PREPARED STATEMENT OF THE
FEDERAL TRADE COMMISSION

Before the

SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

on

"HOW PAY-FOR-DELAY SETTLEMENTS MAKE CONSUMERS AND THE FEDERAL GOVERNMENT PAY MORE FOR MUCH NEEDED DRUGS"

March 31, 2009

"How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs"

Chairman Rush, Ranking Member Radanovich, and members of the Subcommittee, I am Thomas Rosch, a Commissioner of the Federal Trade Commission. I appreciate the opportunity to appear before you today to testify on behalf of the Commission about the need for legislation to prevent anticompetitive agreements between branded and generic drug firms that delay consumer access to generic drugs.[1] This is an issue of great importance, not only to consumers but also to the federal and state governments who spend substantial sums on prescription drugs. Since this issue first arose in 1998, every single member of the Commission, past and present, – whether Democrat, Republican, or Independent – has supported the Commission's challenges to anticompetitive "pay-for-delay" deals.

The threat that these 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. As the President and Congress turn to health care reform, these deals, by delaying generic entry, risk dramatically increasing the costs of those proposals. Over twenty years ago, Congress passed the Hatch-Waxman Act,[2] which has helped control the costs of prescription drugs by ensuring that weak patents do not delay lower-cost generic competition. These deals, which are unique to the pharmaceutical industry, threaten to

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[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 other Commissioner.

[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)). Prior testimony before this Subcommittee discussed the Act's statutory background at 8-9, *available at* http://ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf.

extinguish that benefit. Therefore, congressional action to prohibit anticompetitive patent settlements that impose these costs is both appropriate and timely.

The FTC has sought to use antitrust enforcement to stop what have come to be called "pay-for-delay settlements" (or by some, "exclusion payments" or "reverse payments"). These are settlements of patent litigation in which the brand-name drug firm pays its potential generic competitor to abandon a patent challenge and delay entering the market with a lower cost generic product. Such settlements effectively buy more protection from competition than the assertion of the patent alone provides. And they do so at the expense of consumers, whose access to lower-priced generic drugs is delayed, sometimes for many years.

Agreements to eliminate potential competition and share the resulting profits are at the core of what the antitrust laws proscribe, and for that reason these pay-for-delay settlements should be prohibited under the antitrust laws. But since 2005, court decisions have treated such agreements in drug patent settlements too leniently. As a result, it has become increasingly difficult to bring antitrust cases to stop pay-for-delay settlements, and such settlements have become a common industry strategy. As one investment analyst report put it, the courts' permissive approach to exclusion payments has "opened a Pandora's box of settlements."[3]

The implications of these developments for consumers, and for others who pay for prescription drugs, are troubling. The increased costs resulting from anticompetitive agreements that delay generic competition harm all those who pay for prescription drugs: individual consumers, the federal government, state governments trying to provide access to health care

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[3] Stephanie Kirchgaessner & Patti Waldmeir, *Drug Patent Payoffs Bring a Scrutiny of Side-Effects*, FINANCIAL TIMES UK, Apr. 25, 2006, 2006 WLNR 6910048 (quoting S.G. Cowen & Co. analyst's report describing the Eleventh Circuit's opinion in *Schering-Plough Corp. v. FTC,* 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006)).

with limited public funds, and American businesses striving to compete in a global economy. In 2008, the federal government was projected to have accounted for 31 percent of the $235 billion spent on prescription drugs, and the federal government's share is expected to rise to 40 percent by 2018.[4]

To be sure, the development of new drugs is risky and costly, and preserving incentives to undertake this task is critically important. Due regard for patent rights is thus a fundamental premise of the Act's framework. But the court decisions allowing pay-for-delay settlements grant holders of drug patents the ability to buy more protection from competition based only on an allegation of infringement. This is more protection than congressionally granted patent rights afford. These rulings disrupt the careful balance between patent protections and encouraging generic drug entry that Congress sought to achieve in the Hatch-Waxman Act.

For these reasons, the Commission strongly supports the bill introduced by Chairman Rush, Committee Chairman Waxman, and others, H.R. 1706, to prohibit these anticompetitive settlements.[5] And we are encouraged that the list of those speaking out against pay-for-delay settlements is growing. President Obama's budget proposal expresses the Administration's opposition to these anticompetitive deals,[6] and Assistant Attorney General nominee Christine

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[4] Centers for Medicare and Medicaid Services, Office of the Actuary, Table 11, *Prescription Drug Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2003-2018* (2009), *available at* http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2008.pdf.

[5] Legislation for this purpose has been introduced in the Senate as well as the House. *See* Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009).

[6] President Obama explained in his recent budget that "The Administration will prevent drug companies from blocking generic drugs from consumers by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market." OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 2010 (2009) (proposed), at 28, *available at* http://www.whitehouse.gov/omb/assets/fy2010_new_era/A_New_Era_of_Responsibility2.pdf.

Varney testified as to her support for stopping them.[7] In addition, this past summer, the American Medical Association House of Delegates adopted a resolution announcing its opposition to pay-for-delay settlements.[8]

As is discussed below, the Commission is continuing to bring cases challenging pay-for-delay settlements despite the difficulties created by several recent court decisions. But we believe there are compelling reasons for Congress to act to stop such anticompetitive agreements and that the approach taken in H.R. 1706 is sound.

I. The Need for a Legislative Solution

Legislation can provide a comprehensive solution to a problem that is prevalent, extremely costly, and subverts the goals of the Hatch-Waxman Act.

A. Permissive court decisions have made pay-for-delay settlements commonplace in Hatch-Waxman patent cases

The Sixth Circuit Court of Appeals held in 2003 that a branded drug firm's exclusion payments to a generic firm that had filed a patent challenge were per se unlawful, noting:

> it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market.[9]

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[7] In response to a question in her recent confirmation hearing before the Senate Judiciary Committee, Ms. Varney testified that she supported opposition to "reverse payments" and would work to "align" the positions of the Department of Justice and the FTC. *Executive Nominations: Hearing Before the S. Judiciary Comm.*, 111th Cong. 38-39 (2009) (exchange between Sen. Herb Kohl, Member, S. Judiciary Comm., and Christine Anne Varney, Nominee, Assistant Att'y Gen., Antitrust Division, Department of Justice).

[8] At their 2008 annual meeting, the House of Delegates of the American Medical Association adopted Resolution 520 concerning "'Pay for Delay' Arrangements by Pharmaceutical Companies" and resolved "that our American Medical Association support the Federal Trade Commission in its efforts to stop 'pay for delay' arrangements by pharmaceutical companies," *available at* http://www.ama-assn.org/ama1/pub/upload/mm/38/a08resolutions.pdf.

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

But in 2005, two appellate courts adopted a more permissive – and, respectfully, in our view, incorrect – position on pay-for-delay settlements.[10] The Eleventh Circuit reversed the Commission's decision in the *Schering* case that a substantial exclusion payment, made to induce the generic to abandon its efforts to enter the market before expiration of the branded drug's patent, was illegal.[11] In doing so, the Eleventh Circuit not only rejected the Sixth Circuit's approach to pay-for-delay settlements, it refused to apply any antitrust analysis, either the per se rule or the rule of reason.[12] The Second Circuit in the *Tamoxifen* case likewise upheld the legality of a pay-for-delay settlement.[13] In 2008, a third appellate court adopted a similarly lenient view of pay-for-delay settlements.[14] In that case, *Cipro*, the Federal Circuit Court of Appeals held that "absent fraud before the [Patent and Trademark Office] or sham litigation," the mere presence of a patent entitles the patent holder to purchase protection from competition

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[10] *Schering-Plough Corp. v. FTC,* 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (Pooler, J., dissenting), *amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied,* 127 S.Ct. 3001 (2007). For a detailed discussion of the *Schering* and *Tamoxifen* cases please see the FTC's May 2, 2007 testimony before this Subcommittee at 14-19, *available at* http://www.ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf.

[11] *In the Matter of Schering-Plough Corp.*, Docket No. 9297, Federal Trade Commission, 2003 FTC LEXIS 187, Dec. 8, 2003; *vacated, Schering-Plough Corp. v. FTC,* 402 F.3d 1056, 1065 (11th Cir. 2005).

[12] 402 F.3d at 1065.

[13] *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (Pooler, J., dissenting), *amended*, 466 F.3d 187 (2d Cir. 2006).

[14] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *petition for cert. filed*, __ U.S.L.W. __ (U.S. Mar. 23, 2009) (No. 08-1194).

until patent expiration.[15] Plaintiffs have asked the Supreme Court to review the *Cipro* decision, and we urge the Court to do so.[16]

The Commission believes that the courts' permissive approaches in *Cipro, Tamoxifen*, and *Schering* are misguided and not supported by the law. These holdings disrupt the carefully balanced patent system by overprotecting weak and narrow patents; allowing patent holders to buy protection that their patents cannot provide; and ignoring consumers' interests in competition safeguarded by the antitrust laws. The Commission is not the only advocate to voice concern about the harmful effects of these decisions. Former Solicitor General Paul Clement has criticized the standard set forth in *Tamoxifen* as "erroneous" and "insufficiently stringent . . . for scrutinizing patent settlements."[17] The Solicitor General also observed that "[t]he interests in consumer welfare protected by the antitrust laws militate against adoption of a legal standard that would facilitate a patent holder's efforts to preserve a weak patent by dividing its monopoly profits with an alleged infringer."[18] Forty-one legal scholars, economics

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[15] *Id.* at 1336. Bayer had settled patent litigation with the manufacturer of a generic counterpart, Barr, by making periodic payments to Barr ultimately totaling almost $400 million in exchange for Barr's agreement to delay marketing its generic version of Cipro for almost seven years. The Commission filed an amicus brief in *Cipro* that urged the Federal Circuit to allow an antitrust challenge to the patent settlement to proceed to trial, *available at* http://www.ftc.gov/os/2008/01/ciprobrief.pdf.

[16] *See Ark. Carpenters Health & Welfare Fund, et al., v. Bayer AG, et al.*, __ U.S.L.W. __ (U.S. Mar. 23, 2009) (No. 08-1194).

[17] Brief for the United States as Amicus Curiae at 17, *Joblove v. Barr Labs., Inc.*, 127 U.S. 3001 (2007) (No. 06-830) ("U.S. Tamoxifen Br."), *available at* http://www.usdoj.gov/osg/briefs/2006/2pet/6invit/2006-0830.pet.ami.inv.pdf .

[18] *Id.* at 11.

professors, and other academics likewise deemed the *Tamoxifen* standard to be "far outside the mainstream of judicial and academic analysis."[19]

Because this is such an important competition issue, the Commission continues to use its antitrust enforcement authority to challenge pay-for-delay settlements in other circuits despite the permissive legal treatment afforded these settlements by three of the four circuits that have considered the issue. As the Supreme Court observed, "allowing litigation in multiple forums" by the government ensures that "legal questions of substantial public importance" are thoroughly developed.[20] In *Mendoza*, the Supreme Court concluded that the government is not required to accede to the first unfavorable final adjudication on a particular issue, because to do so would "deprive [the] Court of the benefit it receives from permitting several courts of appeals to explore a difficult question before [the] Court grants certiorari."[21]

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[19] Brief Amici Curiae of 41 Professors of Economics, Business and Law in Support of Granting the Petition at 2, *Joblove v. Barr Labs, Inc.*, 127 S.Ct. 3001 (2007) (No. 06-830), *available at* http://www.orangebookblog.com/Tamoxifen_20cert_20final_20brief.pdf.

[20] *United States v. Mendoza*, 464 U.S. 154, 160, 163 (1984).

[21] *Id.* at 160.

Accordingly, the Commission has filed two cases challenging pay-for-delay settlements since the agency testified before this Subcommittee in May 2007.[22] We also have a number of ongoing non-public investigations of such settlements.

The first case, filed in February 2008, challenges a course of anticompetitive conduct by Cephalon, Inc. to prevent generic competition to its leading product, Provigil, a drug used to treat excessive sleepiness caused by narcolepsy and sleep apnea, with annual sales of more than $800 million.[23] The complaint charges that Cephalon agreed to pay in excess of $200 million collectively to settle patent litigation with four manufacturers of generic versions of Provigil to induce them to abandon their plans to sell generic Provigil for six years, until 2012. Cephalon's CEO observed shortly after entering these agreements: "We were able to get six more years of patent protection. *That's $4 billion in sales that no one expected.*"[24] Cephalon has asked the trial judge to dismiss the case based on the permissive standard adopted by appellate decisions in other circuits. The court has yet to rule on the motion to dismiss, which was fully briefed in

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[22] At the time the agency testified before you on May 2, 2007, the Commission had already challenged the following patent settlements: *Abbott Labs.*, Dkt. No. C-3945 (May 22, 2000) (consent order), complaint *available at* http://www.ftc.gov/os/2000/05/c3945complaint.htm; *Geneva Pharms., Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), complaint *available at* http://www.ftc.gov/os/2000/05/c3946complaint.htm; *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), complaint *available at* http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm; *Bristol-Myers Squibb Co.*, Dkt. No. C-4076, (April 18, 2003), complaint *available at* http://www.ftc.gov/os/caselist/c4076.htm. The consent order in *Abbott Laboratories* is *available at* http://www.ftc.gov/os/2000/03/abbot.do.htm. The consent order in *Geneva Pharmaceuticals* is *available at* http://www.ftc.gov/os/2000/03/genevad&o.htm. The consent order in *Hoechst/Andrx* is *available at* http://www.ftc.gov/os/2001/05/hoechstdo.htm. The consent order in *Bristol-Myers Squibb* is *available at* http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf. *See also 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. 2, 2002) (consent order as to American Home Products).

[23] *FTC v. Cephalon, Inc.*, No. 08-cv-2141 (E.D. Pa. complaint filed Feb. 13, 2008), *available at* http://www2.ftc.gov/os/caselist/0610182/080213complaint.pdf.

[24] John George, *Hurdles Ahead for Cephalon*, PHILADELPHIA BUSINESS JOURNAL, March 17, 2006 (quoting Cephalon CEO Frank Baldino) (emphasis added).

June 2008. In the meantime, Cephalon has instituted two price increases on Provigil since the Commission filed its complaint.

In the second case, the Commission has challenged patent settlement agreements in which Solvay Pharmaceuticals, Inc. agreed to pay generic drug makers Watson Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc., to delay generic competition to Solvay's branded drug AndroGel.[25] According to the February 2009 complaint, Solvay promised payments of hundreds of millions of dollars collectively to induce the generic companies to abandon their patent challenges and agree to forbear bringing a generic AndroGel product to market for nine years, until 2015. The case was filed in California, where one of the four defendants is headquartered. All four defendants have filed a motion seeking to transfer the case to the Northern District of Georgia. If the motion is successful, Eleventh Circuit law and the lenient *Schering* decision will govern the case.

Despite the Commission's ongoing antitrust enforcement efforts to stop pay-for-delay settlements, the appellate court decisions upholding their legality have prompted a resurgence in settlements in which the parties settle with a payment to the generic company and an agreement by the generic company not to market its product. 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 through 2004. But the recent appellate court decisions have triggered a disturbing new trend.

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[25] *FTC v. Watson Pharmaceuticals, Inc.*, No. 09-00598 (C.D. Cal. first amended complaint filed Jan. 12, 2009), *available at* http://www2.ftc.gov/os/caselist/0710060/090212amendedcmpt.pdf.

After a five-year hiatus in payments to generics following the initiation of Commission enforcement actions aimed at pay-for-delay settlements, they have become commonplace.[26] By the end of fiscal year 2005, the year of the Eleventh Circuit's decision in *Schering*, there were three such settlements. After the *Schering* and *Tamoxifen* rulings came out, there were significantly more. The staff's analysis of settlements filed under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 during the fiscal year ending in September 2007 found that almost half of all of the final patent settlements (14 of 33) 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.

Moreover, the findings concerning settlements with first generic filers – that is, settlements that can serve to block FDA approval of later applicants[27] – are even more striking. Since 2005, 69 percent (22 of 32) of the settlements with first generic filers involved a payment to the generic challenger and a restriction on generic entry.[28]

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[26] Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), *available at* http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.

[27] Further discussed, *infra*, Section IV.

[28] Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007: A Report by the Bureau of Competition* (May 2008), *available at* http://www.ftc.gov/os/2008/05/mmaact.pdf; Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006: A Report by the Bureau of Competition* (Apr. 2007), *available at* http://www.ftc.gov/reports/mmact/MMAreport2006.pdf; Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), *available at* http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.

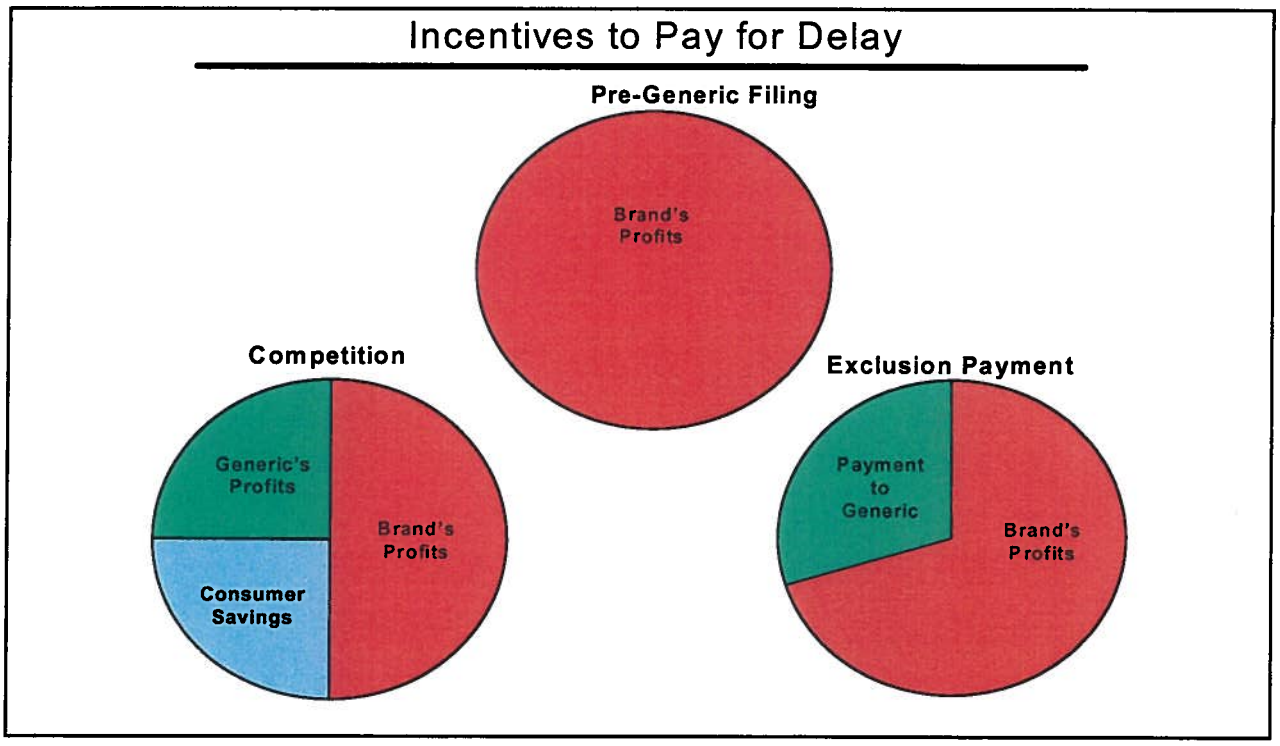
B. The profitability of delaying generic entry means that these agreements will become more prevalent

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 pay-for-delay settlements are highly profitable for both brand-name and generic firms. If such payments are permissible, companies have compelling incentives to use them.

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 – an amount less than the brand-name manufacturer would have lost and more than the generic would have gained – to settle the patent dispute and the latter agrees 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. In other words, these settlements are harmful because the parties are resolving their dispute at the expense of consumers. 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 (1) the generic company would have prevailed in

the lawsuit (as noted in Section I.C., *infra*, the FTC's Generic Drug Study found generic challengers enjoyed a success rate in excess of 70 percent), or (2) because the parties would have negotiated a settlement with an earlier entry date absent the payment (i.e., the payment induced the generic to delay entry longer than it otherwise would have). Instead, consumers pay higher prices because such early generic entry is delayed. By eliminating the potential for competition, the parties can share the consumer savings that would result if they were to compete.



C. Pay-for-delay settlements impose enormous costs on consumers and the health care system

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 cost. Although it is well known that the use of generic drugs – which are priced 20 to 80 percent or more below the price of the branded drug[29] – provides substantial savings, what is not so well known is the important role that generic drug firms' patent challenges play in delivering savings to consumers.

One of the key steps Congress took in the Hatch-Waxman Act 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. Experience has borne out the premise of the Hatch-Waxman patent challenge framework: that many patents, if challenged, will not stand in the way of generic entry,[30] and that successful challenges can yield enormous benefits to consumers. An analysis of Federal Circuit decisions from 2002 through 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim (validity, infringement, or enforceability) found that the generic

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[29] *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").

[30] *See, e.g., Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, No. 2007-1280, 2008 WL 2039065 (Fed. Cir. May 14, 2008) (patents covering blood-clotting drug Lovenox held unenforceable), *petition for cert. filed*, 77 U.S.L.W. 3441 (U.S. Jan. 23, 2009) (No. 08-937); *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007) (patent covering high blood pressure drug Altace found invalid); *Daiichi Sankyo Co., Ltd. v. Apotex Inc.*, 501 F.3d 1254 (Fed. Cir. 2007) (patent covering method of treating ear infections with ofloxacin held invalid); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007) (patent covering hypertension drug Norvasc held invalid); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006) (product-by-process patent covering anti-depressant drug Paxil was invalid); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006) (claims of patent related to extended release urinary incontinence drug Ditropan XL held invalid and not infringed).

challengers had a success rate of 70 percent.[31] The FTC's study of all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and generic applicants[32] found that when cases were litigated to a decision on the merits, the generics prevailed in cases involving 73 percent of the challenged drug products.[33] Many of these successes involved blockbuster drugs and allowed generic competition years before patent expiration.[34] Indeed, generic competition following successful patent challenges involving just four major brand-name drugs (Prozac, Zantac, Taxol, and Platinol) is estimated to have saved consumers more than $9 billion.[35]

These cost savings are lost, however, if branded drug firms are permitted to pay a generic applicant to abandon challenging the brand, thereby deferring entry. So are the savings to the federal government. In 2008, the federal government was projected to have accounted

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[31] Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?* 34 AIPLA Q.J. 1, 20 (2006). *See also* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents,* 26 AIPLA Q.J. 185, 205-06 (1998) (study of all patent validity litigation from 1989-1996 found 46 percent of all patents litigated to judgment held invalid).

[32] *See* the Commission's prior testimony before this Subcommittee at 8-9, *available at* http://ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf, for further discussion of the Hatch-Waxman Act statutory background.

[33] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, 19-20 (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

[34] *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).

[35] *Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm.*, 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_senate_hearings&docid=f:90155.pdf.

for 31 percent of the $235 billion spent on prescription drugs, and that share is expected to rise to 40 percent by 2018.[36] Many of the top-selling prescription drugs in the United States – including such blockbusters as the asthma/allergy drug Singulair, the deep vein thrombosis (blood clot) and pulmonary embolism treatment Lovenox, and the schizophrenia, bipolar, and depression drug Abilify – are currently the subject of patent challenges by generic firms seeking to enter the market under the provisions of the Hatch-Waxman Act. The prospective cost savings to consumers and tax-payers from such challenges is enormous, to the extent that they lead to early, non-infringing generic entry. But under much of the current case law, the parties have a strong economic incentive to enter instead into anticompetitive settlements that deprive consumers of the benefit of low-cost, non-infringing generic drugs.

Prozac provides a telling example of what will be lost if brand and generic companies can enter pay-for-delay settlements. In the course of the Prozac patent litigation, the generic challenger reportedly asked to be paid $200 million to drop its patent challenge. The brand company rejected the idea, stating that such a settlement would violate the antitrust laws.[37] The generic ultimately won that patent litigation, and consumers – as well as federal and state governments – saved over two billion dollars.[38] Under the legal standard articulated in the *Schering*, *Tamoxifen*, and *Cipro* cases, however, the proposed settlement would have been legal and profitable for both parties. The parties would have had every reason to enter the agreement,

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[36] Centers for Medicare and Medicaid Services, Office of the Actuary, Table 11, *Prescription Drug Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2003-2018* (2009), *available at* http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2008.pdf.

[37] 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.

[38] Kirchgaessner & Waldmeir, *supra* note 3.

generic Prozac entry would not have occurred, and consumers and others would have had to pay that extra two billion dollars.

D. Permissive legal treatment of pay-for-delay settlements undermines the Hatch-Waxman Act

The problem of pay-for-delay patent settlements has arisen in – and, to the FTC's knowledge, only in – the context of the special statutory framework that Congress created with the Hatch-Waxman Act. Congress intended that the Hatch-Waxman Act would "make available more low cost generic drugs," while fully protecting legitimate patent claims.[39] The special rules that apply in this area were designed to balance the two policy goals that are of critical significance in the pharmaceutical industry: speeding generic drugs to market and maintaining incentives for new drug development. Legislative action concerning pay-for-delay settlements can be tailored to the special circumstances of pharmaceutical patent settlements and help to ensure that this unique framework works as Congress intends.

Hatch-Waxman was intended to give generic companies an incentive to challenge weak patents and to compete, not to take money in exchange for sitting on the sidelines. Because of pay-for-delay settlements, as Chairman Waxman, one of the authors of the Act, has observed, the law "has been turned on its head."[40]

The reasoning underlying these misguided 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. For example, the Eleventh Circuit's *Schering* decision –

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

[40] Cheryl Gay Stolberg et al., *Keeping Down the Competition; How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES , July 23, 2000, at A11 (quoting Rep. Waxman), *available at* http://www.nytimes.com/2000/07/23/us/keeping-down-competition-companies-stall-generics-keep-themselves-healthy.html?sec=&spon=&pagewanted=all.

which opined that the Hatch-Waxman framework Congress created gave generic firms "considerable leverage in patent litigation," and could therefore "cost Schering its patent"[41] – emphasized that its decision was based on "policy."[42] Congress, however, is the body with the 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 if courts have disturbed the balance Congress struck in Hatch-Waxman between patents and competition, Congress should address the use of exclusion payments in drug patent settlements to correct that balance.

E. Legislation is likely to be swifter and more comprehensive than litigation

While the Commission's enforcement activities are continuing, we recognize the time and uncertainty involved in litigation challenges to anticompetitive settlements. The Commission's *Provigil* case has been stalled at the district court level for almost a year without progress, thus illustrating the delay that can arise in litigation. Although the Commission will continue to be vigilant in this area, litigating another case to conclusion will take years, and the outcome of such litigation is uncertain given the *Schering*, *Tamoxifen*, and *Cipro* decisions. In any event, such litigation will provide little relief for those harmed in the interim by not being afforded the option of a generic alternative. The cost to consumers, employers, and government programs will be substantial. Legislation could provide a speedier and more comprehensive way to address this pressing concern.

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[41] 402 F.3d at 1074.

[42] *Id.* at 1076.

II. The Arguments Against Barring Exclusion Payments Are Contradicted by Experience in the Market

In the debate over legislation to ban pay-for-delay settlements, certain arguments are routinely offered by supporters of these settlements: (1) such settlements typically allow generic entry before patent expiration and therefore benefit rather than harm consumers; (2) it is virtually impossible to settle Hatch-Waxman patent cases without payments to the generic challenger; and (3) barring such payment to generic firms will mean that fewer generic firms will undertake patent challenges. In the Commission's view, these arguments overlook market realities.

First, the suggestion that pay-for-delay patent settlements are procompetitive – by guaranteeing generic entry prior to the expiration of the disputed patent – is contrary to the Commission's experience. The *Provigil* case is a good example. The branded drug company, Cephalon, touted the "obvious benefits and efficiencies" of its settlement to the court because it "permitted the [g]enerics to enter the market three years prior to the expiration of the [] patent."[43] But, in reassuring its investors that generic Provigil entry in 2012 will have little effect on Cephalon's bottom line, Cephalon has told a very different story. Most recently, in a February 13, 2009 earnings call discussing its plan to switch sales from Provigil to its follow-on product, Nuvigil, Cephalon's CEO allegedly stated, "if we do our job right . . . the Provigil number in 2012 [the date the settlement agreement permit the generics to enter the market] that

[43] Ceph. Mem. in Support of its Mtn. to Dismiss at 1, *FTC v. Cephalon, Inc.*, No. 08-2141 (E.D. Pa. Mem. filed May 5, 2008).

will be genericized will be very, very small."[44] If Cephalon is successful in its plan, consumers, by any measure, will have received no benefit from the settlement.

Second, experience does not support the contention that Hatch-Waxman cases can typically only be settled by the transfer of value from the patent holder to the generic challenger. On the contrary, the settlement data that the FTC has for the period from 2000 through 2004 indicate that parties can and do find other ways to settle cases. During that period of successful Commission enforcement, pay-for-delay settlements essentially stopped. But patent settlements – using means other than exclusion payments – continued to occur. In less than five years, there were at least as many settlements as there were in the seven years in which pharmaceutical companies were settling litigation with payments and restrictions on generic entry.[45] Parties simply found different ways to resolve their disputes, presumably on the basis of the relative strength of their cases. And patent settlements will continue if Congress enacts legislation that prohibits anticompetitive payments in settlements of Hatch-Waxman patent cases.

Third, the argument that banning pay-for-delay settlements will discourage generic drug companies from mounting patent challenges overlooks one of the fundamental purposes of the Hatch-Waxman Act: the Congressional judgment that weak patents should not create unwarranted barriers to competition from generic drugs. The Hatch-Waxman Act implements that judgment by establishing special rules and procedures when a generic firm seeks approval

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[44] Cephalon Q4 2008 Earnings Call Transcript at 9 (Feb. 13, 2009), *available at* http://seekingalpha.com/article/87859-cephalon-inc-q2-2008-earnings-call.

[45] The agency lacks data for the approximately three year period between the end of the Generic Drug Study in 2000 and the beginning of the MMA reporting period in 2003. It is likely that there are additional settlements that occurred during this period for which the agency does not have information.

to market its product before all relevant patents have expired. Congress designed the regulatory framework to facilitate generic entry; patent challenges are not an end in themselves. The measure of success of the framework Congress devised is not the number of patent challenges filed, but the extent to which such challenges actually deliver savings to consumers. Permitting patent settlements in which the parties share monopoly profits preserved by delaying generic competition may increase the number of patent challenges that are filed, but it does not promote consumer access to generic drugs or cost savings.

III. The Provisions of H.R. 1706

The Commission believes that certain principles are important in crafting the precise form and scope of a legislative remedy to the pay-for-delay settlements. The fundamental antitrust concern underlying such settlements is the sharing of monopoly profits that are 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. At the same time, legislation should be designed to avoid unwarranted deterrence of settlements that present no competitive problem.

H.R. 1706 embodies these principles. Section 2(a) broadly proscribes settlements in which a generic firm receives "anything of value" and agrees to refrain from selling the product. This bill also provides two mechanisms to prevent settlement avenues from being unduly limited, which might chill certain procompetitive settlements. First, Section 2(b) contains express exclusions from the general prohibition on settlements in which the generic firm receives something of value and agrees to refrain from selling its product. Second, Section 3

provides flexibility by authorizing the FTC to adopt rules to exempt other agreements from the general prohibition.

In sum, H.R. 1706 offers a straightforward means to quickly combat anticompetitive conduct that is pervasive and costly to consumers, while also providing flexibility to protect procompetitive arrangements. We would welcome the opportunity to work with the Subcommittee as it continues to consider the bill.

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

H.R. 1706 also includes a provision that addresses the operation of the Hatch-Waxman Act's 180-day exclusivity period, which currently allows the potential for a settlement between a brand-name company and a first generic filer to generate a bottleneck that prevents *any* generic competition.[46] Hatch-Waxman rewards the first filer to challenge a branded drug patent with 180 days of market exclusivity, and bars the FDA from approving any later applicants until the period has expired or been forfeited. Hatch-Waxman was designed to provide a mechanism for a later filer to eliminate this bottleneck, by specifying that if the later filer can get a court ruling that it does not infringe, the first filer must "use or lose" its exclusivity period.[47] But, as discussed in detail in our previous testimony,[48] brand name companies have been able to use

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[46] When parties enter into a settlement agreement and the generic agrees to forgo market entry until some time in the future (whether with or without an accompanying payment), that agreement does not trigger the running of the exclusivity period. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1102(a)(2), Pub. L. No. 108-173, 117 Stat. 2066, 2457 ("MMA") (amending 21 U.S.C. § 355(j)(5)(B)(iv)) makes settlement of patent litigation a forfeiture event only if "a court signs a settlement order or consent decree that enters a final judgment that includes a finding the patent is invalid or not infringed." If the parties request and the court enters a settlement order that does not include such a finding, as is usually the case in this context, the settlement will not constitute a forfeiture event.

[47] Under current law, 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." MMA, § 1102(a)(2), Pub. L. No. 108-173, 117 Stat. 2066, 2457 (amending 21 U.S.C. § 355(j)(5)(B)(iv)). That decision acts as a forfeiture event that forces the first filer to either use or lose its exclusivity period within 75 days.

[48] *See* http://www.ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf.

strategies to avoid the possibility that the generic company will obtain the favorable court decision it needs to relieve the bottleneck. In particular, there was a danger that a brand company could use the 180-day exclusivity to block entry by (1) choosing not to sue a later-filing generic and (2) avoiding a declaratory judgment action by that generic. Section 4 of H.R. 1706 is designed to address that problem.

Recent legal developments concerning the availability of declaratory judgment suits to later generics seeking to eliminate the 180-day bottleneck suggest that branded drug firms can no longer ensure that they will be able to avoid a declaratory judgment action merely by failing to sue the generic applicant[49] or granting a covenant not to sue.[50] But the ultimate extent and scope of this legal change is unclear. It is important that there be a clear and practical mechanism available to subsequent generic filers to seek to relieve the bottleneck created by the 180-day exclusivity when the brand-name manufacturer and first generic applicant have settled their litigation without resolving the issues of validity or infringement or are involved in

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[49] The Supreme Court recently examined the availability of declaratory judgment jurisdiction in patent cases in *Medimmune, Inc. v. Genetech, Inc.*, 549 U.S. 118 (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. In *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007), the Court of Appeals for the Federal Circuit followed the analysis in *MedImmune* and held that an ANDA applicant could bring a declaratory judgment action challenging patents listed in the Orange Book where the brand company had sued on some but not all of the listed patents. The Federal Circuit has not yet addressed the question of whether an ANDA applicant can bring a declaratory judgment action when the brand company has not sued for infringement of any listed patent.

[50] *See Caraco Pharm. v. Forest Labs.*, 527 F.3d 1278 (Fed. Cir. 2008), *cert denied,* 77 U.S.L.W. 3308 (U.S. Feb. 23, 2009) (No. 08-624) (in the context of Hatch-Waxman Act, the patentee's grant of a covenant not to sue did not eliminate the controversy between the parties). One district court has read *Caraco* to apply only to pre-MMA ANDAs. *See Ivax Pharm. v. AstraZeneca*, No. 08-2165, 2008 WL 4056518 (D.N.J Aug. 28, 2008) ; *Dr. Reddy's Labs. v. AstraZeneca*, No. 08-2496, 2008 WL 4056533 (D.N.J. Aug 28, 2008). Another district court has rejected that view and held that the Federal Circuit's *Caraco* decision applies equally ANDAs filed after enactment of the MMA. *See Dey, L.P. v. Sepracor, Inc.*, No. 08-2496, 2009 WL 230001 (D. Del. Jan 30, 2009).

protracted litigation.[51] Otherwise, even if the subsequent filer has a strong case for non-infringement, the bottleneck postpones consumer access to any lower-priced generic version of the drug. Such a result is contrary to the Hatch-Waxman Act's purposes of encouraging meritorious patent challenges and promoting generic entry.

Conclusion

Thank you for this opportunity to share the Commission's views. The Commission looks forward to working with the Subcommittee to protect consumers in this critical sector of the economy.

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[51] 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. *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).