justify their agreement.⁴²

⁴¹ *Id.* at 3.

⁴² *Id.*

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/brgtherap/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 too 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 patents. 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

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 secrets 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.