**PREPARED STATEMENT OF THE**
**FEDERAL TRADE COMMISSION**

**Before the**

**SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION**

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

[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.

[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

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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-as

[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 Ma

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.

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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 compaas8.00 rgBT72.0000 520.0800 TD0.0000 Tc0hsl0 0.0000 TD( a)Tj0000 Tc0.0000 Tw(compbano(e)Tj5.28

[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.

[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/MMAr5.0400pATj9.4800 0.0000 TD(f)T(n)Tj.0000 TDl(0000 0.00000 1.00000 0.0000

### 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

## 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 oF9 6.9600 Tf0.1200 Tc1800 0.0on.8000 0.0000 TD(d.)Tj w3wbl87x.0000 TD(lid)Tj10.5600 0.00

[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).

[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 1989-199

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.

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

[41] 402 F.3d at 1074.

[42] *Id.* at 1076.

[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, 20

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

[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.

[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 follo0 TD(o)Tj5.0400 0.0000000 TD(o)Tj5.04j5.0400 0.0000 TD(0.5400

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.

[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).