
# Federal Trade Commission

**Antitrust Evaluation of Pay-for-Delay Settlements:**
**A Persistent Quest for Balance**

**Remarks of J. Thomas Rosch***
**Commissioner, Federal Trade Commission**

**before the**

**American Conference Institute's Paragraph IV Disputes Conference**

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I have been asked to update you principally on the Federal Trade Commission's investigative and enforcement activities relating to pay-for-delay settlements. The running theme of my remarks today is *balance*—that is to say, the approach that the Commission should take in applying the antitrust laws to pay-for-delay settlements is to strike an appropriate balance between innovation and competition, between settlements and litigated judgments, and between the interests of brand-name drug manufacturers

* 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, Henry Su, for his invaluable assistance in preparing these remarks.

and generic drug manufacturers. Consistent with this approach, and perhaps to the dismay of industry observers, we should not take sides, nor should we pick winners and losers. Rather, we should function merely as referees charged with enforcing the rules against both teams and otherwise ensuring a level playing field and a hard-fought, competitive game for the fans, that is, the consumers whose interests we are sworn to protect.

The general approach I have described is, of course, not unique to the pharmaceutical industry. More broadly, in antitrust law the very application of the rule of reason is a classic exercise in balance. In designing a legal system for protecting competition, we should purposely limit the number of situations that can be characterized as either per se illegal or per se legal because such situations, by definition, preclude us from examining the underlying facts and circumstances associated with the conduct or transaction being challenged. Whenever we recognize per se rules and safe harbors, we cede our enforcement role as referees to call fouls and first downs as we see them.

My opening comments will take on greater specificity and particular relevance as I review the Commission's recent efforts with respect to pay-for-delay settlements—through ongoing litigation, proposed legislation, and published studies and reports.

## I. Recent Litigation

### A.

On the litigation front, we are still awaiting a decision from the United States Court of Appeals for the Eleventh Circuit in *FTC v. Watson Pharmaceuticals, Inc.*,[1] better known as the *AndroGel* case, which was argued on May 13, 2011. The Commission appealed the district court's grant of motions to dismiss filed by the defendants, Solvay Pharmaceuticals, the brand-name seller of a prescription-only, testosterone-replacement gel marketed under the trademark ANDROGEL®; and three would-be generic sellers, Watson Pharmaceuticals, Paddock Laboratories, and Par Pharmaceuticals.[2]

Those of you who have been following this case know the facts but I will review them briefly for everyone's benefit. Solvay marketed and sold ANDROGEL® in the United States under a license from Besins Healthcare, and it and Besins owned U.S. Patent No. 6,503,894 covering the gel formulation.[3] Watson and Paddock had each filed an abbreviated new drug

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[1] No. 10-12729-DD (11th Cir. argued May 13, 2011). For my prior observations and comments on *Watson*, *see* J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Patent Settlements, Patent Reform, and Mergers: Recent Developments in Pharmaceutical Antitrust, Remarks at the Sixth Annual In-House Counsel Forum on Pharmaceutical Antitrust at 4–5 (May 11, 2011), http://www.ftc.gov/speeches/rosch/110511roschpharma.pdf [hereinafter Rosch, Patent Settlements]; J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, The Antitrust/Intellectual Property Interface: Thoughts on How to Best Wade Through the Thicket in the Pharmaceutical Context, Remarks Before the World Generic Medicine Congress at 2–6 (Nov. 17, 2010), http://www.ftc.gov/speeches/rosch/101117roschworldspeech.pdf [hereinafter Rosch, Pharmaceutical Thicket].

[2] *In re* AndroGel Antitrust Litig., 687 F. Supp. 2d 1371 (N.D. Ga.), *clarified*, No. 1:09-cv-00955-TWT, 2010 U.S. Dist. LEXIS 113593 (N.D. Ga. Sept. 16, 2010).

[3] *Id.* at 1373.

application (ANDA) to market and sell generic versions of ANDROGEL®.[4] Par became involved as well when it struck an agreement with Paddock to market and sell Paddock's generic version.[5]

The Commission brought suit in 2009 against the defendants, challenging the patent litigation settlements between Solvay, on the one hand, and Watson, Paddock, and Par, on the other hand, as anticompetitive, pay-for-delay arrangements.[6] The defendants moved to dismiss, and the district court granted their motion as to the Commission's claims, ruling that these claims failed as a matter of law because the Commission's complaint did "not allege that the settlements exceed the scope of the '894 patent."[7]

In my view, a fundamental flaw in the district court's decision was its overly rigid application of the test in *Schering-Plough Corp. v. FTC*[8] on a motion to dismiss brought under Rule 12 of the Federal Rules of Civil Procedure.[9] Setting aside for the moment the question whether the *Schering-Plough* test supplies the optimum legal standard for assessing the

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[4] *Id.* at 1374.

[5] *Id.*

[6] *Id.* at 1375–76.

[7] *Id.* at 1379.

[8] 402 F.3d 1056, 1066 (11th Cir. 2005) ("[W]e think the proper analysis of antitrust liability requires an examination 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.").

[9] FED. R. CIV. P. 12(b)(6).

anticompetitive effects of a challenged, pharmaceutical patent settlement,[10] it is clear that the Eleventh Circuit fashioned that test as an alternative to traditional per-se or rule-of-reason analysis of the facts and the evidence relating to a challenged settlement, adduced either during trial or on summary judgment.[11] There was no precedent for the district court to apply that test in a literal and exacting manner when evaluating the sufficiency of complaint allegations that only have to state a plausible entitlement to relief under the notice pleading standard of Rule 8 of the Federal Rules of Civil Procedure[12] and *Bell Atlantic Corp. v. Twombly*.[13] Neither *Schering-Plough* nor *Valley Drug* can be fairly read as articulating a heightened standard for pleading Sherman Act claims involving patent settlements.

Indeed, the Eleventh Circuit itself made this clear in *Andrx Pharmaceuticals, Inc. v. Elan Corp.*[14] In that case the court of appeals reversed the district court's grant of a motion to dismiss a pay-for-delay

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[10] *See* J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Pay-for-Delay Settlements, Authorized Generics, and Follow-On Biologics: Thoughts on How the Competition Law Can Best Protect Consumer Welfare in the Pharmaceutical Context, Remarks Before the World Generic Medicine Congress at 5, 8–9 (Nov. 19, 2009), http://www.ftc.gov/speeches/rosch/091119worldgenerics.pdf (expressing my own view that the optimum legal standard is a "truncated" rule-of-reason standard).

[11] *Schering-Plough*, 402 F.3d at 1058, 1065–66 (articulating the test to address the issue whether substantial evidence supported the Commission's conclusion, after an administrative trial, that the Schering-Plough agreements violated Section 1 of the Sherman Act and Section 5 of the FTC Act); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1304 (11th Cir. 2003) ("The analytic focus should be on what conclusions regarding the competitive impact of a challenged restraint can confidently be drawn from the facts demonstrated by the parties.") (addressing a similar issue on summary judgment).

[12] FED. R. CIV. P. 8(a)(2).

[13] 550 U.S. 544, 555–56 (2007).

[14] 421 F.3d 1227 (11th Cir. 2005).

complaint, observing that the notice pleading standard of Rule 8 applies equally to antitrust cases, and that dismissals on the pleadings in antitrust cases are "particularly disfavored" because of their fact-intensive nature.[15] Accordingly, although it referenced the *Schering-Plough* test as a guide, the court of appeals held that it was sufficient for the plaintiff, Andrx, to have alleged that the Elan–SkyePharma settlement agreements "effectively barred any generic competitors from entering the market," in derogation of the provisions of the Hatch–Waxman Act that permit entry of generic versions of previously approved, patented products.[16]

*Andrx* thus recognized that a patent's exclusionary scope cannot be defined in a vacuum; rather, it must be understood in the context of a regulatory scheme under which generic products that would otherwise be excluded by the patent claims are allowed entry under certain, specified conditions.[17] Settlement agreements that have the effect of thwarting entry otherwise permitted under the Hatch–Waxman Act "exceed the scope of the exclusion intended by [the patent in question]."[18] In *Watson*, the Commission alleged, among other things, that "Solvay and Besins were unlikely to

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[15] *Id.* at 1234–35.

[16] *Id.* at 1235.

[17] *Id.* I have made this observation before. *See* Rosch, *supra* note 10, at 12 ("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.").

[18] *Andrx*, 421 F.3d at 1235.

prevent generic entry through their patent lawsuits" because they had to overcome the substantial noninfringement, invalidity, and unenforceability defenses asserted by Watson and Par/Paddock; and that Solvay's agreements with Watson and Par/Paddock "eliminated the potential" that the latter firms would have legitimately entered the market with generic versions under multiple scenarios.[19] Consistent with *Andrx*, these allegations should have been sufficient to plead the second element of the *Schering-Plough* test.

Furthermore, in *Twombly*, the Supreme Court reaffirmed that "when a complaint adequately states a claim, it may not be dismissed based on a district court's assessment that the plaintiff will fail to find evidentiary support for his allegations or prove his claim to the satisfaction of the factfinder."[20] And yet, that was essentially what the district court did in *Watson*. Notwithstanding the factual detail contained in a 44-page, 112-paragraph complaint that included a section entitled "Solvay's Patent Was Unlikely to Prevent Generic Competition to AndroGel,"[21] the district court applied the *Schering-Plough* test to decide whether the Commission could

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[19] 2d Amended Compl. for Inj. and Other Relief ¶¶ 92–94, FTC v. Watson Pharms., Inc., 687 F. Supp. 2d 1371 (N.D. Ga. 2010) (No. 1:09-cv-00955-TWT), ECF No. 114, *available at* https://ecf.gand.uscourts.gov/doc1/05503487663.

[20] *Twombly*, 550 U.S. at 563 (citing for comparison Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) (a district court weighing a motion to dismiss asks "not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims")).

[21] 2d Amended Compl. for Inj. and Other Relief ¶¶ 86–92, FTC v. Watson Pharms., Inc., 687 F. Supp. 2d 1371 (N.D. Ga. 2010) (No. 1:09-cv-00955-TWT), ECF No. 114, *available at* https://ecf.gand.uscourts.gov/doc1/05503487663.

ultimately prove its case that the challenged Solvay settlement agreements were, on balance, anticompetitive.

In summary, our appeal in *Watson* highlights the importance, when we bring an alleged pay-for-delay case, of having the opportunity to develop the facts and the evidence relating to a challenged patent settlement. Regardless of what legal standard a court of appeals has directed the district courts to apply,[22] the facts and the evidence are what ultimately dictate the conclusion. While some challenged settlements may pass muster under a given legal standard based on the underlying facts and circumstances, other settlements may well be struck down as anticompetitive upon closer inspection. The courts should not foreclose this fact-intensive analysis through improvident dismissals under Rule 12.

**B.**

In the Third Circuit we are involved in two cases of note. The first is the district court litigation in *FTC v. Cephalon, Inc.*,[23] pending in the Eastern District of Pennsylvania. Again, those of you who are following the case will be familiar with the facts but let me briefly review them for everyone's benefit.

Cephalon, Inc., the brand-name manufacturer of a prescription drug for promoting wakefulness in adults suffering from sleep disorders, marketed

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[22] Again, to be clear, this is not to say that the Eleventh Circuit's test in *Schering-Plough* supplies the proper legal standard.

[23] No. 2:08-cv-02141-MSG (E.D. Pa. transferred May 8, 2008).

under the trademark PROVIGIL®, entered into patent litigation settlements with four would-be generic sellers, Barr Laboratories, Inc.; Mylan Laboratories, Inc.; Teva Pharmaceutical Industries, Ltd., and its U.S. subsidiary; and Ranbaxy Laboratories, Ltd., and its U.S. subsidiary.[24] Cephalon's main patent covering a formulation of modafinil, the active ingredient in PROVIGIL®, is U.S. Reissue Patent No. 37,516.[25] Our case is one of several antitrust cases challenging the Cephalon patent settlements as anticompetitive, pay-for-delay arrangements.[26]

First, it bears observing that the district court in *Cephalon*, like the district court in *Watson*, also entertained motions to dismiss filed by the defendants, but reached the opposite conclusion.[27] Applying the same framework outlined in *Schering-Plough*,[28] the *Cephalon* district court concluded that the plaintiffs had sufficiently alleged that the Cephalon settlements exceeded the scope of the RE'516 patent's exclusionary potential, because Cephalon could not have obtained the same relief against Barr,

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[24] King Drug Co., Inc. v. Cephalon, Inc., 702 F. Supp. 2d 514, 519 (E.D. Pa. 2010).

[25] *Id.* at 521.

[26] *Id.* at 518–19. In addition to our case, there are cases brought by putative classes of direct purchasers, *King Drug Co., Inc. v. Cephalon, Inc.*; cases brought by putative classes of end payors and indirect purchasers, *Vista Healthplan, Inc. v. Cephalon, Inc.*; and a case brought by another generic manufacturer, *Apotex, Inc. v. Cephalon, Inc.* Unlike the other cases, Apotex's case also includes claims for declaratory judgment of noninfringement, invalidity and unenforceability of the RE'516 patent.

[27] I have made this observation before. *See* Rosch, Patent Settlements, *supra* note 1, at 5; Rosch, Pharmaceutical Thicket, *supra* note 1, at 7.

[28] *King Drug*, 702 F. Supp. 2d at 528 ("After careful consideration, we will apply a framework which examines whether any of the agreements in question exceed the exclusionary patent rights granted to Cephalon.") (reviewing the legal standards from the Second, Sixth, Eleventh, and Federal Circuits).

Mylan, Teva, and Ranbaxy through litigation, given the defenses of noninfringement, invalidity, and unenforceability asserted by the latter generic companies.[29] Furthermore, the *Cephalon* district court distinguished, as I have done here, its examination of a complaint on a motion to dismiss from dismissals made after summary judgment or trial, as seen in *Valley Drug* and *Schering-Plough*.[30] In my view, the *Cephalon* district court's ruling lent further support to our Eleventh Circuit appeal challenging the *Watson* district court's ruling as reversible error.[31]

Second, and more recently, the *Cephalon* district court postponed the filing of any summary judgment motions by the defendants on the plaintiffs' antitrust claims pending its issuance of rulings regarding noninfringement, invalidity, and unenforceability of the RE'516 patent, as asserted in Apotex, Inc.'s declaratory judgment claims.[32] The court subsequently issued, on October 31, 2011, a memorandum opinion finding that the RE'516 patent was invalid because the claimed invention (1) was on sale more than one year before the patent application was filed, (2) was actually invented by another company, (3) was obvious to a person skilled in the art, and (4) was

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[29] *Id.* at 530–32.

[30] *Id.* at 535 ("Moreover, at this stage of the litigation, wherein we are examining the complaints, we must accept as true Plaintiffs' contentions that the agreements were drafted as broadly as possible, affording Cephalon greater exclusionary rights than they may be entitled to under the patent.") & 536 ("We also note that all of the circuit courts, except one (1), who have adopted the scope of the patent framework and dismissed the case, did so where the litigation was at the summary judgment stage of the proceedings.").

[31] *See* Rosch, Pharmaceutical Thicket, *supra* note 1, at 7.

[32] Order, FTC v. Cephalon, Inc., No. 2:08-cv-02141-MSG (E.D. Pa. Aug. 23, 2011), ECF No. 165.

inadequately described in the patent.[33] The court also found that the RE'516 patent was unenforceable because of Cephalon's inequitable conduct.[34]

I am not going to parse the detailed, patent-law analyses of the *Cephalon* district court's memorandum opinion. Suffice it to say, the court's findings of invalidity and unenforceability of the RE'516 patent should bolster the plaintiffs' claims that the Cephalon settlements exceeded the scope of the patent[35] because an invalid or unenforceable patent, as a matter of law, has no exclusionary potential.[36] Because *Cephalon* involves the case of an antitrust plaintiff (Apotex) that is at the same time litigating issues of patent validity and enforceability, the trial court has by necessity conducted in this case a fulsome evaluation of patent strength—an exercise that both the Commission and the Department of Justice fear might make the scope-of-the-patent standard for challenging patent settlements too unwieldy and burdensome to apply.[37] Be that as it may, the inquiry was made here, and the

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[33] Amended Memorandum Opinion at 1, Apotex, Inc. v. Cephalon, Inc., No. 2:06-cv-02768-MSG, 2011 U.S. Dist. LEXIS 125859, at *5 (E.D. Pa. amended Nov. 7, 2011), ECF No. 516, *available at* https://ecf.paed.uscourts.gov/doc1/153110663884.

[34] *Id.*, 2011 U.S. Dist. LEXIS 125859, at *5–6. According to the Memorandum Opinion, a separate decision regarding the issue of noninfringement is forthcoming. *Id.* at 2, 2011 U.S. Dist. LEXIS 125859, at *6.

[35] *See King Drug*, 702 F. Supp. 2d at 533 ("Having determined that the scope of the patent test framework applies, and viewing the complaints and the allegations contained therein in the light most favorable to Plaintiffs, we find that sufficient facts have been alleged to establish that the agreements in question grant greater rights than those conferred under the patent. As detailed above, the complaints allege fraud and misrepresentations to the PTO, non-infringement, patent invalidity,…").

[36] *See, e.g.,* Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1580 (Fed. Cir. 1983) ("The claim being invalid there is nothing to be infringed.").

[37] *See, e.g.,* Brief of the Federal Trade Commission as Amicus Curiae Supporting Appellants and Urging Reversal at 26–27, *In re* K-Dur Antitrust Litig., Nos. 10-2077, -2078, -2079 & -

resulting findings should help the plaintiffs prove their case under the district court's adopted, scope-of-the-patent standard.

The parties were scheduled to appear before the court yesterday (December 6, 2011) for a status conference to discuss the filing of summary judgment motions.[38] Stay tuned for the next episode.

The other case of note in the Third Circuit is the pending appeal in the *K-Dur Antitrust Litigation*,[39] which has been scheduled for oral argument next week (December 12, 2011). Both the Commission and the Department of Justice filed amicus briefs, and on behalf of both Agencies, the Solicitor General moved the court of appeals for leave to participate in the argument.[40]

You probably will not be surprised to hear me report that the Agencies have urged the Third Circuit to adopt a different—and arguably more

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4571 (3d Cir. May 18, 2011) [hereinafter FTC Brief] ("Although [an inquiry into the strength of the patent] is certainly preferable to a rule that protects agreements that perpetuate exclusion based on the weakest patents, … it nevertheless requires that courts and litigants must revisit patent issues the parties previously sought to resolve without litigation.") (footnote omitted); Brief for the United States as Amicus Curiae Supporting Plaintiffs-Appellants at 26–27, *In re* K-Dur Antitrust Litig., Nos. 10-2077, -2078, -2079 & -4571 (3d Cir. May 18, 2011) [hereinafter U.S. Brief] ("Requiring a court to determine whether the patentee would have prevailed—to base antitrust liability on a binary determination of patent validity and infringement *vel non*—would unduly complicate the litigation by requiring at least a mini-trial of the patent issue in the antitrust case, and likely more.") (footnote omitted).

[38] Order, FTC v. Cephalon, Inc., No. 2:08-cv-02141-MSG (E.D. Pa. Nov. 8, 2011), ECF No. 166.

[39] Nos. 10-2077, -2078, -2079 & -4571 (3d Cir. argument scheduled Dec. 12, 2011).

[40] Motion of the United States and the Federal Trade Commission for Leave to Participate in Oral Argument, *In re* K-Dur Antitrust Litig., Nos. 10-2077, -2078, -2079 & -4571 (3d Cir. Sept. 20, 2011).

straightforward—legal standard for assessing the anticompetitive effects of patent litigation settlements than those adopted by other circuits:[41]

- That patent settlements, like other private contracts, are subject to antitrust scrutiny,[42] to be evaluated under the rule of reason rather than the per se rule;[43]
- That patent settlements involving payments in exchange for additional market exclusion (e.g., delayed entry) should be viewed as presumptively unlawful and inherently suspect;[44] and
- That antitrust defendants may rebut the presumption by offering evidence that the payment was for something other than additional market exclusion, or that the terms of the settlement, including the payment, reasonably reflected the parties' contemporaneous evaluations of the impact of a judgment in the patent litigation on the duration and timing of market exclusion.[45]

As I have said before, I generally agree with this approach,[46] but with the added clarification that the burden the antitrust defendants bear should be one of production, that is to say, to come forward with evidence justifying their patent settlement (including why they settled the case), and that the

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[41] By now, we all should know the other cases by heart: Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir.), *reh'g en banc denied*, 625 F.3d 779 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606 (2011); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003); *In re* Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003); Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799 (D.C. Cir. 2001).

[42] FTC Brief at 20; U.S. Brief at 15 & 19.

[43] FTC Brief at 22–23; U.S. Brief at 21–22.

[44] FTC Brief at 22–25; U.S. Brief at 23–25.

[45] FTC Brief at 25–27; U.S. Brief at 31–33.

[46] *See* Rosch, *supra* note 10, at 8–9.

ultimate burden of persuasion regarding the settlement's alleged anticompetitive effects should always rest with the antitrust plaintiffs.

In this manner, the truncated rule-of-reason approach strikes an appropriate balance between antitrust plaintiffs and defendants. On the one hand, the plaintiffs are entitled to an evidentiary presumption because pay-for-delay settlements resemble, on their face, illegal market division agreements and hence should be considered "inherently suspect." On the other hand, defendants should be entitled to explain the nature and rationale underlying their settlements by coming forward with evidence largely in their exclusive possession.

We shall see whether the Third Circuit accepts our invitation to chart a different course from the other circuits. Stay tuned on this case as well.

**C.**

I think it is fair to say that our enforcement and advocacy efforts in the pharmaceutical arena have been girded in the working premise that Congress, in enacting the Hatch–Waxman Act, sought to strike a balance between new-drug innovation by brand manufacturers and follow-on competition by generic manufacturers. This balance is not static, however. The location of the pivot point in this pharmaceutical seesaw depends on the strength and scope of the new-drug patent in question. At the risk of oversimplifying, new drugs protected by weak or narrow patents are less

likely to escape the early onset of generic competition than new drugs protected by strong or broad patents.[47]

By statutory design, the principal way to find out where to set the pivot point is through patent litigation initiated under Paragraph IV.[48] Accordingly, while settlements of litigation are to be encouraged, they should not enable a brand manufacturer to pay a generic manufacturer for the right to move the pivot point further to one side than it would have been had the litigation gone forward. Think about it—such settlements in effect render the Paragraph IV process a nullity; one might as well let the parties decide arbitrarily from the outset where to set the pivot point and not bother at all with the litigation. That cannot be viewed as a "natural byproduct" of the Hatch–Waxman Act.[49]

As I have said, weak or narrow patents are less able to forestall the early onset of generic competition. In other words, early generic entry can occur under the Hatch–Waxman Act if a new-drug patent is found to be invalid or unenforceable, or if it is found not to cover the generic version. To

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[47] Granted, broad patents are not always strong patents because the breadth of their claims may potentially put them in conflict with the prior art. But the point I am making here—again, at the risk of oversimplifying—is that patents claiming particular drug formulations or methods of use are generally likely to be easier for generics to work around than patents that claim drug compounds.

[48] 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV), (2)(B) & (5)(B)(iii) (2010). None of the other certifications raises a challenge to patent strength (i.e., validity or enforceability) or scope (i.e., infringement). *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I–III) (2010).

[49] *See* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005) ("The Commission's inflexible compromise-without-payment theory neglects to understand that 'reverse payments are a natural by-product of the Hatch-Waxman process.'" (quoting *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003))).

reinforce this concept, the Hatch–Waxman Act includes a provision that allows a generic defendant, in the context of a Paragraph IV infringement action, to counterclaim for a court order that would require the brand plaintiff to "correct or delete the patent information" for a listed new drug on the ground that the patent does not in fact claim the new drug or "an approved method of using the drug."[50] The goal of this provision is clear—to facilitate early generic entry if a new-drug patent does not in fact claim the new drug for which a generic version would be offered, or "an approved method of using the drug" for which a generic version would be indicated.

This brings me to the next case in which we are involved, *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*,[51] pending in the Supreme Court and just argued on Monday of this week (December 5, 2011). As you may know, the question presented in this case is whether the counterclaim provision I have just described "applies where (1) there is 'an approved method of using the drug' that 'the patent does not claim,' and (2) the brand submits 'patent information' to the FDA that misstates the patent's scope, requiring 'correct[ion].'"[52] The Solicitor General participated in the argument as amicus curiae,[53] supporting the petitioners and representing the

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[50] 21 U.S.C. § 355(j)(5)(C)(ii) (2010).

[51] 601 F.3d 1359 (Fed. Cir.), *reh'g en banc denied*, 615 F.3d 1374 (Fed. Cir. 2010), *cert. granted*, 131 S. Ct. 3057 (2011) (No. 10-844).

[52] Question Presented, Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, No. 10-844 (U.S. June 27, 2011), *available at* http://www.supremecourt.gov/qp/10-00844qp.pdf.

[53] For a copy of the United States' amicus brief, *see* Brief for the United States as Amicus Curiae Supporting Petitioners, Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, No. 10-844

interests of the Commission as well as the Food and Drug Administration and the Patent and Trademark Office.

I expect the Court to rule in the petitioners' favor. Why? Simply put, the phrase "an approved method of using the drug" must be construed in the context of the statutory provision in which it appears. Abstract debates over competing dictionary definitions of the article "an" do not yield an answer to the question presented. Instead, looking at the language and structure of the counterclaim provision, it is clear that this phrase is used to describe one of the grounds, i.e., "the patent does not claim … an approved method of using the drug," that would warrant an order requiring "correction or deletion" of erroneous patent information (which includes "use codes" that are supposed to track the approved method(s) of use claimed by a patent).[54] And the only logical reason that a generic defendant would avail itself of this provision and seek such relief is if it were seeking to offer a generic version of the new drug for a particular indication—"an approved method of using the drug"—that happens not to be claimed by a new-drug patent.[55]

Thus understood, even if a patent indisputably claims an approved method "A", correction would still be proper and required if the patent does not claim an approved method "B" for which the generic version would be

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(U.S. Sept. 6, 2011), *available at* http://www.americanbar.org/content/dam/aba/publishing/previewbriefs/Other_Brief_Updates/10-844_petitioneramcuusa.authcheckdam.pdf.

[54] 21 U.S.C. § 355(j)(5)(C)(ii) (2010).

[55] 21 U.S.C. § 355(j)(2)(A)(viii) (2010).

indicated.[56] Otherwise, the very purpose of the counterclaim provision within the Paragraph IV process—to facilitate early entry by noninfringing generic versions—would be thwarted. In arguing that correction of erroneous patent information is not required as long as the patent correctly claims an (i.e., at least one) approved method of using the drug, the respondents have proffered what is in my view a tortured construction of the phrase "an approved method of using the drug."[57]

## II. Proposed Legislation and the Option of Rulemaking

Let me switch gears now to talk about pay-for-delay legislation that has been proposed in the 112th Congress, and to offer a few thoughts about the alternative route of rulemaking available to the Commission.

### A.

We now have pending in Congress two separate Senate bills relating to pay-for-delay settlements.[58] The first one is Senate Bill 27, known and referred to

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[56] Of course, if a patent does not claim any of the approved methods, then the proper remedy would not be correction, but deletion altogether.

[57] Another way to understand the fallacy in the respondents' argument is to consider the counterclaim provision as a conditional, if–then statement: *If a patent does not claim an approved method of using the drug, then correction or deletion is required*. The respondents would have the Supreme Court infer that the inverse of this conditional statement is also true, when in fact it is not necessarily so: *If a patent does claim an approved method of using the drug, then correction or deletion is not required*. Only the conditional statement is always true because the "if" clause supplies the condition (an error) that warrants the stated action. The inverse is not necessarily true because the condition does not rule out the existence of an error that would make the stated action (no correction or deletion required) false.

[58] Neither bill currently has a counterpart in the House.

by name as the Kohl–Grassley "Preserve Access to Affordable Generics" Act.[59] It was introduced on January 25, 2011, and reported favorably out of committee without amendment on July 22, 2011. The other one is Senate Bill 1882, known and referred to by name as the Bingaman–Vitter "Fair and Immediate Release of Generic Drugs Act."[60] It was introduced and referred to committee on November 16, 2011.

The Kohl–Grassley bill represents a proposed legislative solution to anticompetitive, pay-for-delay settlements, and it would amend the FTC Act to specifically empower the Commission to enforce Section 5 against such settlements,[61] as well as to engage in related rulemaking.[62] As I have publicly stated,[63] a proposed legislative solution to the pay-for-delay problem is too important an issue to be tacked on to any other legislation—such as the deficit reduction package that was being considered by the "super committee"—and adopted based on its purported and speculative savings of "billions" of dollars over a ten-year period. Instead, Senate Bill 27 should be considered on its own merits by Congress.

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[59] Preserve Access to Affordable Generics Act, S. 27, 112th Cong. (2011), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-112s27rs/pdf/BILLS-112s27rs.pdf.

[60] Fair and Immediate Release of Generic Drugs Act, S. 1882, 112th Cong. (2011), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-112s1882is/pdf/BILLS-112s1882is.pdf.

[61] S. 27 § 3(a) (proposed FTC Act § 28(a)(1)).

[62] *Id.* (proposed FTC Act § 28(e)).

[63] *See* J. Thomas Rosch, Letter to the Editor, POLITICO (Nov. 9, 2011, 1:35 PM), http://www.politico.com/news/stories/1111/67963.html. The text is also available at http://www.ftc.gov/speeches/rosch/111109lteonleibowitz.pdf.

I have also noted that the Kohl–Grassley bill does not take a sledgehammer to the pay-for-delay problem by condemning such settlements outright.[64] Instead, the approach is nuanced; it creates a presumption that pay-for-delay settlements are anticompetitive,[65] which the settlement parties may rebut with "clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement."[66] A fact-finder is required to consider various "competitive factors" in deciding whether the settlement parties have met their burden on rebuttal.[67]

However, consistent with my views on the optimum judicial standard for evaluating anticompetitive pay-for-delay settlements,[68] I think that the Kohl–Grassley bill may stack the deck too much in the Commission's favor.[69] Specifically, the settlement parties' burden should be one of production, that is, to come forward with reasons justifying their settlement, and not one of persuasion. The burden of proving that the anticompetitive effects of a challenged settlement outweigh any procompetitive benefits should always remain with the Commission.

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[64] *Id.*

[65] S. 27 § 3(a) (proposed FTC Act § 28(a)(2)(A)).

[66] *Id.* (proposed FTC Act § 28(a)(2)(B)).

[67] *Id.* (proposed FTC Act § 28(b)).

[68] *See* Rosch, *supra* note 10, at 8–9.

[69] Rosch, *supra* note 63.

Furthermore, even if the settlement parties' burden were properly one of persuasion, the standard of proof should not be by clear and convincing evidence. As far as I know, there is no precedent for employing this heightened standard, and such a standard may unduly chill settlements of litigation, which are encouraged under recognized federal policy.[70] The Kohl–Grassley bill may thus be doubly flawed.

I do not have much to say about the recently introduced Bingaman–Vitter bill[71] other than to note that it approaches the pay-for-delay problem from a regulatory angle, as opposed to an enforcement angle. Specifically, in contrast to the Kohl–Grassley bill, which charges the Commission with the task of prosecuting anticompetitive, pay-for-delay settlements as violations of the FTC Act, the Bingaman–Vitter bill would neutralize the impact of such agreements on timely generic entry.[72] The bill's basic approach is to grant

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[70] *See, e.g.,* Williams v. First Nat'l Bank, 216 U.S. 582, 595 (1910); Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1369 (Fed. Cir. 2001).

[71] For ease of reference, I am leaving off the names of two other sponsors of this bill, Senators Brown and Merkley.

[72] The bill's sponsors refer to the problem as one of "parked exclusivities." *See* Summary, Sen. Jeff Bingaman, Bingaman–Vitter–Brown–Merkley Fair and Immediate Release of Generic Drugs Act of 2011 (Nov. 16, 2011), http://bingaman.senate.gov/policy/FAIRGenerics.pdf (asserting that "the root cause of anti-competitive pay-for-delay settlements between brand and generic pharmaceutical manufacturers" is "the unintended, structural flaw in the Hatch-Waxman Act that allows 'parked' exclusivities to block generic competition"). *See also* Press Release, Sen. Jeff Bingaman, Bipartisan Bill Would Bring Generic Drugs to Market Sooner, Saving Americans Millions of Dollars in Health Care Costs (Nov. 16, 2011), http://bingaman.senate.gov/news/20111116-02.cfm.

"shared exclusivity" to "any generic filer who wins a patent challenge in the district court or is not sued for patent infringement by the brand company."[73]

**B.**

I have suggested in the past that rulemaking remains an alternative available to the Commission should its efforts in the courts and before Congress not prove to be successful.[74] And the press has picked up on the possibility of this avenue as well.[75] But critics have raised two arguments against this alternative, to which I want to respond today. One argument is that rulemaking would be improper because the Commission would be resorting to this option only as a result of not having had much success in the courts or before Congress.[76] Another argument is that rulemaking would not stand up in the courts because the Commission in essence would be telling

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[73] FAIR Generics Act Summary, *supra* note 72. Specifically, the bill appears to amend the current definition of "first applicant" in the Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) (2010), so that this term would exclude any first ANDA filer that enters into a "disqualifying" (i.e., pay-for-delay) agreement, Fair and Immediate Release of Generic Drugs Act, S. 1882 §§ 2 & 3, 112th Cong. (2011) (proposed 21 U.S.C. § 355(j)(5)(B)(v)(I) & (vii)(II), respectively), but include any subsequent ANDA filer that successfully obtains a judgment of invalidity or noninfringement in any ensuring Paragraph IV litigation and does not enter into a "disqualifying" agreement, *id.* § 2 (proposed 21 U.S.C. § 355(j)(5)(B)(vi)).

[74] Rosch, Patent Settlements, *supra* note 1, at 6–7.

[75] *See, e.g.,* Sara Forden, *Pay-for-Delay Drug Deals Said to Be Target for Rule at FTC*, BLOOMBERG (June 9, 2011, 8:45 AM), http://www.bloomberg.com/news/2011-06-09/pay-for-delay-pharmaceutical-settlements-said-to-be-target-of-new-ftc-rule.html; Ed Silverman, *FTC May Use Rules to Thwart Pay-to-Delay Deals*, PHARMALOT (June 9, 2011, 10:10 AM), http://www.pharmalot.com/2011/06/ftc-may-use-rules-to-thwart-pay-to-delay-deals/.

[76] Forden, *supra* note 75 ("The 'If you don't at first succeed try, try, and try again' approach to policy making by an independent agency isn't appropriate." (quoting Sean Heather, executive director of the global regulatory cooperation project at the U.S. Chamber of Commerce)); Silverman, *supra* note 75 (same).

judges that they are wrong to encourage settlements that avoid litigation costs.[77]

Here is my response to the first argument. As a threshold matter, rulemaking has always been an option available to the Commission. Specifically, when Congress enacted the FTC Act in 1914, it chose to leave the task of defining "unfair methods of competition" to the Commission in the first instance.[78] Congress therefore empowered the Commission, as an independent agency, to pursue this task either through the adjudicative process under Section 5(b) of the Act[79] or the rulemaking process under Section 6(g) of the Act.[80]

The D.C. Circuit has made clear that Section 6(g) permits the Commission to promulgate substantive rules defining the "unfair methods of competition" that the agency is empowered under Section 5(b) to prevent.[81] Rulemaking complements case-by-case adjudication by allowing the Commission "to proceed more expeditiously, give greater certainty to

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[77] Forden, *supra* note 75 ("Judges who have been trained to encourage settlements to avoid the costs of litigation now have the FTC trying to tell them they're wrong. It's a tough sell." (quoting Marc Schildkraut, a lawyer with Dewey & LeBoeuf LLP and counsel to Schering-Plough Corp. in the FTC enforcement proceedings)); Silverman, *supra* note 75 (same).

[78] S. REP. NO. 63-597, at 13 (1914); FTC v. Texaco Inc., 393 U.S. 223, 225–26 (1968); FTC v. Beech-Nut Packing Co., 257 U.S. 441, 453 (1922).

[79] 15 U.S.C. § 45(b) (2010).

[80] 15 U.S.C. § 46(g) (2010) (enumerating as an additional power of the Commission, the ability "[f]rom time to time …. to make rules and regulations for the purpose of carrying out the provisions of this subchapter").

[81] Nat'l Petroleum Refiners Ass'n v. FTC, 482 F.2d 672, 698 (D.C. Cir. 1973) ("[U]nder Section 6(g), 15 U.S.C. § 46(g), in particular, the Federal Trade Commission is authorized to promulgate rules defining the meaning of the statutory standards of the illegality the Commission is empowered to prevent.").

businesses subject to the Act, and deploy its internal resources more efficiently[.]"[82] And indeed, the use of rulemaking "to make innovations in agency policy may actually be fairer to regulated parties than total reliance on case-by-case adjudication" because it opens up the agency's policymaking process "to a broad range of criticism, advice and data that is ordinarily less likely to be forthcoming in adjudication[,]" and it produces rules that, unlike adjudicative holdings, "are more specific as to their scope" and therefore more likely to provide clearer notice and to secure industry compliance.[83]

Moreover, the Supreme Court has made clear that "the choice made between proceeding by general rule or by individual, ad hoc litigation is one that lies primarily in the informed discretion of the administrative agency."[84] Thus, it is up to the Commission to decide whether and when the time is ripe to resort to rulemaking. And the fact that we have not heretofore resorted to rulemaking in addressing the pay-for-delay problem is not a valid basis for arguing that we may not do so in the future, regardless of what our success rate with other processes has been.[85]

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[82] *Id.* at 690.

[83] *Id.* at 681, 683, 690–91. *See also* Cmty. Television v. Gottfried, 459 U.S. 498, 511 (1983) ("[R]ulemaking is generally a 'better, fairer, and more effective' method of implementing a new industrywide policy than is the uneven application of conditions in isolated license renewal proceedings.").

[84] SEC v. Chenery Corp., 332 U.S. 194, 203 (1947). *Accord* NLRB v. Bell Aerospace Co., 416 U.S. 267, 294 (1974).

[85] United States v. Morton Salt Co., 338 U.S. 632, 647–48 (1950) ("The fact that powers long have been unexercised well may call for close scrutiny as to whether they exist; but if granted, they are not lost by being allowed to lie dormant, any more than nonexistent powers can be prescripted by an unchallenged exercise.… We find no basis for holding that any power ever granted to the Trade Commission has been forfeited by [nonuse].") (rejecting an

In response to the second argument, I would point out that under *Chevron*,[86] courts are required to give deference to the Commission's rulemaking since it would involve an area in which Congress "has explicitly left a gap for the agency to fill."[87] In the area of pay-for-delay settlements, we not only have Congress' delegation of legislative authority over "unfair methods of competition" generally under Sections 5(a) and 6(g) of the FTC Act, but also our enforcement powers under the Hatch–Waxman Act (which specifically invokes our enforcement of Section 5)[88] and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (which specifically provides for rulemaking with respect to our review of agreements filed under that Act).[89]

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argument that the Commission's ordering of reports under Sections 6(a) and 6(b) to detail respondents' continuing compliance with a cease-and-desist order was "novel and unprecedented").

[86] Chevron U.S.A., Inc. v. Natural Res. Defense Council, Inc., 467 U.S. 837 (1984).

[87] *Id.* at 843–44 ("If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute."). *See also* FTC v. Colgate-Palmolive Co., 380 U.S. 374, 385 (1965) ("This Court has frequently stated that the [FTC's] judgment is to be given great weight by reviewing courts.").

[88] 21 USC 355(j)(5)(D)(i)(V) (2010) ("… the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 45 of title 15 to the extent that that section applies to unfair methods of competition)").

[89] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1115–16, 117 Stat. 2066, 2463 (2003) (providing civil penalties and equitable relief for noncompliance and the promulgation of "such other rules as may be necessary and appropriate to carry out the purposes of this subtitle").

Furthermore, it strikes me that courts should be less unfriendly to the Commission's rulemaking if we were to proceed, as I have outlined,[90] with a rule that does not ban pay-for-delay settlements outright but rather, treats them as "inherently suspect." Specifically, the Commission would bear the initial burden of showing the existence of a quid pro quo between the "payment" and the "delay"; the respondents would then bear a burden of production with respect to their justifications for the agreement; and the Commission would bear the ultimate burden of showing that the agreement is anticompetitive under the rule of reason. Not only would such a rule comport with the Administrative Procedure Act,[91] which governs Section 6(g) rulemakings, but it would also provide expedition and fairness to adjudicative proceedings instituted based on the rule.[92] Such a rule would also strike a balance between the judicial policy favoring settlements of litigation and the congressional policy directing that Paragraph IV disputes over patent validity and infringement be resolved by the courts, and not the FDA.[93]

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[90] Rosch, Patent Settlements, *supra* note 1, at 7.

[91] *See* 5 U.S.C. §§ 553 & 556(d) (2010).

[92] *See* Nat'l Petroleum Refiners Ass'n v. FTC, 482 F.2d 672, 690 (D.C. Cir. 1973) ("With the issues in Section 5 proceedings reduced by the existence of a rule delineating what is a violation of the statute or what presumptions the Commission proposes to rely upon, proceedings will be speeded up."), *and id.* at 692 ("[S]ome opportunity must be given for a defendant in a Section 5 proceeding to demonstrate that the special circumstances of his case warrant waiving the rule's applicability, as where the rationale of the rule does not appear to apply to his own situation or a compelling case of hardship can be made out.").

[93] *See* 21 U.S.C. §§ 355(j)(5)(B)(iii) & (C) (2010). Proponents of the federal settlement policy forget that there is a significant counterweight here. Unlike other disputes between private parties, including other types of patent infringement litigation, Paragraph IV litigation has a

## III. Studies and Reports

I will wrap up my remarks today with a discussion of the Commission's staff report on authorized generic drugs, issued in August 2011,[94] and our enforcement of the filing provisions under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[95] which I will call the "MMA," for short.

### A.

Authorized generic drugs are defined under the Food, Drug and Cosmetic Act as drugs that have been approved as brand-name drugs but are marketed, sold, or distributed as generic drugs.[96] Importantly, an authorized generic can be launched and marketed by a brand-name manufacturer during the 180-day market exclusivity period awarded to the first ANDA filer, thereby competing with the first-filer's generic version, as well as with other generic versions that subsequently come onto market. Accordingly, in 2005 the

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particularly strong public-interest dimension because Congress intended that meritorious disputes over the validity and infringement of new-drug patents would be resolved by the courts, in aid of the FDA process of approving ANDAs for generic drugs. Although settlements conserve litigation resources and promote judicial economy, they can also frustrate this legislative policy of having the courts clear the roadblocks to early generic entry posed by weak or narrow new-drug patents. *See generally* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1574, 1596–97 (2006) (discussing the "judicial reflex favoring settlement" and the "congressional judgment" favoring litigated challenges).

[94] FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT (2011), *available at* http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf. *See also* Press Release, Fed. Trade Comm'n, FTC Report Examines How Authorized Generics Affect the Pharmaceutical Market (Aug. 31, 2011), http://www.ftc.gov/opa/2011/08/genericdrugs.shtm.

[95] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. IX, subtit. B, 117 Stat. 2066, 2461–64 (2003).

[96] 21 U.S.C. § 355(t)(3) (2010).

Commission was asked by some members of Congress to examine the impact of authorized generics on prices and output of generic drugs, both during the 180-day exclusivity period and beyond, and whether authorized generics in any way undermine the incentives under the Hatch–Waxman Act for entry by ANDA generics.[97]

In June 2009, the Commission issued an interim report,[98] and I issued a statement concurring with the report's bottom-line conclusion that the findings cannot properly be read to support a legislative ban on the marketing of authorized generics, whether during the 180-day exclusivity period or any other period, or to suggest that authorized generics are harmful to consumers.[99] My statement also clarified that we needed to distinguish between the impact of authorized generics on generic drug revenues available to the first-filer and any other ANDA filers, and their impact on overall market prices and output for generics.[100] As an antitrust and consumer protection agency, our principal concern is with the latter—that is, whether the marketing of an authorized generic leads to higher prices or reduced output,

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[97] Letter from Sen. Patrick Leahy, Sen. Chuck Grassley & Sen. John Rockefeller to Chairman Deborah Majoras & the Commissioners (May 9, 2005) (attached as App. A to the Authorized Generics Report); Letter from Rep. Henry Waxman to Chairman Deborah Majoras (Sept. 13, 2005) (attached as App. B to the Authorized Generics Report).

[98] FED. TRADE COMM'N, AUTHORIZED GENERICS: AN INTERIM REPORT (2009), *available at* http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf. *See also* Press Release, Fed. Trade Comm'n, FTC Issues Interim Report on "Authorized Generic" Drugs (June 24, 2009), http://www.ftc.gov/opa/2009/06/generics.shtm.

[99] J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Rosch Concurring Statement on the Release of the Commission's Interim Report on Authorized Generics at 1 (June 24, 2009), http://www.ftc.gov/os/2009/06/P062105authgenconcurringrosch.pdf.

[100] *Id.* at 1–2.

thereby harming consumers—and not with the former—that is, whether ANDA filers stand to make less as a result of ordinary price competition from an authorized generic.[101]

My concurring statement also took issue with the interim report's consideration of the question whether forbearance from marketing an authorized generic may be used as "value" given in exchange for delayed ANDA generic entry in a pay-for-delay settlement, because this was not a question that Congress had asked us to address.[102] Moreover, to the extent that authorized generics were being used as consideration in pay-for-delay settlements, the solution was not to ban the marketing of authorized generics during the exclusivity period, but to treat pay-for-delay settlements that involve authorized generics as "inherently suspect"—no differently than pay-for-delay settlements that involve other forms of "value."[103]

I have summarized my concurring statement because my views have not changed with the issuance of the final report on authorized generics. Indeed, the final report confirmed that authorized generics can provide aggressive price competition for ANDA generics, resulting in lower retail and wholesale generic prices, and expectedly, lower revenues for ANDA filers, both

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[101] I use the word "ordinary" to exclude unusual pricing practices such as below-cost pricing that may well be unlawful under the antitrust laws. *See* Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 222 (1993).

[102] Rosch, *supra* note 99, at 3.

[103] *Id.*

during the 180-day exclusivity period and beyond.[104] With respect to the impact of authorized generics on the incentives to challenge new-drug patents under Paragraph IV, the final report concluded "that the reduced revenue stemming from authorized generic competition during 180-day exclusivity has not affected the generic's incentives in a way that has measurably reduced the number of patent challenges by generic firms."[105] This conclusion reinforces my view that the Commission staff's findings cannot properly be read to support a legislative ban on the marketing of authorized generics during the 180-day exclusivity period.

In summary, the Commission's authorized generics report is another example of how we should strive for balance in enforcing the antitrust laws in the pharmaceutical industry. As an antitrust and consumer protection agency, we should not choose sides and condemn a practice like the marketing of authorized generics, for example, simply because it might conceivably be used by brand-name manufacturers as a ploy to deter generic entry. Instead, we should carefully study and consider the actual market effects, including whether authorized generics yield lower wholesale and retail prices that redound to the benefit of consumers.

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[104] AUTHORIZED GENERIC DRUGS, *supra* note 94, at ii–iii.

[105] *Id.* at iii.

**B.**

As you may know, the MMA requires that brand-name drug companies and generic drug applicants file certain agreements with the Commission and the Justice Department's Antitrust Division within ten business days after their execution.[106] Patent settlements that address the timing of generic entry or the 180-day exclusivity period fall within the ambit of the filing requirement. The Commission has used the filings to create and publish an annual report of patent settlements that may potentially involve some pay-for-delay arrangement.[107] I stress the word "potentially" because as the MMA makes clear, the filing of an agreement does not constitute or create a violation of any competition law.[108] Our staff still has to analyze the agreements and conduct its own investigation before we can bring an enforcement action.

That being the case, there is no excuse for companies not to comply with the MMA's filing requirement. In May 2011, the Commission's Bureau of Competition determined that Sanofi-Aventis, Watson Pharmaceuticals, and Synthon Holdings, B.V. had failed to comply with the filing

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[106] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1112–13, 117 Stat. 2066, 2461–63 (2003). For a summary of the filing requirements, *see* Summary, Fed. Trade Comm'n, Medicare Prescription Drug and Improvement Act Requires Drug Companies to File Certain Agreements with the Federal Trade Commission and U.S. Department of Justice (Jan. 6, 2004), http://www.ftc.gov/os/2004/01/040106pharmrules.pdf.

[107] *See, e.g.,* FED. TRADE COMM'N, BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2011 (Oct. 2011), *available at* http://www.ftc.gov/os/2011/10/1110mmaagree.pdf.

[108] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1117, 117 Stat. 2066, 2463 (2003).

requirement.[109] Although the Bureau could have recommended that the Commission seek civil penalties against the companies as provided under the MMA,[110] it chose instead to use the opportunity to put the companies, and the pharmaceutical industry as a whole, on notice of the MMA's filing requirement, the consequences of noncompliance, and how the Commission staff was applying the statute to the agreements in question.

In my view, the Bureau of Competition took the right approach in resolving this matter. Rather than penalizing the teams, we issued a warning but it was an important one. Simply put, we cannot function properly as referees for competition if we cannot see the plays as they are being executed by the teams.

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Thank you for your attention today. I look forward to taking any questions that you may have.

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[109] Press Release, Fed. Trade Comm'n, FTC Staff Finds Sanofi-Aventis, Watson Pharmaceuticals, and Synthon Holding B.V. Failed to Report Drug Patent Agreements as Required by Law (May 10, 2011), http://www.ftc.gov/opa/2011/05/sanofi.shtm.

[110] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1115(a), 117 Stat. 2066, 2463 (2003).