Prepared Statement of The Federal Trade Commission

Before the

Committee on Judiciary
United States Senate

Washington, D.C.

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I. Introduction

Mr. Chairman, I am Timothy J. Muris, Chairman of the Federal Trade Commission. I am pleased to appear before the Committee today to testify on behalf of the Commission regarding competition in the pharmaceutical industry, and, in particular, findings and recommendations in the July 2002 FTC Study of Generic Drug Entry Prior to Patent Expiration.[1]

Advances in the pharmaceutical industry continue to bring enormous benefits to Americans. Because of pharmaceutical innovations, a growing number of medical conditions often can be treated more effectively with drugs and drug therapy than with alternative means *(e.g.*, surgery). The development of new drugs is risky and costly. Expenditures on pharmaceutical products continue to grow. The growth of prescription drug spending at retail outlets has "exceeded that of other health services by a wide margin, increasing 17.3 percent in 2000, the sixth consecutive year of double-digit growth."[2] Pharmaceutical expenditures are thus a concern not only to individual consumers, but also to government payers, private health plans, and employers.

To address the issue of escalating drug expenditures, and to ensure that the benefits of pharmaceutical innovation would continue, Congress passed the Hatch-Waxman Amendments[3] ("Hatch-Waxman" or "the Amendments") to the Food, Drug and Cosmetic Act ("FDC Act").[4] Hatch-Waxman established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers.[5] Without question, Hatch-Waxman has increased generic drug entry. The Congressional Budget Office estimated that, by purchasing generic equivalents of brand-name drugs, consumers saved $8-10 billion on retail purchases of prescription drugs in 1994 alone.[6] With patents set to expire within the next several years (or those that have recently expired) on brand-name drugs having combined U.S. sales of almost $20 billion,[7] the already substantial savings are likely to increase dramatically.

Yet, in spite of this remarkable record of success, the Amendments have also been subject to some abuse. Although many drug manufacturers - including both brand-name and generic companies - have acted in good faith, others have attempted to "game" the system, securing greater profits for themselves without providing a corresponding benefit to consumers. Responding to these abuses, the Senate last year passed S. 812, the Greater Access to Affordable Pharmaceuticals Act introduced by Senators McCain and Schumer and S. 754 , the Drug Competition Act, introduced by Senator Leahy. In addition, last October, the Food and Drug Administration ("FDA") proposed rules to limit certain of these abuses,thi79(i)13(t)t ia sav2(c)-3(t)2(houteekTJ T* [3(n)13)-1())4(pr (t)2(o)13n(e)13(ady)(o)13zai)13d* [3(n)113

Commissioners have addressed the subject of pharmaceutical competition before a variety of audiences, both to

however, the filing of that suit triggers an automatic 30-month stay of FDA approval of the ANDA.[25] During this period, unless the patent litigation is resolved in the generic's favor, the FDA cannot approve the generic product.

The second significant component of Hatch-Waxman is the "180-day period of exclusivity." The Amendments provide that the first generic manufacturer to file an ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity, during which the FDA may not approve a subsequent applicant's ANDA.[26] The 180-day exclusivity period increases the economic incentives for a generic company to be the first to file an ANDA, because the generic applicant has the potential to reap the reward of marketing the only generic product (and, thus, to charge a hig

Our "second generation" of enforcement activities has involved allegations that individual brand-name manufacturers have delayed generic competition through the use of improper Orange Book listings[36] that trigger a Hatch-Waxman provision prohibiting the FDA from approving a generic applicant for 30 months. Brand-name drug manufacturers may sometimes act strategically to obtain *more than one* 30-month stay of FDA approval of a particular generic drug. The Commission recently described the consumer harm that occurs when an invalid patent forms the basis of such 30-month stays.[37]

1. Clarification of *Noerr-Pennington* Doctrine: *In re Buspirone*

Unlike the settled cases discussed above, which involved alleged collusion between private parties, an improper Orange Book listing strategy involves unilateral abuse of the Hatch-Waxman process itself to restrain trade. Such conduct has raised *Noerr-Pennington* antitrust immunity issues, an area of longstanding Commission interest. The *Noerr* doctrine[38] provides antitrust immunity for parties "petitioning" government. While the *Noerr* doctrine is an

In August 2002, the Commission issued a consent order against two generic drug manufacturers to resolve charges that they entered into an agreement that unreasonably reduced competition in the market for a generic anti-hypertension drug.[55] According to the Commission's complaint, Biovail Corporation (Biovail) and Elan Corporation PLC (Elan) agreed not to compete in marketing 30 mg and 60 mg generic Adalat CC products, and that the agreement lacked any countervailing efficiencies.[56]

The order, which has a ten-year term, remedies the companies' alleged anticompetitive conduct by requiring them to terminate the agreement and barring them from engaging in similar conduct in the future.[57] The order maintains commercial supply of the incumbent generic Adalat products while the companies unwind their agreement, and eliminates the anticompetitive obstacles to entry of a second 30 mg and a second 60 mg generic Adalat CC product.

IV. The Commission's Industry-Wide Generic Drug Competition Study

A. Background and Introduction

In light of the questions its various generic drug investigations raised, the Commission proposed an industry-wide study of generic drug competition in October 2000. The FTC Study focused solely on the procedures used to facilitate generic drug entry *prior to* expiration of the patent(s) that protect the brand-name drug product - that is, generic entry through the procedures involving Paragraph IV certifications.[58] The Commission undertook the study for three reasons:

(1) To determine whether alleged anticompetitive agreements that relied on certain Hatch-Waxman provisions were isolated instances or more typical, and whether particular provisions of the Amendments are susceptible to strategies to delay or deter consumer access to generic alternatives to brand-name drug products;

(2) To respond to Representative Henry Waxman's request for the Commission to "investigate and produce a study on the use of agreements between and among pharmaceutical companies and potential generic competitors and any other strategies that may delay generic drug competition throughout the U.S."; and

(3) To ensure that there are no roadblocks in the way of generic competition for the substantial sales volume of brand-name drug products coming off patent in the next several years.[59] Brand-name companies seeking to protect the sales of brand-name drugs may have an incentive and ability to enter into agreements with would-be generic competitors, or engage in other types of activities, that would slow or thwart the entry of competing generic drug products.

In April 2001, the Commission received clearance from the Office of Management and Budget ("OMB") to conduct the study.[60] The Commission issued nearly 80 special orders - pursuant to Section 6(b) of the FTC Act[61] - to brand-name companies and to generic drug manufacturers, seeking information about certain practices that were outlined in the Federal Register notices that preceded OMB clearance to pursue the study.[62] The Commission staff focused the special orders on brand-name drug products that were the subject of Paragraph IV certifications filed by generic applicants. Only those NDAs in which a generic applicant notified a brand-name company with a Paragraph IV certification after January 1, 1992, and prior to January 1, 2001, were included in the FTC Study. The selection criteria resulted in 104 drug products, as represented by NDAs filed with the FDA, within the scope of the study and included so-called "blockbuster" drugs such as Capoten, Cardizem CD, Cipro, Claritin, Lupron Depot, Neurontin, Paxil, Pepcid, Pravachol, Prilosec, Procardia XL, Prozac, Vasotec, Xanax, Zantac, Zocor, Zoloft, and Zyprexa.

Responses from the 28 brand-name companies and nearly 50 generic applicants generally were completed by the end of 2001. The Commission staff compiled the information received to provide a factual description of how the 180-day marketing exclusivity and 30-month stay provisions affect the timing of generic entry prior to patent expiration. The FTC Study did not provide an antitrust analysis of each of the types of agreements submitted, nor did it examine other issues involved in the debate over generic drugs, such as bioequivalence or the appropriate length of patent restorations under Hatch-Waxman.

In addition to the final settlements with the first generic applicant, brand-name companies entered final patent settlements with the second generic applicant in seven instances. In six of the seven, the brand-name company also had settled with the first generic applicant.

F. Recommendations: The 180-Day Exclusivity Provision

To mitigate the possibility of abuse of the 180-day exclusivity provision, the FTC Study recommended that Congress pass the Drug Competition Act

generic applicant.[77] Moreover, if the later court issues a non-infringement decision, the reasoning underlying the holding may not apply to the first generic applicant's ANDA, depending upon the facts of the case.

Recommendation 3: *Clarify that a court decision dismissing a declaratory judgment action for lack of subject matter jurisdiction constitutes a "court decision" sufficient to trigger the 180-day exclusivity.*

One court of appeals has held that a dismissal of a declaratory judgment action for lack of a case or controversy is a "court decision" of non-infringement sufficient to trigger the 180-day exclusivity.[78] In the FTC Study, the Commission found the court's reasoning persuasive, and recommended that Congress adopt such a rule.

The U.S. Court of Appeals for the District of Columbia confronted a situation in which the brand-name company did not sue any of the generic applicants for patent infringement. To trigger the first generic applicant's 180-day exclusivity (because it had not yet been approved by the FDA), the second generic applicant sought a declaratory judgment that its ANDA did not infringe the brand-name product's patents. The district court hearing the case dismissed the lawsuit for lack of subject matter jurisdiction, because the brand-name company indicated that it would not sue the second generic applicant for patent infringement, thus eliminating its reasonable apprehension of a patent infringement suit and the existence of a case or controversy. This dismissal also estopped the brand-name company from suing the generic applicant in the future.

The Court of Appeals determined that the dismissal for lack of case or controversy was, in fact, a court decision,

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>.

14. *See*, *e.g.*, Sheila F. Anthony, *Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property* (June 1, 2000), *available at* <http://www.ftc.gov/speeches/anthony/sfip000601.htm>; Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes* (Nov. 3, 2000), *available at* <http://www.ftc.gov/speeches/leary/learypharma.htm>; Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II* ("Part II") (May 17, 2001), *available at* <http://www.ftc.gov/speeches/leary/learypharma2.htm> (available)

33. *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), complaint

45. *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972).

46. *Id.* at 513. *See also Primetime 24 Joint Venture v. National Broadcasting Co.,* 219 F.3d 92, 101 (2d Cir. 2000) (district court should not have dismissed on *Noerr* grounds plaintiff's allegations that defendants violated Section 1 of the Sherman Act by filing repeated, baseless signal strength challenges under the Satellite Home Viewer Act); *USS-POSCO Indus. v. Contra Costa County Bldg. & Constr. Trades Council*, 31 F.3d 800, 811 (9th Cir. 1994) ("When dealing with a series of lawsuits, the question is not whether any one of them has merit - some may turn out to, just as a matter of chance - but whether they are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival.").

47. *Bristol-Myers* Analysis to Aid Public Comment, *supra*

patents are invalid and that one patent is not infringed by the generic applicant's ANDA. There has not yet been a ruling on the other patents and ANDA applicants involved in the case.

65. FDA approval of ANDAs submitted by first generic applicants who were not sued by the brand-name company took, on average, 25.5 months from the ANDA filing date.

66. The only instances in which a generic applicant has entered the market prior to a district court resolving the patent infringement litigation has been when the litigation involved a patent that was listed in the Orange Book *after* the generic applicant had filed its ANDA.

67. *See supra* note 39 and accompanying text. Although the FDC Act does not create a private right of action that would permit a generic drug manufacturer to bring a suit to de-list a patent in the first instance, or to seek de-listing via a counterclaim, the Federal Circuit has held that a district court may order de-listing as a remedy when, in the course of patent infringement litigation, a listed patent is held to be invalid or unenforceable. *Abbott Laboratories v. Novopharm Ltd.*, 104 F.3d 1305, 1309 (Fed. Cir. 1997); *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1333 (Fed. Cir. 2001). *See also* Memorandum of Law of Federal Trade Commission as *Amicus Curiae* Concerning Torpharm's Cross Motion for Entry of an Amended Order, *supra* note 37.

68. Last week, the FDA issued a final rule amending its regulations governing the availability of, and triggers for, the 30-month stay provisions and to clarify its patent listing requirements. *See supra* note 8. This rule is discussed in Section G *infra*.

69. The Federal Circuit's recent decision in *Allergan* may implicate whether a patentee can sue under Section 271(e)(2) of the Patent Act for patents covering unapproved uses of the drug. S*ee Allergan, Inc. v. Alcon Labs,* Docket No. 02-1449 (Fed. Cir. Mar. 28, 2003). We recommended that the analysis of whether an infringement suit is appropriate is distinct from the analysis of whether a patent is appropriately listed in the Orange Book and, therefore, a potential basis for a 30-month stay.

70. One of these agreements is subject to litigation currently pending at the FTC. *See Schering-Plough Corp.*

Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed, Final Rule (June 12, 2003).