

**Prepared Statement of
The Federal Trade Commission**

Before the

**Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives**

Washington, D.C.

October 9, 2002

I. Introduction

Mr. Chairman, I am Timothy J. Muris, Chairman of the Federal Trade Commission. I am pleased to appear before the Subcommittee today to testify on behalf of the Commission regarding competition in the pharmaceutical industry.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, however, which increases the prices of prescription drugs. 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 Amendments³

¹ The 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 K. Levit, C. Smith, C. Cowan, H. Lazenby & A. Martin, “Inflation Spurs Health Spending in 2000,” 21:1 *Health Affairs* 179 (2002), citing data from the Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, of which the authors are members.

³ Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

(“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 estimates 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 four years 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 companies and generics – have acted in good faith, others have attempted to “game” the system, securing greater profits for themselves without providing a corresponding benefit to consumers. This testimony will describe the Commission’s past and present response to these anticompetitive efforts.

The Commission has pursued numerous antitrust enforcement actions affecting both brand-name and generic drug manufacturers.⁸ In addition, the Commission recently released a study entitled “Generic Drug Entry Prior to Patent Expiration” (“FTC Study”). That study examines whether the conduct that the FTC has challenged represented isolated instances or is more typical of business practices in the pharmaceutical industry, and whether certain provisions of Hatch-Waxman are susceptible to strategies to delay or deter consumer access to generic alternatives to brand-name drug products.⁹ The Commission has gained expertise regarding competition in the pharmaceutical industry through other means as well. The Commission staff has conducted empirical analyses of competition in

⁴ 21 U.S.C. § 301 *et seq.*

⁵ *See infra* note 14 and accompanying text. The Amendments also were intended to encourage pharmaceutical innovation through patent term extensions.

⁶ Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) (“CBO Study”), available at <<http://www.cbo.gov/showdoc.cfm?index=655&sequence=0>>.

⁷ *Id.* at 3.

⁸ *See, e.g., Biovail Corp. and Elan Corp. PLC*, Dkt. No. C-4057 (Aug. 20, 2002) (consent order); *Biovail Corp.*, Dkt. No. C-4060 (Oct. 2, 2002) (consent order); *FTC v. Mylan Laboratories, Inc. et al.*, 62 F. Supp. 2d 25 (D.D.C. 1999); *Roche Holding Ltd.*, 125 F.T.C. 919 (1998) (consent order); *Ciba-Geigy Ltd.*, 123 F.T.C. 842 (1997) (consent order).

⁹ Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), available at <<http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>>.

the pharmaceutical industry, including in-depth studies by the staff of the Bureau of Economics.¹⁰ The Commission's efforts have included filing comments with the Food and Drug Administration ("FDA") regarding the competitive aspects of Hatch-Waxman implementation,¹¹ as well as previous testimony before Congress.¹² Furthermore, individual Commissioners have addressed the subject of pharmaceutical competition before a variety of audiences, both to solicit input from affected parties and to promote discussion about practical solutions.¹³

After reviewing the relevant Hatch-Waxman provisions, this testimony will address the

¹⁰ Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999), available at <<http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>>; David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002) ("Reiffen and Ward"), available at <<http://www.ftc.gov/be/econwork.htm>>.

¹¹ *FDA: Citizen Petition*, Comment of the Staff of the Bureau of Competition and of the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Mar. 2, 2000), available at <<http://www.ftc.gov/be/v000005.pdf>> (recommending modifications to the FDA's Proposed Rule on citizen petitions intended to discourage anticompetitive abuses of the FDA's regulatory processes); *FDA: 180-Day Marketing Exclusivity for Generic Drugs*, Comment of the Staff of the Bureau of Competition and of the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Nov. 4, 1999) ("Marketing Exclusivity Comment"), available at <<http://www.ftc.gov/be/v990016.htm>> (recommending that the FDA's Proposed Rule on 180-day marketing exclusivity be modified to limit exclusivity to the first ANDA filer and to require filing of patent litigation settlement agreements).

¹² 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>>.

¹³ 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/learypharmaceutical_settlement.htm>; Timothy J. Muris, *Competition and Intellectual Property Policy: The Way Ahead*, at 5-6 (Nov. 15, 2001), available at <<http://www.ftc.gov/speeches/muris/intellectual.htm>>.

Commission's vigorous enforcement of the antitrust laws with respect to generic drug competition. These efforts have entailed several types of conduct relating to certain Hatch-Waxman provisions. One type of conduct involves allegedly anticompetitive settlements between brand-name companies and generics. Because the Commission became aware of and challenged such settlements first, this testimony refers to those matters as "first-generation litigation." Other, more recent types of conduct, such as allegedly improper Orange Book listings and potentially anticompetitive settlements between generic manufacturers themselves, are the subject of the Commission's "second-generation actions."

Next, the testimony will address the Commission's industry-wide study of generic drug entry prior to patent expiration. An understanding of the Commission's cases in this area will provide the framework for the issues that the Commission examined in this study.

II. Regulatory Background: The Hatch-Waxman Drug Approval Process

A. The Hatch-Waxman Balance

The stated purpose of Hatch-Waxman is to "make available more low cost generic drugs."¹⁴ The concern that the FDA's lengthy drug approval process was unduly delaying market entry by generic versions of brand-name prescription drugs motivated Congress's passage of the Amendments. Because a generic drug manufacturer was required to obtain FDA approval before selling its product, and could not begin the approval process until any conflicting patents on the relevant brand-name product expired, the FDA approval process essentially functioned to extend the term of the brand-name manufacturer's patent. To correct this problem, Congress provided in the Amendments that certain conduct related to obtaining FDA approval, which would otherwise constitute patent infringement, would be exempted from the patent laws.

Congress continued to regard patent protection, however, as critical to pharmaceutical innovation and an important priority in its own right. Hatch-Waxman thus represented a compromise: an expedited FDA approval process to speed generic entry balanced by additional intellectual property protections to ensure continuing innovation. As one federal appellate judge explained, the Amendments "emerged from Congress's efforts to balance two conflicting policy objectives: to induce brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."¹⁵

Pursuant to the FDC Act, a brand-name drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application ("NDA"). At the time the NDA is filed, the NDA filer must also provide the FDA with certain categories of information regarding

¹⁴ H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

¹⁵ *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting) (citations omitted).

patents that cover the drug that is the subject of its NDA.¹⁶ 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.”¹⁷

Rather than requiring a generic manufacturer to repeat the costly and time-consuming NDA process, the Amendments permit the company to file an Abbreviated New Drug Application (“ANDA”), which references data that the “pioneer” manufacturer has already submitted to the FDA regarding the brand-name drug’s safety and efficacy. Under the ANDA process, an applicant must demonstrate that the generic drug is “bioequivalent” to the relevant brand-name product.¹⁸ The ANDA must contain, among other things, a certification regarding each patent listed in the Orange Book in conjunction with the relevant NDA.¹⁹ One way to satisfy this requirement is to provide a “Paragraph IV certification,” asserting that the patent in question is invalid or not infringed.²⁰

Filing a Paragraph IV certification potentially has significant regulatory implications, as it is a prerequisite to the operation of two provisions of the statute. The first of these is the automatic “30-month stay” protection afforded to patent holders and the NDA filer – most typically, brand-name companies. An ANDA filer that makes a Paragraph IV certification must provide notice to both the patent holder and the NDA filer, including a detailed statement of the factual and legal basis for the ANDA filer’s assertion that the patent is invalid or not infringed.²¹ Once the ANDA filer has provided such notice, a patent holder wishing to take advantage of the statutory stay provision must bring an infringement suit within 45 days.²² If the patent holder does not bring suit within 45 days, the FDA may approve the ANDA as soon as other regulatory conditions are fulfilled.²³ If the patent holder does bring suit, however, the filing of that suit triggers an automatic 30-month stay of FDA approval of the

¹⁶ 21 U.S.C. § 355(b)(1).

¹⁷ *Id.* at § 355(j)(7)(A).

¹⁸ *Id.* at § 355(j)(2)(A)(iv).

¹⁹ *Id.* at § 355(j)(2)(A)(vii).

²⁰ *Id.* at § 355(j)(2)(A)(vii)(IV).

²¹ *Id.* at § 355(j)(2)(B). Although the patent holder and the NDA filer are often the same person, this is not always the case. Hatch-Waxman requires that all patents that claim the drug described in an NDA be listed in the Orange Book. Occasionally, this requires an NDA filer to list a patent that it does not own.

²² *Id.* at § 355(j)(5)(B)(iii).

²³ *Id.* For example, the statute requires the ANDA applicant to establish bioequivalence. *Id.* at § 355(j)(2)(A)(iv).

ANDA.²⁴ 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 potential competitor’s ANDA.²⁵ Through this 180-day provision, the Amendments provide an increased incentive for companies to challenge patents and develop alternative forms of patented drugs.²⁶ The 180-day period is calculated from the date of the first commercial marketing of the generic drug product or the date of a court decision declaring the patent invalid or not infringed, whichever is sooner.²⁷ The 180-day exclusivity period increases the economic incentives for a generic company to be the first to file an ANDA.²⁸ Of course, during the 180 days, the generic competes with the brand-name product. After the 180 days, subject to regulatory approvals and determination of the outcomes of any patent suits, other generics can enter the market.

B. Competitive Implications

The 30-month stay and the 180-day period of exclusivity were both parts of the Hatch-Waxman balance. The imposition of a 30-month stay of FDA approval of an eligible ANDA could forestall generic competition during that period of time. The 180-day period of exclusivity can, in some circumstances, limit the number of generic competitors during this 180-day period. Over the past few years the Commission has observed through its investigations, law enforcement actions, and industry-wide study that some brand-name and generic drug manufacturers may have “gamed” these two provisions, attempting to restrict competition beyond what the Amendments intended. The next section of this testimony discusses the Commission’s efforts to investigate vigorously and to prosecute such abuses.

²⁴ *Id.* at § 355(j)(5)(B)(iii).

²⁵ *Id.* at § 355(j)(5)(B)(iv).

²⁶ *See Granutec, Inc. v. Shalala*, 139 F.3d 889, 891 (4th Cir. 1998).

²⁷ 21 U.S.C. § 355(j)(5)(B)(iv).

²⁸ There has been litigation over what acts trigger the 180-day period of exclusivity. *See* FTC Study, *supra* note 9. This study is discussed in detail below.

III. Promoting Competition Through Antitrust Enforcement

A. First-Generation FTC Litigation: Settlements Between Brand-Name Companies and Generic Applicants

Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a significantly lower price than its brand-name counterpart, and gains substantial share from the brand-name product.²⁹ Subsequent generic entrants may enter at even lower prices and cause the earlier entrants to reduce their prices. These are precisely the procompetitive consumer benefits that the Amendments were meant to facilitate.

This competition substantially erodes the profits of brand-name pharmaceutical products. Although successful generic applicants are profitable, their gain is substantially less than the loss of profits by the brand-name product, because of the typical difference in prices between brand-name and generic products. As a result, both parties may have economic incentives to collude to delay generic entry. By blocking entry, the brand-name manufacturer may preserve monopoly profits. A portion of these profits, in turn, can be used to fund payments to the generic manufacturer to induce it to forgo the profits it could have realized by selling its product. Furthermore, by delaying the first generic's entry – and with it, the triggering of the 180 days of exclusivity – the brand-name and first-filing generic firms can sometimes forestall the entry of other generics.

The Commission's first-generation litigation focused on patent settlement agreements between brand-name companies and generic applicants that the Commission alleged had delayed the entry of one or more generic applicants. Of course, resolving patent infringement litigation through settlement can be efficient and procompetitive. Certain patent settlements between brand-name companies and generic applicants, however, drew the Commission's attention when it appeared that their terms may have reduced competition through abuses of the Hatch-Waxman regime.

Two leading cases illustrate the Commission's efforts in the area: *Abbott/Geneva* and *Hoechst/Andrx*. The first of these cases involved an agreement between Abbott Laboratories and Geneva Pharmaceuticals, Inc. relating to Abbott's brand-name drug Hytrin. The Commission's complaint alleged that Abbott paid Geneva approximately \$4.5 million per month to delay the entry of its generic Hytrin product, potentially costing consumers hundreds of millions of dollars a year.³⁰ The complaint further alleged that Geneva agreed not to enter the market with *any* generic Hytrin product – including a non-infringing product – until (1) final resolution of the patent infringement litigation involving

²⁹ See CBO Study, *supra* note 6; see generally Reiffen and Ward, *supra* note 10.

³⁰ *Abbott Laboratories*, Dkt. No. C-3945 (May 22, 2000) (consent order), complaint available at <<http://www.ftc.gov/os/2000/05/c3945complaint.htm>>; *Geneva Pharmaceuticals, Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), complaint available at <<http://www.ftc.gov/os/2000/05/c3946complaint.htm>>.

Geneva's generic Hytrin tablets, or (2) market entry by another generic Hytrin manufacturer. Geneva also allegedly agreed not to transfer its 180-day marketing exclusivity rights.

The second case involved an agreement between Hoechst Marion Roussel, Inc. and Andrx Corp. relating to Hoechst's brand-name drug Cardizem CD. The Commission's complaint alleged that Hoechst paid Andrx over \$80 million, during the pendency of patent litigation, to refrain from entering the market with its generic Cardizem CD product.³¹ As in the *Abbott/Geneva* case, the Commission's complaint also asserted that the agreement called for Andrx, as the first ANDA filer, to use its 180-day exclusivity rights to impede entry by other generic competitors.

The Commission resolved both cases by consent order.³² The orders prohibit the respondent companies from entering into brand/generic agreements pursuant to which a generic company that is the first ANDA filer with respect to a particular drug agrees not to (1) enter the market with a non-infringing product, or (2) transfer its 180-day marketing exclusivity rights. In addition, the orders require the companies to obtain court approval for any agreements made in the context of an interim settlement of a patent infringement action that provide for payments to the generic to stay off the market, with advance notice to the Commission to allow it time to present its views to the court. The orders also require advance notice to the Commission before the respondents can enter into such agreements in non-litigation contexts.

Although each case turns on its own specific facts, these cases highlight the Commission's concern about settlements whose primary effect appears to be to delay generic entry, leading to less vigorous competition and higher prices for consumers. Of course, not all settlements are problematic. The Commission has not attempted to provide a comprehensive list of potentially objectionable settlement provisions. However, it is possible to identify from the Commission's reported matters a few provisions that, within the Hatch-Waxman context, have drawn antitrust scrutiny. These include:

³¹ *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), complaint available at <<http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>>.

³² 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.pdf>>. In another matter, *Schering-Plough*, the Commission resolved all claims against one of three respondents, American Home Products ("AHP"), by issuing a final consent order. *Schering-Plough Corp.*, Dkt. No. 9297 (consent order as to AHP issued Apr. 2, 2002), available at <http://www.ftc.gov/os/2002/04/scheringplough_do.htm>.

The case against the other two respondents is in litigation before the Commission. See *Schering-Plough Corp., et al.*, Dkt. No. 9297 (Initial Decision) (July 2, 2002), available at <<http://www.ftc.gov/os/2002/07/scheringinitialdecision1.pdf>>.

(1) *Provisions that provide for “reverse” payments.* “Reverse” payments (*i.e.*, payments from the patent holder to the alleged infringer) may merit antitrust scrutiny because they may represent an anticompetitive division of monopoly profits.

(2) *Provisions that restrict the generic’s ability to enter with non-infringing products.* Such provisions can extend the boundaries of the patent monopoly without providing any additional public disclosure or incentive to innovate, and therefore have the potential to run afoul of the principles of antitrust law.³³

(3) *Provisions that restrict the generic’s ability to assign or waive its 180-day marketing exclusivity rights.* Because a second ANDA filer may not enter the market until the first filer’s 180-day period of marketing exclusivity has expired, restrictions on assignment or waiver of the exclusivity period can function as a bottleneck, potentially delaying subsequent generic entry for an extended period.³⁴

B. Second-Generation FTC Actions: Improper Orange Book Listings

1. *In re Buspirone*

A principal focus of the Commission’s second-generation activities has been improper Orange Book listings.³⁵ 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.

³³ *Cf. Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964) (holding that “enlarg[ing] the monopoly of the patent” by collecting post-expiration royalties constitutes patent misuse).

³⁴ *But see* Leary, Part II, *supra* note 13, at 7 (arguing that agreements regarding waiver of 180-day exclusivity period may have no anticompetitive effect absent reverse payment).

³⁵ The Commission first raised concerns about the potential anticompetitive impact of improper Orange Book listings in *American Bioscience, Inc. v. Bristol-Myers Squibb Co., et al.*, Dkt. No. CV-00-08577 (C.D. Cal. Sept. 7, 2000). *See* Federal Trade Commission Brief as *amicus curiae*, available at <<http://www.ftc.gov/os/2000/09/amicusbrief.pdf>>. In that case, the parties sought court approval of a settlement containing a specific factual finding that Bristol-Myers was required to list American Bioscience’s patent of Bristol-Myers’s branded drug Taxol in the Orange Book. The Commission was concerned that the court’s approval of the settlement would amount to a judicial finding that the patent met the statutory requirements for listing in the Orange Book and would prejudice parties who might later challenge the listing.

The *Noerr* doctrine³⁶ provides antitrust immunity for individuals “petitioning” government. While the *Noerr* doctrine is an important limitation on the antitrust laws that protects the right of individuals to communicate with government entities, some courts have interpreted the doctrine too broadly in ways that are inconsistent with Supreme Court precedent.

To address the concern that the *Noerr* doctrine was being interpreted too expansively, a *Noerr-Pennington* Task Force of Commission staff began work in June 2001. One of the objectives of the Task Force was to examine certain aspects of the *Noerr* doctrine, such as the scope of “petitioning” conduct and the continuing existence of a misrepresentation exception to *Noerr* immunity.

One of the first potential abuses the Task Force considered was the improper listing of patents in the FDA’s Orange Book. Pursuant to current policy, the FDA does not review patents presented for listing in the Orange Book to determine whether they do, in fact, claim the drug product described in the relevant NDA.³⁷ Instead, the FDA takes at face value the declaration of the NDA filer that the listing is appropriate. As a result, an NDA filer acting in bad faith can successfully list patents that do not satisfy the statutory listing criteria. Once listed in the Orange Book, these patents have the same power to trigger a 30-month stay of ANDA approval as any listed patent, thereby delaying generic entry and potentially costing consumers millions, or even billions, of dollars without valid cause.

In January of this year, lawsuits relating to Bristol-Myers’s alleged monopolization through improper listing of a patent on its brand-name drug BuSpar³⁸ presented the Commission with an opportunity to clarify the *Noerr* doctrine in a way that might have a significant impact on the Commission’s ongoing pharmaceutical cases. Specifically, plaintiffs alleged that, through fraudulent

³⁶ The *Noerr* doctrine was first articulated as an interpretation of the Sherman Act in *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965).

³⁷ See 21 C.F.R. § 314.53(f); see also *Abbreviated New Drug Application Regulations – Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50343 (1994) (“FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims.”); *Abbreviated New Drug Application Regulations*, 54 Fed. Reg. 28872, 28910 (1989) (“In deciding whether a claim of patent infringement could reasonably be asserted . . . the agency will defer to the information submitted by the NDA applicant.”).

³⁸ *In re Buspirone Patent Litigation/In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (“*In re Buspirone*”). Some of the same plaintiffs previously had brought suit under the FDC Act, requesting that the court issue an order compelling Bristol-Myers to de-list the objectionable patent. Although plaintiffs prevailed at the district court level, the Federal Circuit reversed that decision, holding that the FDC Act did not provide a private right of action to compel de-listing of a patent from the Orange Book. See *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1331-32 (Fed. Cir. 2001).

filings with the FDA, Bristol-Myers caused that agency to list the patent in question in the Orange Book, thereby blocking generic competition with its BuSpar product, in violation of Section 2 of the Sherman Act.³⁹

Bristol-Myers responded to these allegations by filing a motion to dismiss that raised, principally, a claim of *Noerr-Pennington* immunity. Given the importance of the issue to competition in the pharmaceutical industry, as well as to the Commission's ongoing investigations, the Commission filed an *amicus* brief opposing the motion to dismiss.⁴⁰ On February 14, 2002, the court issued an opinion denying Bristol-Myers's immunity claim and accepting most of the Commission's reasoning on the *Noerr-Pennington* issue.⁴¹

In light of the *Buspirone* decision, the *Noerr-Pennington* doctrine may not prove as large an obstacle to using the antitrust laws to remedy improper Orange Book filings as some may have anticipated. It is worth noting, and indeed emphasizing, that *Buspirone* does not mean that all improper Orange Book filings will give rise to antitrust liability. Any antitrust liability must be predicated on a clear showing of a violation of substantive antitrust law. *Buspirone* makes it clear, however, that Orange Book filings are not *immune* from those laws or *exempt* from their scrutiny.

2. *Biovail (Tiazac)*

Last week, the Commission announced that it had issued a consent order against Biovail Corporation,⁴² settling charges that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book for the purpose of blocking generic competition to its brand-name drug Tiazac. This was the Commission's first enforcement action to remedy the effects of an allegedly improper, anticompetitive Orange Book listing.

Prior to the events giving rise to the Commission's complaint, Biovail already had triggered a 30-month stay of FDA final approval of Andrx's generic Tiazac product, by commencing an infringement lawsuit against Andrx. Andrx prevailed in the courts, however, so that the stay would have

³⁹ 15 U.S.C. § 2.

⁴⁰ Memorandum of Law of *Amicus Curiae* Federal Trade Commission in Opposition to Defendant's Motion to Dismiss, available at <<http://www.ftc.gov/os/2002/01/busparbrief.pdf>>. (The Commission argued that Orange Book filings are not "petitioning activity" immune from antitrust scrutiny.)

⁴¹ *In re Buspirone*, *supra* note 38

⁴² *Biovail Corp.*, *supra* note 8.

been lifted by February 2001. According to the Commission's complaint,⁴³ Biovail, in anticipation of pending competition from Andrx, undertook a series of anticompetitive actions to trigger a new stay and maintain its Tiazac monopoly. Just before the stay was to terminate, Biovail acquired exclusive rights to a newly issued patent from a third party and listed that patent in the Orange Book as claiming Tiazac – thereby requiring Andrx to re-certify to the FDA and opening the door to Biovail's suit against Andrx for infringement of the new patent and commencement of a second 30-month stay.

The Commission's complaint alleged that Biovail's patent acquisition, wrongful Orange Book listing, and misleading conduct before the FDA were acts in unlawful maintenance of its Tiazac monopoly, in violation of Section 5 of the Federal Trade Commission Act⁴⁴ ("FTC Act"), and that the acquisition also violated Section 7 of the Clayton Act⁴⁵ and Section 5 of the FTC Act.

The consent order requires Biovail to divest the exclusive rights to their original owner with certain exceptions; to achieve dismissal with prejudice of any and all claims relating to enforcement of the patent in relation to Tiazac; and to refrain from any action that would trigger another 30-month stay on generic Tiazac entry. Further, the order prohibits Biovail from unlawfully listing patents in the Orange Book and requires Biovail to give the Commission prior notice of acquisitions of patents that it will list in the Orange Book for Biovail's FDA-approved products. These measures should not only remedy Biovail's allegedly unlawful conduct, but also send a strong message that the Commission will act decisively to eliminate anticompetitive practices in the pharmaceutical industry.

C. Settlements Between Generic Manufacturers

Although agreements between first and second generic entrants have attracted significantly less attention to date, they too can raise competitive concerns and may draw antitrust scrutiny. As in the case of agreements between brand-name companies and generic applicants, the economic incentives to collude can be strong. Studies indicate that the first generic typically enters the market at 70 to 80 percent of the price of the corresponding brand⁴⁶ and rapidly secures as much as a two-thirds market share. The second generic typically enters at an even lower price and, like the first, rapidly secures market share. Collusion between the generic firms can thus be a means of preventing price erosion in the short term, though it may become substantially less feasible if subsequent ANDAs are approved and additional competitors enter the market.

In August 2002, the Commission issued a consent order against two generic drug

⁴³ The Commission's complaint against Biovail is available at <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm>.

⁴⁴ 15 U.S.C. § 45.

⁴⁵ *Id.* at § 18.

⁴⁶ See CBO Study, *supra* note 6; Reiffen and Ward, *supra* note 10, at 22.

manufacturers to resolve charges that they entered into an agreement that unreasonably reduced competition in the market for a generic anti-hypertension drug.⁴⁷ According to the Commission's complaint, Biovail Corporation (Biovail) and Elan Corporation PLC (Elan) agreed not to compete, in violation of the FTC Act. The complaint alleged that the companies' agreement substantially reduced their incentives to introduce competing 30 mg and 60 mg generic Adalat CC products, and that the agreement lacked any countervailing efficiencies.⁴⁸

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.⁴⁹ 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.⁵⁰ 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

⁴⁷ *Biovail Corp. and Elan Corp. PLC*, *supra* note 8.

⁴⁸ The Commission's complaint against Biovail and Elan is available at <http://www.ftc.gov/os/2002/08/biovalcmp.pdf>.

⁴⁹ The consent order in the *Biovail/Elan* matter is available at <http://www.ftc.gov/os/2002/08/biovaldo.pdf>.

⁵⁰ The FTC Study does not address other procedures for generic entry.

(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.⁵¹ 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.⁵² The Commission issued nearly 80 special orders – pursuant to Section 6(b) of the FTC Act⁵³ – 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.⁵⁴ 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.

B. Findings: Litigation Frequency and Outcomes

The FTC Study sought to determine the frequency with which brand-name companies have triggered the 30-month stay provision by suing generic applicants for patent infringement within the required 45-day period. For 72 percent of drug products the study covered, brand-name companies

⁵¹ National Institute for Health Care Management, “Prescription Drugs and Intellectual Property Protection” at 3 (Aug. 2000).

⁵² The Commission was required to obtain OMB clearance before it could begin the study because the number of special orders to be sent triggered the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. Ch. 35, as amended.

⁵³ 15 U.S.C. § 46(b).

⁵⁴ See 65 Fed. Reg. 61334 (Oct. 17, 2000); 66 Fed. Reg. 12512 (Feb. 27, 2001).

initiated patent infringement litigation against the first generic applicant. There was no suit in the other 28 percent, and the FDA has approved most of the generic products, thus allowing generic entry to occur.

In 70 percent of the cases (53 of the 75 drug products) in which the brand-name company sued the first generic applicant, either there has been a court decision (30 of the 53 drug products) or the parties have agreed to a final settlement without a court decision on the merits of the patent infringement lawsuit (20 of the 53 drug products).⁵⁵ In the other 30 percent of the cases (22 of the 75 drug products), a district court had not yet ruled as of June 1, 2002.

Of all the patent infringement cases (with the first generic applicant) in which a court had rendered a decision as of June 1, 2002, generic applicants prevailed in 73 percent of the cases (22 out of 30) and brand-name companies prevailed in 27 percent (8 out of 30). Of the decisions favoring the first or any subsequent generic applicant, there were slightly more non-infringement decisions (14) than patent invalidity decisions (11). The U.S. Court of Appeals for the Federal Circuit overturned district court decisions of patent invalidity for drug products in this study in only eight percent of cases.

In 62 percent of the cases involving litigation with the first and second generic applicants, brand-name companies initiated patent litigation in just five federal judicial districts – the District of New Jersey, the Southern District of New York, the Southern District of Indiana, the Northern District of Illinois, and the Southern District of Florida.

C. Findings: Orange Book Patent Listing Practices

The 30-month stay provision of the Amendments protects brand-name companies beyond their existing intellectual property rights. It has received increased attention because it can have a significant impact on market entry by generic drugs. Since 1998, two new phenomena appear to be emerging in relation to patent listing practices that affect patent litigation: (1) an increase in the number of patents listed in the Orange Book for “blockbuster” drug products; and (2) the listing of patents after an ANDA has been filed for the particular drug product.

The Commission found that, for drug products with substantial annual net sales, brand-name companies are suing generic applicants over more patents. Since 1998, for five of the eight “blockbuster” drug products for which the brand-name company filed suit against the first generic applicant, the brand-name company alleged infringement of three or more patents. In comparison, in only one of the nine “blockbuster” suits filed before 1998 by a brand-name company against the first generic applicant did the complaint allege infringement of three or more patents.

In the future, patent infringement litigation brought by brand-name companies against generic applicants that have filed ANDAs with Paragraph IV certifications may take longer to resolve. The

⁵⁵ There were three additional suits that had other resolutions.

data suggest that cases involving multiple patents take longer than those involving fewer patents. As of June 1, 2002, for six out of the seven cases that were pending for more than 30 months before a decision from a district court, the brand-name company has alleged infringement of three or more patents.

By the timely listing of additional patents in the Orange Book after a generic applicant has filed its ANDA (“later-issued patents”), brand-name companies can obtain additional 30-month stays of FDA approval of the generic applicant’s ANDA. In eight instances, brand-name companies have listed later-issued patents in the Orange Book after an ANDA has been filed for the drug product. For those eight drug products, the additional delay of FDA approval (beyond the first 30 months) ranged from four to 40 months. In all of the four cases so far with a court decision on the validity or infringement of a later-issued patent, the patent has been found either invalid or not infringed by the ANDA.

Moreover, several of the later-issued patents in the Orange Book raise questions about whether the FDA’s patent listing requirements have been met. For example, several of the later-issued patents do not appear to claim the approved drug product or an approved use of the drug. The FTC Study describes three categories of patents that raise significant listability questions – *i.e.*, issues concerning whether the listed patents fall within the statutorily defined class. These categories include (1) patents that may not be considered to claim the drug formulation or method of use approved through the NDA; (2) product-by-process patents that claim a drug product produced by a specific process; and (3) patents that may constitute double-patenting because they claim subject matter that is obvious in view of the claims of another patent obtained by the same person.

D. Recommendations: The 30-Month Stay Provision

To reduce the possibility of abuse of the 30-month stay provision, the Commission recommended in its study that only one 30-month stay be permitted per drug product per ANDA to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant’s ANDA. This should eliminate most of the potential for improper Orange Book listings to generate unwarranted 30-month stays. One 30-month stay period alone has historically approximated the time necessary for FDA review and approval of the generic applicant’s ANDA⁵⁶ or a district court decision on the patent infringement litigation that caused the 30-month stay. Thus, it does not appear that, on average, one 30-month stay provision per drug product per ANDA would have a significant potential to delay generic entry beyond the time already necessary for FDA approval of the generic applicant’s ANDA or a district court decision in the relevant litigation.

Limiting brand-name drug companies to one 30-month stay per drug product per ANDA is likely to eliminate most problems related to potentially improper Orange Book listings. Nonetheless, the Commission notes that there is no private right of action to challenge an improper listing, nor does

⁵⁶ 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.

the FDA review the propriety of patent listings.⁵⁷ The lack of a mechanism to review or delist patents may have real-world consequences. For example, the Commission is aware of at least a few instances in which a 30-month stay was generated solely by a patent that raised legitimate listability questions. One proposal to deal with this problem has been to establish an administrative procedure through which generic applicants could obtain substantive FDA review of listability. At a minimum, it appears useful for the FDA to clarify its listing requirements as the FTC Study suggests. Another remedy that may warrant consideration would be to permit a generic applicant to raise listability issues as a counterclaim in the context of patent infringement litigation that the brand-name company already initiated in response to a Paragraph IV notice from the generic applicant. A challenge limited to a counterclaim would avoid generating additional litigation.

One minor change to the patent statute, which would clarify when brand-name companies can sue generic applicants for patent infringement, would ensure that brand-name companies have recourse to the courts to protect their intellectual property rights in later-issued patents. To do this, Congress may wish to overrule a recent district court decision, *Allergan, Inc. v. Alcon Labs, Inc.*, 200 F. Supp. 2d 1219 (C.D. Cal. 2002), which questions the rights of brand-name companies to sue for patent infringement regarding patents obtained or listed after an ANDA with a Paragraph IV certification has been filed.

E. Findings: Patent Settlements and the 180-Day Marketing Exclusivity

Certain patent settlement agreements between brand-name companies and potential generic competitors have received antitrust scrutiny in recent years because not only might they affect when the generic applicant may begin commercial marketing, but they also may affect when the FDA can approve subsequent generic applicants after the first generic applicant's 180-day exclusivity runs. Parties have debated whether these settlements increased or harmed consumer welfare. Twenty final⁵⁸ and four interim⁵⁹ agreements that settled litigation between the brand-name company and the first generic applicant were produced in response to the FTC's special orders.

The final patent settlements can be classified into three categories:

(1) Nine of these settlements contained a provision by which the brand-name company, as one

⁵⁷ See *supra* note 37 and accompanying text.

⁵⁸ One of these agreements is subject to litigation currently pending at the FTC. See *Schering-Plough Corp., et al.*, Dkt. No. 9297 (Initial Decision) (July 2, 2002) *supra* note 32.

⁵⁹ For three out of the four interim agreements, see *Abbott Laboratories*, Dkt. No. C-3945 (May 22, 2000) (consent order) (relating to two drug products, Hytrin tablets and Hytrin capsules); *Geneva Pharmaceuticals, Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order); and *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), all *supra* note 32.

part of the settlement, paid the generic applicant (settlements involving “brand payments”);

(2) Seven of the 20 settlements involved the brand-name company licensing the generic applicant to use the patents for the brand-name drug product prior to patent expiration; and

(3) Two of the settlements allowed the generic applicant to market the brand-name drug product as a generic product, under the brand-name company’s NDA but not under the generic applicant’s own ANDA.⁶⁰

Fourteen of the final settlements with the first generic applicant had the potential to “park” the 180-day marketing exclusivity for some period of time such that the first generic applicant would not trigger the exclusivity, and thus FDA approval of any subsequent eligible generic applicant would be delayed. (If the 180-day exclusivity for the first generic applicant does not run, the FDA cannot approve subsequent eligible generic applicants.) The data from the FTC Study suggest, however, that the 180-day exclusivity provision by itself generally has not created a bottleneck to prevent FDA approval of subsequent eligible generic applicants.

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 Act⁶¹ to require brand-name companies and first generic applicants to provide copies of certain agreements to the Federal Trade Commission and the Department of Justice. The Commission believes that review of these agreements by these agencies will help ensure that the 180-day provision is not manipulated in a way to delay entry of additional generic applicants.

Empirical research demonstrates that as additional generic competitors enter the market, generic prices decrease to lower levels, thus benefitting consumers. The FTC Study makes three minor recommendations to ensure that, once a subsequent generic applicant is ready to market, the 180-day exclusivity is not a roadblock to that entrant’s beginning commercial marketing. The recommendations are:

(1) To clarify that “commercial marketing” includes the first generic applicant’s marketing of the brand-name product;

⁶⁰ The remaining two settlements do not fit into any of these three categories.

⁶¹ S. 754, 107th Cong. (2001) (introduced by Sen. Leahy).

(2) To clarify that the decision of any court on the same patent being litigated by the first generic applicant constitutes a “court decision” sufficient to start the running of the 180-day exclusivity; and

(3) To 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.

V. Conclusion

Thank you for this opportunity to share the Commission's views on competition in the pharmaceutical industry. As you can see, the Commission has been and will continue to be very active in protecting consumers from anticompetitive practices that inflate drug prices. The Commission looks forward to working closely with the Subcommittee, as it has in the past, to ensure that competition in this critical sector of the economy remains vigorous. In keeping with this objective, the Commission will likewise endeavor to ensure that the careful Hatch-Waxman balance – between promoting innovation and speeding generic entry – is scrupulously maintained.