PREPARED STATEMENT OF THE
FEDERAL TRADE COMMISSION

Before the

COMMITTEE ON THE JUDICIARY

of the

UNITED STATES SENATE

on

ANTICOMPETITIVE PATENT SETTLEMENTS IN THE PHARMACEUTICAL INDUSTRY: THE BENEFITS OF A LEGISLATIVE SOLUTION

January 17, 2007

Summary

Chairman Leahy, Ranking Member Specter, and Members of the Committee, I am Jon Leibowitz, Commissioner of the Federal Trade Commission. I appreciate the opportunity to appear before you today to testify on behalf of the Commission regarding anticompetitive agreements between branded and generic drug firms.[1]

Prescription drugs represent a substantial component of health care spending. Protection of competition in the pharmaceutical sector has been and continues to be among the FTC's highest priorities. In that regard, the agency has directed significant efforts at antitrust challenges to what have come to be called "exclusion payment settlements" (or, by some, "reverse payments"), a term used to describe settlements of patent litigation in which the brand-name drug firm pays its potential generic competitor to abandon the patent challenge and delay entering the market. Such settlements restrict competition at the expense of consumers, whose access to lower-priced generic drugs is delayed, sometimes for many years.

Recent court decisions, however, have made it more difficult to bring antitrust cases to stop exclusion payment settlements, and the impact of those court rulings is becoming evident in the marketplace. These developments threaten substantial harm to consumers and others who pay for prescription drugs. For that reason, the Commission supports legislation to prohibit these anticompetitive settlements and strongly supports the intent of the legislation introduced by Senators Kohl, Leahy, Grassley, and Schumer, including the objective to adopt a bright-line approach to addressing exclusion payments.

Generic drugs play a crucial role in containing rising prescription drug costs by offering consumers therapeutically-identical alternatives to brand-name drugs at a significantly reduced

[1] This written statement represents the views of the Federal Trade Commission. My oral presentation and responses are my own and do not necessarily reflect the views of the Commission or of any Commissioner.

cost. To speed market entry of generic drugs, and to ensure that the benefits of pharmaceutical innovation would continue, in 1984 Congress passed the Hatch-Waxman Act.[2] Hatch-Waxman established a regulatory framework that sought to balance two fundamental objectives: maintaining incentives for continued innovation by research-based pharmaceutical companies and encouraging market entry by generic drug manufacturers.[3] One of the key steps Congress took to promote more rapid introduction of generics was establishing special rules and procedures to encourage firms seeking approval of generic drugs to challenge invalid or narrow patents on branded drugs. The Act likewise encourages brand name drug companies to file infringement suits at an early stage.

Almost six years ago, this Committee held a hearing to examine the implications of some settlements reached under this patent challenge process that Hatch-Waxman established. At that time, the Committee was considering a bill introduced by Senators Leahy and Grassley to facilitate antitrust enforcement by requiring that all such settlements be filed with the FTC and the Department of Justice. Thanks to this filing requirement, which Congress enacted in 2003 as part of a package of reforms to Hatch-Waxman, the FTC staff is able to review all settlements of

[2] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

[3] *See infra* Section I.A. The Act also was intended to encourage pharmaceutical innovation through patent term extensions.

court decisions handed down in 2005 took an extremely lenient view of exclusion payment settlements.

Pharmaceutical companies are responding to this change in the legal landscape. Although settlements with payments to the generic patent challenger had essentially stopped in the wake of antitrust enforcement by the FTC, state attorneys general, and private parties during 2000 to 2004, the recent court decisions have triggered a disturbing new trend. The staff's analysis of settlements filed during the fiscal year ending in September 2006 found that half of all of the final patent settlements (14 of 28) involved compensation to the generic patent challenger and an agreement by the generic firm to refrain from launching its product for some period of time. In the current legal climate, there is every reason to expect the upsurge in such settlements to continue, and early entry of generics under Hatch-Waxman to decline. Why? Because exclusion payment settlements are highly profitable for brand-name and generic firms. If such payments are lawful, companies have compelling incentives to use them.

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[4] *See infra* note 14.

[5] *Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm.*, 107th Cong. (Apr. 23, 2002) (statement

[6] *See, e.g., Schering-Plough Corp.*, 2003 FTC LEXIS 187 (FTC Dec. 8, 2003), *vacated*, 402 F.3d 1056 (11 Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); *Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp.*, Dkt. No. 9297 (Apr. 5, 2002) (consent order as to American Home Products); *FTC v. Perrigo and Alpharma*, Civ. Action No. 1:04CV01397 (D.D.C. Aug. 12, 2004) (stipulated judgment); *Bristol-Myers Squibb Co.*, Dkt. No. C-4076 (Ap

the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives, *Competition in the U.S. Pharmaceutical Industry* (Oct. 9, 2002), *available at* <http://www.ftc.gov/os/2002/10/genericte stimony021009.pdf>; Testimony of the Federal Trade Commission before the Committee on Commerce, Science, and Transportation, United States Senate, *Competition in the Pharmaceutical Industry* (Apr. 23, 2002), *available at* <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>; Testimony of the Federal Trade Commission before the Committee on the Judiciary, United States Senate, *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements* (May 24, 2001), *available at* <http://www.ftc.gov/os/2001/05/pharmtstmy.htm>.

[10] *See, e.g.,* Brief for the Federal Trade Commission as Amicus Curiae Supporting *en banc* petition, *In re Tamoxifen Litigation*, (2d Cir. Nov. 30, 2005) ((No. 03-7641), *available at* <http://www.ftc.gov/os/2005/12/051202amicustamoxifen.pdf>: Brief for the Federal Trade Commission as Amicus Curiae Supporting *en banc* petition, *Teva Pharm. v. Pfizer Inc.*, (Fed. Cir. Feb. 5, 2005) (03CV-10167), *available at* <http://www.ftc.gov/ogc/briefs/050208teva.pdf>.

[11] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* <http://www1),

eva.

The testimony also briefly describes how brand-name drug firms can effectively block generic entry by settling with the first generic applicant and declining to sue subsequent applicants.

I. The Benefits of Generic Competition

Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a price that is 70 to 80 percent of the brand-name counterpart, and gains substantial share from the brand-name product in a short period of time.[13] Subsequent generic entrants may enter at even lower prices – discounted as much as 80 percent or more off the price of the brand name drug – and prompt the earlier generic entrants to reduce their prices. As a result of price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture anywhere from 44 to 80 percent of branded sales within the first full year after launch of a lower-priced generic product.[14]

A. Statutory Background

Congress intended that the Hatch-Waxman Act would "make available more low cost generic drugs," while fully protecting legitimate patent claims.[15] The Act allows for accelerated FDA approval of a drug through an Abbreviated New Drug Application ("ANDA"), upon showing, among other things, that the new drug is "bioequivalent" to an approved drug.[16]

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[13] *See* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), *available at* <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0> (hereinafter "CBO Study"); *see generally* David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REVIEW OF ECON. & STAT. 37-79 (2005).

[14] CBO Study, xiii.

[15] H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2661.

[16] 21 U.S.C. § 355(j).

A brand-name drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application ("NDA") that, among other things, demonstrates the drug product's safety and efficacy. At the time the NDA is filed, the NDA filer also must provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA.[17] Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled "Approved Drug Products with Therapeutic Equivalence," commonly known as the "Orange Book."[18]

The Hatch-Waxman Act establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic product prior to the expiration of a patent or patents relating to a brand name drug upon which the generic is based. In such cases, the applicant must: (1) certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a "Paragraph IV certification"[19]

[17] 21 U.S.C. § 355(b)(1).

[18] *Id.* § 355(j)(7)(A).

[19] *Id.* § 355(j)(2)(A)(vii)(IV).

may not approve a potential competitor's ANDA.[20] Although a first-filer can forfeit its exclusivity under certain conditions,[21] ordinarily it will be entitled to 180 days of exclusivity beginning on the date of the first commercial marketing of the generic drug product.[22] Even if the first filer substantially delays marketing its product, under the prevailing interpretation of the Hatch-Waxman Act, a later ANDA filer may not enter the market until the first filer's 180-day period of marketing exclusivity has expired.[23]

B. Consumer Savings from Challenges to Drug Patents

Experience has borne out the efficacy of the Hatch-Waxman process and the correctness of its premises: that many patents, if challenged, will not stand in the way of generic entry, and that successful challenges can yield enormous benefits to consumers. The Commission studied all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic challengers, and found that the generics prevailed in cases involving 73 percent of the challenged drug products.[24] Many of these successes involved blockbuster drugs and allowed generic competition years before patent expiration (see chart).[25]

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[20] *Id.* § 355(j)(5)(B)(iv).

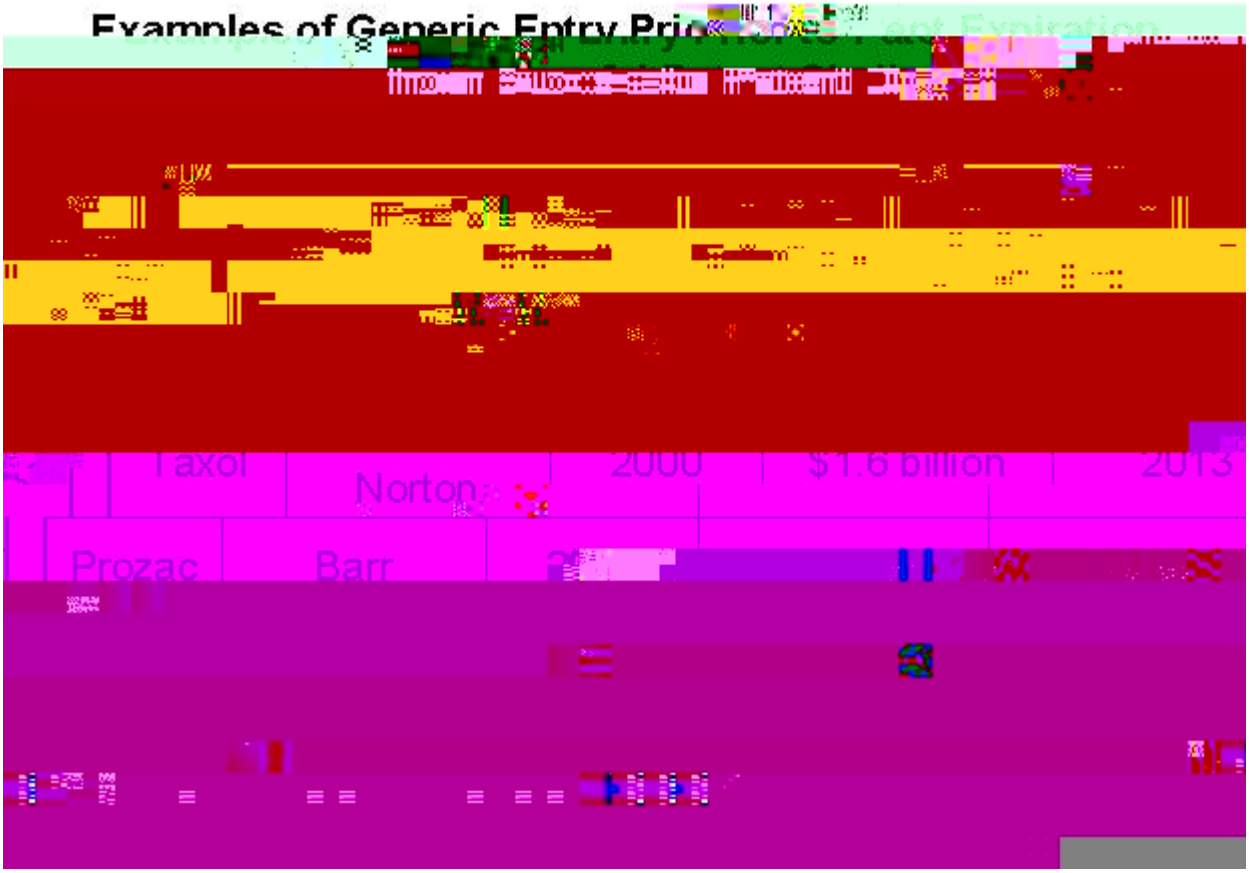
[21] *Id.* § 355(j)(5)(D)

[22] *Id.*

[23] *See id.* § 355(j)(5)(B)(iv).

[24] *Generic Drug Study*, at 19-20.

[25] *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp.2d 1011 (N.D. Ill. 2003), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005) (patent claiming Paxil held invalid); *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp.2d 423 (S.D.N.Y. 2002), *aff'd sub nom., In re Omeprazole Patent Litig.*, 84 Fed. App. 76 (Fed. Cir. 2003) (noninfringement of patents claiming Prilosec); *American Biosciences, Inc. v. Baker Norton Pharms. Inc.*, 2002 U.S. Dist. LEXIS 512 (C.D. Cal. Jan. 10, 2002) (patent claiming Taxol held invalid); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (patent claiming antidepressant Prozac held invalid); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) (noninfringement of patents claiming Zantac).

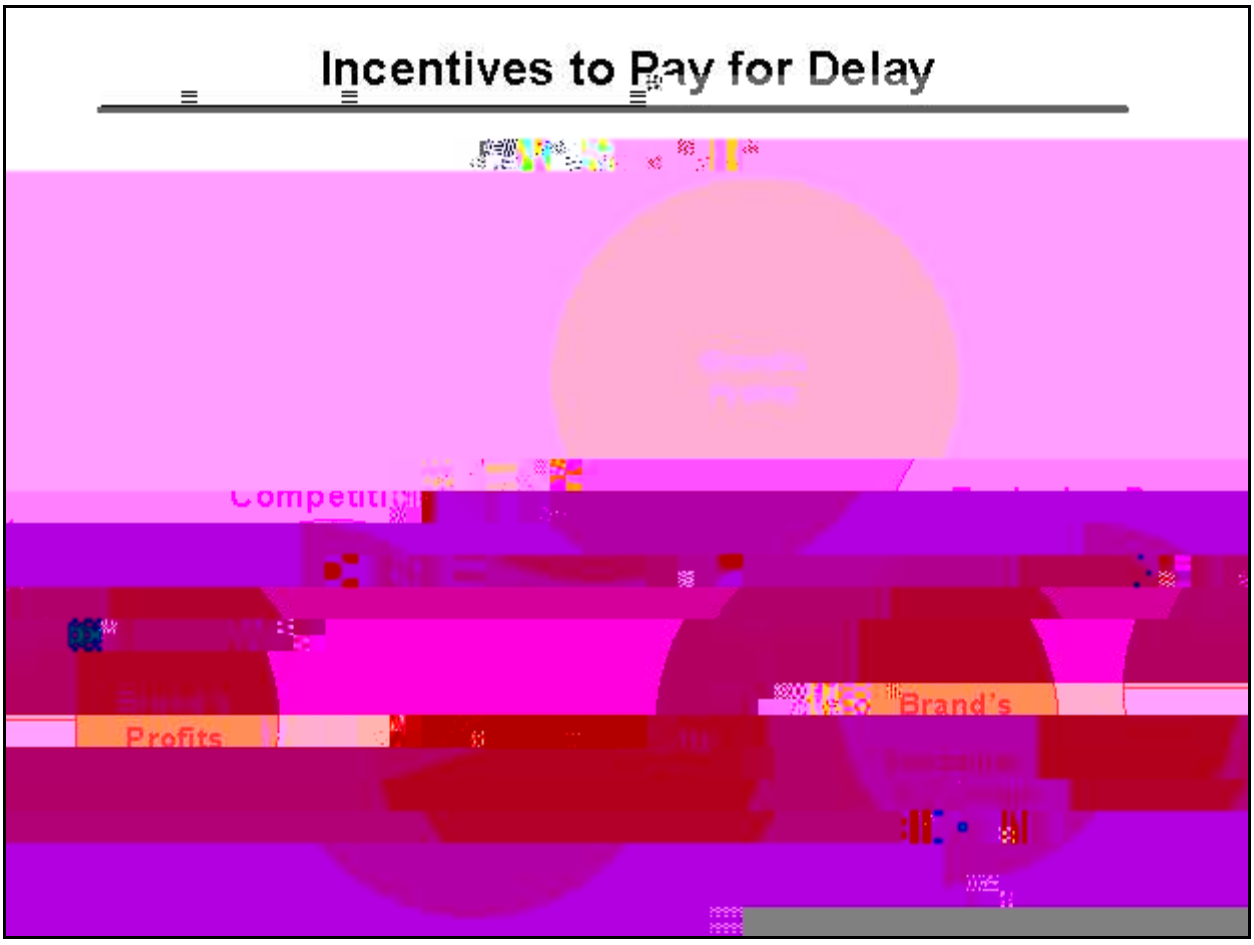


II. The Economics of Exclusion Payment Settlements and the Role of Antitrust Enforcement

Although patent challenges have the potential for substantial consumer savings, the competitive dynamic between brand-name drugs and their generic equivalents creates an incentive for brand and generic manufacturers to conspire to avoid competition and share the resulting profits. The reason is simple: In nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the amount of profit the brand-name drug company stands to lose from the same sales. This is because the generic

firm sells at a significant discount off the price of the brand name product; the difference between the brand's loss and the generic's gain is the money consumers save.

Consequently, it will typically be more profitable for both parties if the brand-name manufacturer pays the generic manufacturer to settle the patent dispute and agree to defer entry. As is illustrated below, by eliminating the potential for competition, the parties can share the consumer savings that would result if they were to compete.



Although both the brand-name companies and generic firms are better off with such settlements, consumers lose the possibility of earlier generic entry, which may occur either because the

[26] S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002).

[27] *Abbott Labs.*, Dkt. No. C-3945 (M

[30] *Schering-Plo*

result of these agreements, Schering continued to enjoy supracompetitive profits from K-Dur 20 for several more years, at the expense of consumers.

The court of appeals set aside the Commission's decision.[33] The court purported to assess whether the agreement exceeded the exclusionary potential of Schering's patent. In so doing, the court relied on the incorrect supposition that the patent provided Schering with "the legal right to exclude Upsher and [AHP] from the market until they proved either that the . . . patent was invalid or that their products . . . did not infringe Schering's patent,"[34] and noted that there was no allegation that the patent claim was a "sham."[35] In particular, the court ruled that a payment by the patent holder, accompanied by an agreement by the challenger to defer entry, could not support an inference that the challenger had the legal r[36]

[33] *Schering*, 402 F.3d at 1058.

[34] *Id.* at 1066-67.

[35] *Id.* at 1068.

[36] *Id.* at 1076.

[43] *See supra* note 6.

[44] For example, for a hypothetical patent infringement claim with a 50% chance of success, with 10 years remaining in the patent term, continued litigation between the parties affords consumers an overall expected value of 5 years of competition, taking into account the likelihood of the two possible outcomes. If the parties instead reach a settlement in which the patent holder makes a payment to the challenger, and the challenger agrees to enter only one year prior to the expiration date, consumers are worse off, on average, than had the litigat

patent challenges, and by the empirical evidence that gener

[45] *Generic Drug Study* at 19-20.

[46] Bethany McLean, *A Bitter Pill*, FORTUNE, Aug. 13, 2001, at 5, *available at* <http://money.cnn.com/magazines/fortune/fortune_archive/2001/08/13/308077/index.htm>.

over two billion dollars.[47] Under the legal standard articulated in the *Schering* and *Tamoxifen* cases, however, the proposed settlement would have been legal, generic entry would not have occurred, and consumers would have had to pay higher prices until the patent expired.

IV. Addressing Anticompetitive Hatch-Waxman Settlements through Legislation

The Commission strongly supports a legislative remedy for the problem of exclusion payment settlements between branded pharmaceutical firms and would-be generic entrants. Congressional action on this issue is warranted for several reasons. First, the threat that such agreements pose to our nation's health care system is a matter of pressing national concern. The enormous costs that result from unwarranted delays in generic entry burden consumers, employers, state and local governments, and federal programs already struggling to contain spiraling costs.

Second, the problem is prevalent. Because exclusion payment settlements are so profitable for both branded and generic firms, if they are legal they would threaten to eliminate most pre-patent-expiration generic competition. The settlements filed with the FTC in 2006 demonstrate that it is now common for settlements of Hatch-Waxman patent litigation to invo274ent atent t30 Tl

[47] Stephanie Kirchgaessner & Patti Waldmeir, *supra* note 41.

drugs to market and maintaining incentives for new drug development. Legislative action concerning exclusion payment settlements can be tailored to the special circumstances of pharmaceutical patent settlements and help to ensure that this unique framework works as Congress intends.

Fourth, the reasoning underlying the recent appellate court rulings underscores the need for action by Congress. These decisions reflect judicial judgments about the policy choice that Congress made in Hatch-Waxman. Indeed, the Eleventh Circuit's *Schering* opinion emphasized that its decision was based on "policy."[48] As the court saw it, the Hatch-Waxman framework Congress created gave generic firms "considerable leverage in patent litigation," and could therefore "cost Schering its patent."[49] Congress, however, is the body with constitutional responsibility to set patent policy. Striking the balance so as to promote innovation while also promoting generic entry is fundamentally a legislative choice. Accordingly, it is fitting that Congress address the use of exclusion payments in drug patent settlements.

Finally, a legislative remedy offers the prospect of a relatively swift solution to this important issue. While the Commission's enforcement activities are continuing, we recognize the time and uncertainty involved in litigation challenges to anticompetitive settlements. Legislation could provide a speedier and more comprehensive way to address this pressing concern.

[48] 402 F.3d at 1076.

[49] *Id.* at 1074.

For these reasons, the Commission strongly supports the intent behind the bipartisan legislation introduced by Senators Kohl, Leahy, Grassley, and Schumer." We would welcome the opportunity to work with the Committee as it considers the bill.

Certain principles may be useful to consider in crafting the precise form and scope of a legislative remedy. A law must be broad enough to prevent evasion or other anticompetitive practices that could render the legislation ineffective, but it should avoid unwarranted deterrence of settlement. The fundamental concern underlying exclusion payment settlements is the sharing of profits preserved by an agreement not to compete, whatever form the compensation to the generic takes. Thus, legislation must be sufficiently broad to encompass the various ways that a branded firm may share its profits with the generic, including not only the ways we have seen to date, but also those that may arise in the future.

In addition, it is important that the law encompass all arrangements that are part of the settlement, even if not part of a written settlement agreement. That is, it should be clear that substance, not form, governs in assessing what transactions are actually part of the parties' settlement agreement.

At the same time, settlement avenues should not be unduly limited. All settlements provide some value to the generic, even if it is nothing more than termination of the litigation. And settlements in which the value received by the generic amounts to nothing more than the right to sell a generic version of the branded drug the innovator firm is seeking to protect – whether it be the right to sell the generic drug product before patent expiration, a waiver of the brand's market exclusivity based on testing of a drug for pediatric use, or a waiver of patent infringement damages against a generic for entry that has already occurred – are unlikely to

involve a sharing of profits preserved by avoiding competition. Legislation should preserve such settlement options.

Finally, a statutory bar on exclusion payment settlements should include meaningful remedies. Delaying generic competition to a blockbuster drug can be enormously profitable for the brand-name-drug seller. Remedies should take into account the economic realities of the pharmaceutical industry.

V. The 180-Day Exclusivity as a Bottleneck to Prevent Generic Entry

Hatch-Waxman patent settlements present an additional issue that warrants a legislative remedy. The operation of the Hatch-Waxman Act's 180-day exclusivity creates the potential for a settlement between a brand-name company and a first generic filer to generate a bottleneck that prevents *any* generic competition. When they enter into an agreement for the generic to delay market entry, whether with or without an accompanying payment, the agreement does not trigger the running of the exclusivity period. Although Hatch-Waxman was designed to provide a mechanism to eliminate the bottleneck when the later filer can get a court ruling that it does not infringe, forcing the first filer to "use or lose" its exclusivity period, court decisions have prevented generic firms from using this mechanism. Consequently, the exclusivity creates a bottleneck that prevents any subsequent generic applicant from entering the market until after the first generic enters and the period runs.[50]

[50] *See* Generic Drug Study at vii-xi, 57-58, 62-63.

A subsequent generic can relieve the bottleneck only by obtaining a court decision that the patent supporting the 180-day exclusivity period is invalid or not infringed.[51] That decision acts as a forfeiture event that forces the first filer to either use or lose its exclusivity period within 75 days.[52] A problem arises if the brand-name company does not sue the subsequent generic filer on every patent supporting the exclusivity, thereby eliminating the possibility that the generic company will obtain a favorable court decision on every patent and relieve the bottleneck. Having settled with the first challenger, perhaps for delayed entry, a brand-name company can preempt all subsequent generic challenges and the chance of any earlier generic entry by declining to sue subsequent filers.

A brand name drug firm has a significant incentive to use this strategy, and a trend by brand-name companies to do so is increasingly evident.[53] Some generic companies facing this scenario have attempted to bring declaratory judgment actions of non-infringement and invalidity, but these efforts have been unsuccessful thus far because the courts have dismissed those actions for lack of a Constitutionally-required "case or controversy."[54] However, even if a

[51] The decision must be "a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorai) has been or can be taken that the patent is invalid or not infringed." Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1102(a)(1), Pub. L. No. 108-173, 117 Stat. 2066, 2457 ("MMA") (amending 21 U.S.C. § 355(j)(5)(B)(iv)).

[52] The other forfeiture events established by the Medicare Modernization Act are a court-entered settlement that the patents are invalid or not infringed, or withdrawal of the patents from the Orange Book by the brand company. MMA, § 1102(a)(1), Pub. L. No. 108-173, 117 Stat. At 2457(amending 21 U.S.C. § 355(j)(5)(B)(iv)). Both require action by the brand company.

[53] *See, e.g., Teva Pharms. USA, Inc., v. FDA*, 2005 WL 2692489 (D.D.C. Oct. 21, 2005); *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp.2d 187 (S.D.N.Y. 2005); *Glaxo Group Ltd. v. Dr. Reddy's Labs, Ltd.*, 325 F. Supp.2d 502 (D.N.J. 2004); *Mutual Pharm. Co. v. Pfizer, Inc.*, 307 F. Supp.2d 88 (D.D.C. 2004).

[54] *Teva Pharms. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005). The Supreme Court recently examined the availability of declaratory judgment jurisdiction in patent cases in *Medimmune, Inc. v. Genetech, Inc.*, No. 05-068 (U.S.S.Ct. Jan. 9, 2007). The Court held that the case or controversy requirement did not require a patent licensee to breach its license agreement before seeking a declaratory judgment that the underlying patent is invalid or not infringed. Although the Supreme Court criticized language in *Teva v.*

generic company could bring that declaratory judgment action, the brand company could still prevent an adjudicated court decision on the patent merits by granting the generic a covenant not to sue. Dismissal of a declaratory judgment action, even when based on a covenant not to sue, is not a "court decision" sufficient to trigger a forfeiture event.[55]

As a result, a subsequent generic filer that faces a bottleneck but has not been sued, or has been offered a covenant not to sue, has no mechanism to relieve that bottleneck. Even if the subsequent filer has a strong casnot a "co

Pfizer, the effect of this decision on declaratory judgment jurisprudence in the Hatch-Waxman context awaits further development in the courts.

[55] *Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006) (upholding FDA's decision to treat only an adjudicated holding on the patent merits as a "court decision" for purposes of triggering the 180-day exclusivity).

[56] The Commission made a similar recommendation in its 2002 Generic Drug Study at x-xi.

Conclusion

Thank you for this opportunity to share the Commission's views. The Commission looks forward to working with the Committee, as it has in the past, to protect competition in this