UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Before the
FOOD AND DRUG ADMINISTRATION
Rockville, MD 20852

In the Matter of
180-Day Generic Drug Exclusivity
for Abbreviated New Drug Applications

Docket No. 85N-0214

COMMENT OF THE STAFF OF THE BUREAU OF COMPETITION AND OF POLICY PLANNING OF THE FEDERAL TRADE COMMISSION

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I. The FTC's Interest in this Proceeding.

The staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission (FTC) welcomes this opportunity to present its views on important competition issues raised in the above-captioned proceeding. (1) In this proceeding, the Food and Drug Administration (FDA) has issued a Proposed Rule with the purpose of clarifying existing eligibility requirements for abbreviated new drug application (ANDA) applicants and remedying its rules in light of recent court decisions invalidating portions of FDA's current regulations. (2) The FDA intends that the Proposed Rule will permit the prompt entry of generic drug products into the market while maintaining the incentive of marketing exclusivity for generic drug manufacturers. (3) In particular, the Proposed Rule is designed to address problems that have arisen with generic and branded (4) companies entering into certain types of agreements that result in hindering, rather than speeding, generic competition. (5)

The FTC is an independent administrative agency charged with promoting the efficient functioning of the marketplace by taking law enforcement action against commercial practices injurious to consumers and by increasing consumer choice by promoting vigorous competition. Staff approaches the competition issues presented in this proceeding from experience in enforcing Section 7 of the Clayton Act (6) and Section 5 of the Federal Trade Commission Act (7) and from antitrust enforcement activities affecting the generic drug industry. (8) The staff of the FTC's Bureau of Economics has recently released a report studying the competition issues in the pharmaceutical industry, which also informs this view. (9)

Briefly, this comment notes the competitive benefits of lower prices and greater innovation that the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) has spurred in the pharmaceutical industry by streamlining the approval process for generic drug products. The comment notes that the Proposed Rule to clarify the circumstances in which applicants may obtain a 180-day exclusive marketing period may remedy the delayed generic competition that has resulted from certain types of agreements between generic and innovator companies. The FTC recently has initiated several investigations of agreements between branded companies and

their generic counterparts that may have the effect of forestalling generic competition. The comment also suggests that the FDA consider a requirement that both patent litigation settlement agreements (either full or partial settlements) between branded companies and ANDA applicants and agreements related to the filing of an ANDA by a potential applicant be filed confidentially with the agency in a timely manner and be accessible to the federal antitrust authorities on a non-public basis so that the antitrust agencies will be aware of any possible anticompetitive issues involved with such settlements.

II. Background.

In 1984, Congress enacted the Hatch-Waxman Act to establish a streamlined approval process for the FDA to use in approving generic versions of previously approved branded drugs. The Hatch-Waxman Act specifies in detail the required contents of an ANDA. Under the Hatch-Waxman Act, for each patent listed in the Orange Book (10) for the relevant branded drug, an ANDA applicant must certify one of the following claims: (1) that such patent information has not been filed; (2) that such patent has expired; (3) that the proposed drug will not be marketed until expiration of the patent; or (4) that either the proposed generic drug does not infringe the patent or the patent is invalid. (11)

It is this fourth type of certification with which the FDA Proposed Rule and this comment are concerned. If an ANDA applicant files a paragraph IV certification, the Hatch-Waxman Act requires the applicant to provide the patent holder with notice of that certification (12) and provides the patent holder with a 45-day window, during which it may bring suit against the applicant. (13) If patent litigation is initiated during this period, the FDA may not approve the ANDA until the earlier of (1) 30 months from the patent holder's receipt of the notice (the 30-month stay) or (2) the issuance of a non-appealable court decision finding the patent invalid or not infringed. This allows the patent holder time to enforce its patent in court before the generic competitor is allowed to enter the market.

Often more than one company will file an ANDA that includes a paragraph IV certification because these companies also seek to provide generic competition to a particular branded drug. However, the Hatch-Waxman Act provides that such subsequent ANDA applications will not be approved until 180 days after the earlier of (1) the date of the first commercial marketing of the first-filed ANDA applicant's generic drug or (2) the date of a decision of a court in an action holding the relevant patent invalid, unenforceable, or not infringed. Thus, the Hatch-Waxman Act effectively grants the first-filed ANDA holder 180 days of marketing exclusivity. As the FDA notes, "[t]he award of a 180-day period of market exclusivity for certain ANDA applicants with paragraph IV certifications was designed to maintain [a] balance by rewarding generic firms for their willingness to challenge unenforceable and invalid innovator patents, or design noninfringing drug products." (14)

In implementing this provision in the past, the FDA added a requirement that the first ANDA applicant must have "successfully defended against a suit for patent infringement" before the applicant is eligible for the 180-day marketing exclusivity period. Two recent court of appeals decisions, however, held that the FDA had exceeded its statutory authority in imposing the "successful-defense requirement" as a prerequisite to obtaining the 180-day marketing exclusivity. (15)

In this proceeding, the FDA proposes new rules implementing the 180-day marketing exclusivity provision and clarifies which applicants are eligible for the marketing exclusivity. The Proposed Rule is designed to address the FDA's expressed concern that, "[u]nder current regulatory provisions, the first generic applicant to file a substantially complete ANDA with a paragraph IV certification can delay generic competition by entering into certain commercial arrangements with an innovator company." (16) Such agreements may have the effect of forestalling the triggering of the 180-day period and may, therefore, bar other generic firms from entering the market even when their products would not infringe a valid patent. (17) In such circumstances, the FDA is barred from providing final approval for all subsequent ANDA applicants and, thus, generic competition is precluded from occurring.

The FDA has proposed to amend its rules by placing a time limit (180 days) on when the first-filed ANDA applicant must trigger its rights to obtain the 180-day marketing exclusivity period and by clarifying which applicants are eligible for the 180-day marketing exclusivity.

III. Consumers Have Benefitted from the Hatch-Waxman Act.

Since the enactment of the Hatch-Waxman Act, American consumers have had greater access to generic drugs at lower prices than their branded counterparts. Indeed, the generic drug share of prescription drug volume has increased by almost 150 percent since enactment of the Hatch-Waxman Act in 1984. (18) Empirical research has shown that relaxation of entry impediments has given rise to significant entry and price competition in drug markets. (19)

Total generic drug market share has increased as well in the years since the Hatch-Waxman Act passed. According to a recent report by the Congressional Budget Office (CBO), sales of generic drugs increased from 19 percent of U.S. prescription sales in 1983 to over 40 percent in 1995. (20) The industry has also seen an increase in the percent of branded drugs that have a generic competitor on the market. Today, nearly 100 percent of the top-selling drugs with expired patents have generic versions available, versus only 36 percent in 1983. (21)

In addition, evidence from the CBO Study indicates that for many branded drugs whose patents have recently expired, generic copies quickly gain a large share of the market. For example, with regard to 21 innovator drugs whose first generic competitors entered the market between 1991 and 1993, the CBO Study determined that during the first full calender year in which those 21 drugs faced generic competition, generic drug products already accounted for an average of 44 percent of prescriptions dispensed through pharmacies. (22) Consumers have saved billions of dollars by purchasing these generic drugs in place of their more expensive branded counterparts. In turn, insurance and pharmaceutical benefits management companies have positively responded to the increased availability of generic drugs by contracting with generic manufacturers for bulk purchases. Enrollees benefit from these relationships through cost savings realized via multi-tiered drug co-payment structures. Finally, in response to generic competition, innovator companies research, develop, and market increasing numbers of improved new drugs. Such additions to the marketplace may satisfy previously unmet medical needs, break new therapeutic ground or compete with older drugs.

Moreover, the Hatch-Waxman Act has helped to expand the number of generic drug manufacturers producing the same drug. This increased breadth and depth of generic drug market presence has augmented pharmaceutical competition on three levels: brand-brand, brand-generic, and generic-generic. The benefits of this increased competition have been confirmed in FTC staff investigations of the pharmaceutical industry. Generally, the staff has found that the more generic versions of the same drug product that are on the market, the lower the price consumers pay for a generic version, regardless of which generic company is marketing the drug product. For example, the entry of a second generic drug product generally doubles the price decrease introduced by the first generic product from the branded drug product's price. Three or more companies offering a generic version of a listed drug can lower the price by at least fifty percent, if not substantially more, from the branded price. These price discounts tend to show that the sooner more companies offer the same generic product, the greater the price competition and the lower price consumers pay for a generic version of a drug product.

IV. The "Triggering Period" Proposed by the FDA Would Assist in Ensuring that Generic Competition Is Not Delayed.

The FDA has proposed to implement a "use it or lose it" triggering period in which first-filed paragraph IV ANDA applicants have 180 days to start (or "trigger") the 180-day marketing exclusivity period. The triggering period would begin after a second generic drug application with a paragraph IV certification has received tentative approval. During the triggering period, the first-filed ANDA applicant would be required either to obtain a final court decision finding the patent to be invalid, unenforceable, or not infringed by the ANDA product or to begin commercial marketing of the generic drug. In three instances, the triggering period will start not only after a subsequent ANDA receives tentative approval but also after, depending upon the circumstance, (1) the 30-month stay of ANDA approval has expired if the first-filed ANDA applicant is involved in patent litigation; (2) a preliminary injunction prohibiting the marketing of an ANDA product (if a court has issued one) has expired; or (3) where applicable, the statutorily described exclusivity period for the listed drug has expired.

A "use-it-or-lose-it" triggering period appears to be helpful in implementing the Hatch-Waxman Act's intent to "make available more low cost generic drugs." (23) The 180-day time period appears more than adequate to permit the applicant to prepare to launch the generic product; as the FDA noted in the Proposed Rule, generic drug products are "routinely marketed within a 2-month period following ANDA approval." (24) In addition, the Mova court indicated that the FDA could prescribe a period within which a first ANDA applicant must bring its product to market in order to benefit from the 180-day marketing exclusivity period. (25) Moreover, such an obligation does not absolutely require the first-filed ANDA applicant to begin commercial marketing, but only to begin commercial marketing or obtain a final court order if it seeks to obtain the 180 days of marketing exclusivity.

In practical effect, the "use-it-or-lose-it" triggering period ensures that, once there is another generic product that has received tentative approval from the FDA -- and, where applicable, the other relevant statutory or court-ordered time periods have expired (26) -- the first-filing ANDA applicant must fish or cut bait, i.e., it must either move to commercial marketing or a final court order within 180 days or lose the 180-day marketing exclusivity. Either way, the FDA's proposed triggering rule ensures that the ongoing potential for generic competition is maintained so that consumers may benefit by a ready supply of generic versions of a drug product. By adding another triggering event -- tentative approval for a second generic drug -- that is not within the control of either the first-filing ANDA applicant or the branded company, the Proposed Rule would reduce the ability and incentive of generic and branded companies to enter into agreements that can forestall generic competition.

V. The FDA's Proposal to Limit 180-Day Marketing Exclusivity to the First ANDA Applicant Is Preferable to Rolling Eligibility.

The FDA has proposed to continue its current approach that only the first substantially complete ANDA for a listed drug with a paragraph IV certification would be eligible for exclusivity. No other ANDA applicant with a paragraph IV certification will be eligible for the 180-day marketing exclusivity for that drug product, even if the first ANDA applicant later loses its status as the first-filer (e.g., by withdrawing or changing its application as a result of losing or settling its patent suit). The proposed policy appears to be a reasonable part of a solution to the delay of generic competition that the FDA has observed. (27)

This policy is preferable to a rolling eligibility policy in which the next-in-line ANDA applicant obtains the right to the 180-day marketing exclusivity period if the first-filing ANDA applicant loses its status as the first-filer. A rolling eligibility process might result in successive agreements between branded drug and generic companies, each of which would have the effect of forestalling competition, and thus cause indefinite delays in generic competition. Such indefinite delay could cause consumers to continue to pay significantly higher prices for prescription drugs than they would if generic competition got underway.

VI. Filing of Patent Litigation Settlement Agreements.

The FDA notes in the Proposed Rule that in order to remedy the alleged use of settlement agreements to block generic competitor entry, it prefers the triggering period approach (discussed above) over a notification approach that would require that the FDA be notified of a settlement or other agreement that alters an adversarial relationship between the first-filing ANDA applicant and either the patent owner or the NDA holder. (28) Regardless of which approach the FDA ultimately adopts, the FDA may wish to consider requiring that (1) patent litigation agreements (either full or partial settlements) between branded companies and ANDA applicants and (2) agreements related to the filing of an ANDA by a potential applicant be filed confidentially with the agency in a timely manner and be accessible to the federal antitrust authorities on a non-public basis so that the antitrust agencies will be aware of any possible anticompetitive issues involved with such agreements.

Often the antitrust authorities are at a disadvantage in learning about a whole range of agreements involving intellectual property rights that may impede competition while affording no countervailing competitive benefits. Indeed, the Assistant Attorney General for Antitrust has stated that "whenever there is even a more than trivial possibility of infringement, the costs of litigation skew the parties' decisions, steering them away from a serious test of

the bounds of the rights of the patentee or copyright holder and towards agreements that too often make teammates out of rivals." (29)

As noted earlier, the Federal Trade Commission has initiated several investigations of agreements between branded companies and their generic counterparts. These investigations were initiated when Commission staff became aware of the agreements -- often months, and sometimes over a year, after the agreements were made. Although the Commission has the authority to seek disgorgement or restitution of ill-gotten gains from the companies, (30) consumers pay millions of dollars in higher prices during the pendency of these often-complicated investigations.

Accordingly, a system of filing with the FDA could assure better detection of anticompetitive arrangements that harm consumer welfare. If the FDA suspected the possibility of anticompetitive effects in connection with a particular agreement, it could share that agreement with the antitrust authorities pursuant to a confidentiality agreement that would protect the commercial interests of the parties to the agreement.

VII. Conclusion.

The FDA has proposed to amend its rules to implement the Hatch-Waxman Act by clarifying which applicants are eligible for the 180-day marketing exclusivity and by placing a time limit on when the first-filing ANDA applicant must trigger its rights to obtain the 180-day marketing exclusivity period. Staff of the Bureau of Competition and of Policy Planning at the FTC support the FDA's proposed rule for the reasons articulated in this comment. In addition, the FDA may wish to consider a requirement that all patent litigation settlement agreements and agreements related to the filing of an ANDA application be filed with the FDA in a timely manner in order to notify the agency of possible anticompetitive issues involved with such settlements.

Respectfully submitted,

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Endnotes:

1. This comment represents the views of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, and not necessarily the views of the Commission itself or any individual Commissioner.

2. Proposed Rule, 64 Fed. Reg. 42873 (Aug. 6, 1999).

3. 64 Fed. Reg. at 42873.

4. This comment uses the term "branded" in ways synonymous with the FDA's use of the term "innovator" - that is, it refers to a patented drug or a company that has done the innovative work required to earn a patent on a drug.

5. 64 Fed. Reg. at 42882-83.

6. 15 U.S.C. § 18 (1988). Mergers subject to Section 7 are prohibited if their effect "may be substantially to lessen competition, or to tend to create a monopoly." See, e.g., Hoechst AG, 120 F.T.C. 1010 (1995) (merger with Marion Merrell Dow, Inc.).

7. 15 U.S.C. § 41 et seq.

8. See, e.g., Federal Trade Commission v. Mylan Laboratories, Inc. et al., 1999-2 Trade Cas. (CCH) ¶72,573 (D.D.C. 1999), appeal filed.

9. Staff of the Federal Trade Commission, "The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change" (Mar. 1999) (FTC Staff Report) <http://www.ftc.gov/reports/pharmaceutical/drugexsum.htm>.

10. The Orange Book contains a listing of all FDA-approved drug products. Any patent protection still afforded an approved drug product is also listed in the Orange Book.

11. 21 U.S.C. § 355(j)(2)(A)(vii).

12. 21 U.S.C. § 355(j)(2)(B)(i)(I).

13. 21 U.S.C. § 355(j)(5)(B)(iii).

14. 64 Fed. Reg. at 42882. The FDA's notice explains that "[t]he Hatch-Waxman Amendments benefit consumers by bringing lower priced generic versions of previously approved drugs to market, while simultaneously promoting new drug innovation through the restoration of patent life lost during regulatory proceedings." Id.

15. Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998); Granutec, Inc. v. Shalala, Nos. 97-1873, 97-1874, 1998 U.S. App. LEXIS 6685 (4th Cir. Apr. 3, 1998).

16. 64 Fed. Reg. at 42882.

17. Such delay could occur, for example, when the first ANDA applicant agrees not to market its product until the completion of the patent litigation so that there is neither a date at which commercial marketing has begun nor a final court decision (the two statutory triggers that start the running of the 180-day marketing exclusivity). The FDA explains:

A necessary condition for such arrangements is that the economic gains to the innovator from delaying generic competition exceed the potential economic gains to the generic applicant from 180 days of market exclusivity. Such instances are becoming more frequent because a successful strategy to extend market exclusivity can mean tens of millions of dollars in increased revenue for an innovator firm. Under such circumstances, it can be mutually beneficial for the innovator and the generic company that is awarded 180 days of generic exclusivity to enter into agreements that block generic competition for extended periods.

64 Fed. Reg. at 42882-83.

18. FTC Staff Report at 13.

19. Id.

20. Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" (CBO Study) at Summary, p. 1 (July 1998).

21. Id. at 5.

22. Id. at Ch. III, p. 17.

23. H.R. Rep. No. 98-857, 98th Cong., 2d Sess., Pt. 1 at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647.

24. Proposed Rule, 64 Fed. Reg. at 42878.

25. Mova Pharmaceutical, 140 F.3d at 1071 n.11.

26. See discussion above of exceptions to immediate applicability of the triggering period once a second generic drug has received tentative approval from the FDA.

27. We note the theoretical possibility that limiting the 180-day marketing exclusivity to the first-filing ANDA applicant might reduce the incentives of subsequent ANDA applicants actually to follow through and come to market. A hypothetical reduction in incentive appears likely to be small given that the FDA already follows the proposed policy and that subsequent filers already expect that they are entering a market in which the first-filing ANDA applicant already competes.

28. 64 Fed. Reg. at 42880.

29. Joel I. Klein, Acting Assistant Attorney General, Antitrust Division, U.S. Department of Justice, "Cross-Licensing and Antitrust Law," American Intellectual Property Law Association (May 2, 1997) <http://www.usdoj.gov/atr/public/speeches/1123.htm >.

30. Federal Trade Commission v. Mylan Laboratories, Inc. et al., supra, n. 8.