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

November 4, 1999*

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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

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.

A "use-it-or-lose-it" triggering period appears to be helpful in implementing the Hatch-

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

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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. §

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 40 subs entie a seccc(l)-16g<n 0 Tw 1n 42880u