UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, a corporation,	)	Docket No. 9297
and	)	
American Home Products Corporation, a corporation.	)	

ORDER DENYING MOTIONS OF RESPONDENTS SCHERING-PLOUGH AND UPSHER-SMITH TO DISMISS THE COMPLAINT

I. PROCEDURAL BACKGROUND

On June 7, 2001, Respondent Schering-Plough Corporation ("Schering") filed a motion for partial dismissal of the Complaint for failure to state a claim upon which relief could be granted. Complaint Counsel filed an opposition on June 25, 2001. Schering filed a reply in support of its motion on July 6, 2001. Oral arguments of counsel were heard on July 25, 2001.

On July 20, 2001, Respondent Upsher-Smith Laboratories, Inc. ("Upsher-Smith") filed a motion to dismiss the Complaint in its entirety as deficient as a matter of law. Complaint Counsel filed an opposition on August 8, 2001. Upsher-Smith filed a reply in support of its motion on August 15, 2001.

For the reasons set forth below, Schering's and Upsher-Smith's motions are DENIED.

II. STATUTORY AND REGULATORY FRAMEWORK STATED IN THE COMPLAINT

The Complaint contains the following allegations regarding federal regulation of prescription drugs:

- Under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., approval by the Food and Drug Administration ("FDA") is required before a company may market or sell a prescription drug in the United States. Complaint at ¶ 9. Newly developed prescription drugs are often protected by patents and marketed under proprietary brand names and are commonly referred to as "brand name drugs" or "branded drugs." *Id.* at ¶ 10. FDA approval for a branded drug is generally sought by filing a New Drug Application ("NDA") with the FDA. *Id.*

- In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act, which simplified the procedure for obtaining approval of generic drugs. *Id.* at ¶ 11. Under the Hatch-Waxman Act, manufacturers of generic drugs are required to submit an Abbreviated New Drug Application ("ANDA"). *Id.* at ¶ 12. An ANDA applicant has to demonstrate that the generic drug is bioequivalent to the brand name drug that it references. *Id.*

- When a brand name drug is protected by one or more patents, an ANDA applicant that intends to market its generic product prior to expiration of any patent must certify that the patent on the brand name drug is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA applicant seeks approval. *Id.* at ¶ 13. This is called a "Paragraph IV Certification." *Id.*

- If the ANDA contains a Paragraph IV Certification, the ANDA applicant must provide notice to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers. *Id.* at ¶ 14. Upon receiving notice of a Paragraph IV Certification, the patent holder has 45 days in which to file a patent infringement suit against the generic manufacturer. *Id.* If a patent infringement suit is initiated against the ANDA applicant, the FDA must stay its final approval of the ANDA for the generic drug until the earliest of (1) the patent expiration, (2) a judicial determination of the patent litigation, or (3) the expiration of a 30-month waiting period. *Id.*

- The Hatch-Waxman Act provides that the first to file a Paragraph IV certified ANDA ("the first filer") is eligible for a 180-day period of exclusivity ("the 180-day exclusivity period"). *Id.* at ¶ 15. That is, during those 180 days, the FDA will not approve any other ANDA for the same generic product until the earlier of the date on which (1) the first firm begins commercial marketing of its generic

version of the drug, or (2) a court finds the patents claiming the brand name drug are invalid or not infringed. *Id.*

III. RELEVANT ALLEGATIONS OF THE COMPLAINT

The Complaint contains the following allegations:

- Respondents entered into unlawful horizontal agreements to delay entry of low-cost generic competition to Schering's prescription drug K-Dur 20. Complaint at ¶ 1. These agreements have cost consumers in excess of $100 million. *Id.* at ¶ 2.

- Schering has monopoly power in the market that includes K-Dur 20 and that entry of generic competition would significantly erode Schering's market share and profits. *Id.* at ¶¶ 17, 26-30, 37. To protect the profits of K-Dur 20 from the threat of generic competition, Schering conspired with two manufacturers of generic pharmaceuticals, Upsher-Smith and American Home Products Corporation ("AHP"), by paying each millions of dollars to delay their products' entry into the marketplace. *Id.* at ¶¶ 44-45, 55, 57, 63-64.

- Schering manufactures and markets two extended-release microencapsulated potassium chloride products: K-Dur 20 and K-Dur 10, both of which are marketed as brand name drugs. *Id.* at ¶ 31. Schering's K-Dur 20 and K-Dur 10 are covered by a formulation patent owned by Schering, patent number 4,863,743 (the ""743 patent"), which expires on September 5, 2006. *Id.* at ¶ 34.

- On August 6, 1995, Upsher-Smith filed an ANDA with the FDA to market Klor Con M20, a generic version of Schering's K-Dur 20. *Id.* at ¶ 38. Upsher-Smith's ANDA was the first for a generic version of K-Dur 20. *Id.* Upsher-Smith submitted a Paragraph IV Certification with this ANDA and, on November 3, 1995, Upsher-Smith notified Schering of its Paragraph IV Certification and ANDA. *Id.*

- As the first ANDA filer with a Paragraph IV Certification for a generic version of Schering's K-Dur 20, Upsher-Smith is eligible for the 180-day exclusivity period. *Id.* at ¶ 41. Because Upsher-Smith is eligible for the 180-day exclusivity period, no other generic manufacturer can obtain final FDA approval to market a generic version of K-Dur 20 until after the exclusivity period has expired. *Id.* at ¶ 42.

- Schering sued Upsher-Smith for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995, alleging that Upsher-Smith's Klor Con M20 infringed Schering's '743 patent. *Id.* at ¶ 39. On June 17,

1997, Schering and Upsher-Smith agreed to settle their patent litigation. *Id.* at ¶ 44. Under the settlement agreement, Schering agreed to make unconditional payments of $60 million to Upsher-Smith; Upsher-Smith agreed not to enter the market, either with the allegedly infringing generic version of K-Dur 20 or with any other generic version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until September 2001; both parties agreed to stipulate to the dismissal of the litigation without prejudice; and Schering received licenses to market five Upsher-Smith products. *Id.* at ¶ 44.

- On December 29, 1995, ESI Lederle, Incorporated ("ESI"), a division of AHP, submitted an ANDA to the FDA to market a generic version of Schering's K-Dur 20. *Id.* at ¶ 51. ESI submitted a Paragraph IV Certification with this filing and notified Schering of its Paragraph IV Certification and ANDA. *Id.* Schering sued ESI for patent infringement in the United States District Court for the Eastern District of Pennsylvania on February 16, 1996, alleging that ESI's generic version of Schering's K-Dur 20 infringed Schering's '743 patent. *Id.* at ¶ 53.

- On June 19, 1998, Schering and ESI executed a settlement agreement to their patent litigation whereby, ***inter alia***, Schering agreed to pay ESI up to $30 million; AHP and ESI agreed to refrain from marketing the allegedly infringing generic version of K-Dur 20 or any other generic version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until January 2004. *Id.* at ¶ 54-55.

III. ARGUMENTS OF THE PARTIES

The Complaint alleges that Schering's settlement agreements with Upsher-Smith and with ESI violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 ("FTC Act") because they delayed the entry of Upsher-Smith's and ESI's generic versions of K-Dur 20. The Complaint also alleges that Schering's agreement with Upsher-Smith violates the FTC Act because it has the effect of keeping off the market other generic drugs manufactured by third parties.

Schering and Upsher-Smith urge dismissal or partial dismissal on the grounds that the Complaint fails to state a claim upon which relief could be granted. Schering asserts, first, that the Complaint's allegations that Schering's agreements with Upsher-Smith and ESI violate Section 5 of the FTC Act because they allegedly delayed entry of Upsher-Smith's and AHP's generics fail to state a claim because: (a) the Complaint fails to allege patent invalidity or non-infringement; and (b) the Complaint fails to allege that the patent suit was not bona fide or that the settlement was more anticompetitive than the probable outcome of the litigation. Schering asserts, second, that the Complaint's allegations that Schering's agreement with Upsher-Smith violates Section 5 of the FTC Act because it allegedly has the effect of blocking generics

manufactured by third parties fails to state a claim because: (a) the Complaint misstates the FDA law; and (b) any effect the agreement had was by operation of federal law and thus immune from antitrust liability under the Noerr-Pennington doctrine.

Upsher-Smith asserts that the Complaint is deficient as a matter of law because it does not dispute that: (a) the patent suit was not bona fide; (b) the settlement resolved that dispute by compromise; or (c) the settlement was more anticompetitive than the probable outcome of the litigation.

Complaint Counsel responds to Schering's first argument and Upsher-Smith's argument by asserting that the allegations of the Complaint that Schering paid Upsher-Smith and AHP to delay their entry and withdraw their challenges to Schering's patent state an antitrust claim and provide a clear basis for that claim. Complaint Counsel asserts that, to state a claim, the Complaint need not contain allegations that Schering's patent is invalid or is not infringed. In Complaint Counsel's view, a patent settlement violates the antitrust laws, regardless of invalidity or infringement issues, when the patent-holder entices its competitors to delay entry or withdraw its challenges to the patent in exchange for a share of the monopoly profits. Complaint Counsel next asserts that proof of the parties' probabilities of winning the patent litigation is not necessary for proving an antitrust violation. Complaint Counsel asserts that all that is required - and is alleged - is that the settlements harmed competition.

Complaint Counsel responds to Schering's second argument by asserting that "the current state of the [FDA] law . . . in no way contradicts complaint allegations concerning the 180-day exclusivity period or the exclusionary effect of Schering's agreement with Upsher-Smith." Complaint Counsel's Response to Schering's Motion for Partial Dismissal of the Complaint at p. 24. Complaint Counsel next asserts that the Noerr-Pennington doctrine does not provide antitrust immunity where competitors enter into an agreement that manipulates the regulatory scheme and triggers the exclusionary effect identified in the Complaint.

IV. MOTION TO DISMISS STANDARD

Schering's and Upsher-Smith's motions are filed pursuant to Section 3.22(e) of the Commission's Rules of Practice which authorizes the filing of a motion to dismiss a complaint. 16 C.F.R. § 3.22(e). Although the Commission's Rules of Practice do not have a rule identical to Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Commission has acknowledged a party's right to file, and the Administrative Law Judge's authority to rule on, a motion to dismiss for failure to state a claim upon which relief could be granted. *E.g., Times Mirror Co.*, 92 F.T.C. 230 (July 25, 1978); *Florida Citrus Mutual*, 50 F.T.C. 959, 961 (May 10, 1954) (ALJ may "dismiss a complaint if in his opinion the facts alleged do not state a cause of action.").

Section 3.11(b)(2) of the Commission's Rules of Practice sets forth that the Commission's complaint shall contain a "clear and concise factual statement sufficient to inform each respondent with reasonable definiteness of the type of acts or practices alleged to be in violation of the law." 16 C.F.R. § 3.11(b)(2). This rule requires only that the complaint contain "a factual statement sufficiently clear and concise to inform respondent with reasonable definiteness of the types of acts or practices alleged to be in violation of law, and to enable respondent to frame a responsive answer." *New England Motor Rate Bureau, Inc.*, 1986 FTC LEXIS 5, *114 (Dec. 12, 1986). "Commission complaints, like those in the federal courts, are designed only to give a respondent 'fair notice of what . . . the claim is and the grounds upon which it rests.'" *Id.* (*quoting Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

A motion to dismiss for failure to state a claim upon which relief can be granted is judged by whether a review of the complaint allegations clearly shows that the allegations, if proven, are sufficient to make out a violation of Section 5. *TK-7 Corp.*, 1989 FTC LEXIS 32, *3 (May 3, 1989). For purposes of a motion to dismiss, the factual allegations of the complaint are presumed to be true and all reasonable inferences are to be made in favor of complaint counsel. *TK-7 Corp.*, 1989 FTC LEXIS 32, *3 (*citing Miree v. DeKalb County*, 433 U.S. 25, 27 n.2 (1977); *Jenkins v. McKeitchen*, 395 U.S. 411, 421-22 (1969)).

If the motion to dismiss raises issues of fact which are in dispute, dismissal is not appropriate. *Herbert R. Gibson*, 1976 FTC LEXIS 378, *1 (April 23, 1976); *Jewell Companies, Inc.* 81 F.T.C. 1034, 1972 FTC LEXIS 277, *4 (Nov. 10, 1972) (denying motion to dismiss where there was a substantial dispute on questions of fact). *See also College Football Assoc.*, 1990 FTC LEXIS 485 (Dec. 27, 1990) (Where facts are needed to make determination on a "close question," the motion to dismiss will be denied.).

This standard used in Commission proceedings mirrors the standard used for evaluating motions to dismiss raised in federal courts under Rule 12(b)(6) of the Federal Rules of Civil Procedure. The Supreme Court has held that it "is axiomatic that a complaint should not be dismissed unless 'it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" *McClain v. Real Estate Board of New Orleans, Inc.*, 444 U.S. 232, 246 (1980) (*quoting Conley v. Gibson*, 355 U.S. 41, 45-46 (1957)). Moreover, it is well established that, in ruling on a motion to dismiss, allegations in the complaint must be accepted as true and construed favorably to the plaintiff. *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974). "[I]n antitrust cases, where 'the proof is largely in the hands of the alleged conspirators,' dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Hospital Building Co. v. Trustees of Rex Hospital*, 425 U.S. 738, 746 (1976) (*quoting Poller v. Columbia Broadcasting*, 368 U.S. 464, 473 (1962)).

V. ANALYSIS

A. Allegations That Schering's Agreements with Upsher-Smith and with AHP Delayed the Entry of Upsher-Smith and AHP

The Complaint alleges that Schering entered into two separate agreements whereby Schering paid Upsher-Smith and ESI to delay the entry of Upsher-Smith's and ESI's generic versions of K-Dur 20. Complaint ¶ ¶ 44, 55. Complaint Counsel asserts that an evaluation of whether Schering's patent was valid or not infringed or of whether the settlement was more anticompetitive than the probable outcome of the patent litigation is not necessary for a determination of whether the agreements delayed entry.

The dispositive issue is whether, under any alleged factual scenario, the Complaint's allegations demonstrate a violation of Section 5 of the FTC Act. In any given case, there may be many different scenarios or facts, which are not alleged, that also support a violation of the law. Hypothetical fact patterns or scenarios which contradict facts alleged in the Complaint are not dispositive when considering a motion to dismiss.

Respondents, by arguing that the Complaint fails to allege patent invalidity or non-infringement and fails to allege the patent suit was not bona fide or that the settlements were more anticompetitive than the probable outcome of the patent litigation, urge the Court to accept a different set of facts than alleged in the Complaint. In essence, Respondents argue that if Schering's patent was valid and was infringed by Upsher-Smith's and AHP's products, then Schering has a legal right to exclude those proposed products from the market until September 2006. Memorandum in Support of Respondent Schering-Plough Corporation's Motion for Partial Dismissal of the Complaint at p. 7. Under this scenario, Respondents assert, the agreements which allow Upsher-Smith and AHP to bring their generics to market prior to September 2006 are legal and indeed are procompetitive because the agreements allow the generics to enter the market sooner than the products otherwise would have.

As Complaint Counsel has pled the facts, Schering combined with Upsher-Smith and with AHP to delay entry into the market. On a motion to dismiss, a court cannot consider facts that contradict those pled in the complaint and must accept the allegations pled in the complaint as true. *See In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 653 (E.D. Mich. 2000) ("The mere fact that Defendant Andrx can come up with other plausible and legally permissible explanations as to why it prolonged its entry into the market is to no avail."); *Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 767-68 (D. N.J. 1999) (refusing to dismiss antitrust claims under Rule 12(b)(6) and reasoning "while it is possible that Andrx is not marketing its generic product because it does not want to risk potential patent infringement damages, it is also certainly possible that Andrx is not marketing its generic product -- and hence stalling the exclusivity period -- because defendants are paying it forty million dollars a year not to do so. This court simply cannot make this call on the pleadings.").

Agreements not to compete that unreasonably restrain trade have been found to violate the antitrust laws. *National Collegiate Athletic Assoc. v. Board of Regents*, 468 U.S. 85, 100 (1984); *Northwest Wholesale Stationers, Inc. v. Pacific Stationary & Printing Co.*, 472 U.S. 284, 289-90 (1985). "Antitrust law looks at entry into the market as one mechanism to limit and deter exploitation of market power by those who may temporarily possess it." *Andrx Pharmaceuticals, Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 814 (D.C. Cir. 2001).

At least one court has held that a party challenging an agreement similar to Schering's agreements with Upsher-Smith and AHP could state a claim for antitrust injury without first demonstrating that the brand name drug company's patent was invalid. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 2001 U.S. Dist. LEXIS 15386, *29 (E.D.N.Y. Oct. 1, 2001). If Complaint Counsel's allegations that the agreements delayed Upsher-Smith's and AHP's entry into the market and harmed consumers are taken as true, the Complaint need not allege that Schering's patent was invalid or not infringed and need not allege that the patent suits were not bona fide or that the settlements were more anticompetitive than the probable outcome of the litigation in order to state a cause of action under the motion to dismiss standard. Similarly, it is not necessary for the Complaint to dispute that the settlement of the patent litigation between Schering and Upsher-Smith resolved the patent dispute by compromise. Accordingly, the allegations of the Complaint will not be dismissed.

B. Allegations That Schering's Agreement with Upsher-Smith Delayed the Entry of Other Potential Generic Entrants

1. Upsher-Smith's 180 day exclusivity period

The Complaint alleges that, absent Schering's cash payments under its agreement with Upsher-Smith, Upsher-Smith would not have agreed to delay the launch of its generic product for as long as it did. Complaint ¶ 64. The Complaint further alleges that the delay of the launch of Upsher-Smith's generic product had the effect of delaying other potential generic manufacturers from entering the market. Complaint ¶ 47, 66.

The Complaint states that, as the first ANDA filer with a Paragraph IV Certification, Upsher-Smith is eligible for the 180-day exclusivity period. Complaint ¶ 41. Although it is the Hatch-Waxman Act that makes Upsher-Smith eligible for the 180-day exclusivity period, the Complaint alleges that it is the agreement between Schering and Upsher-Smith that preserves the exclusivity period or delays the start of it. Complaint ¶ 47, 66. But for the agreement, according to the Complaint, the 180-day exclusivity period would have been triggered earlier, either by Upsher-Smith prevailing in the patent litigation and entering the market earlier than September 2001, or by Schering prevailing in the patent litigation, resulting in the forfeiture of the 180-day exclusivity period. *Id.* This concerted action to preserve the exclusivity period is alleged to have delayed entry by other potential generic competitors. *Id.*

Schering asserts, first, that it is unclear whether the Hatch-Waxman Act grants the 180-day exclusivity period to a first filer who settles a patent suit. Schering asserts, second, that if the first filer is entitled to the 180-day exclusivity period, it is by operation of federal law with no resulting antitrust liability.

Although eligibility for the 180-day exclusivity period is by operation of federal law, the start date for triggering the exclusivity period is alleged to have been manipulated by the parties. It is the concerted action to manipulate the trigger date and preserve the exclusivity period that is alleged to violate the FTC Act. Actions taken to subvert a regulatory scheme for anticompetitive purposes are subject to the antitrust laws. *Woods Exploration & Producing Co. v. Aluminum Co. of Am.*, 438 F.2d 1286, 1303 (5th Cir. 1972) (*cited in Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d at 768). Further, "a reasonable trier of fact could conclude that an agreement between two competitors to delay the applicability of an exclusivity period for the purpose of keeping another competitor out of the market is an unreasonable restraint of trade or a wilful attempt to maintain or obtain a monopoly." *Biovail*, 49 F. Supp. 2d at 767. *See also Key Pharmaceuticals, Inc. v. ESI-Lederle, Inc.*, 1997 U.S. Dist. LEXIS 13328, *12 (E.D. Pa. 1997) (agreement to delay others' entry into market may be an illegal restraint on trade).

The Court of Appeals for the District of Columbia recently held that allegations that a settlement agreement to a patent dispute between a brand name drug manufacturer and a generic manufacturer to delay the start of the 180-day exclusivity period states a cause of action. *Andrx Pharmaceuticals, Inc. v. Biovail Corp. Int'l*, 256 F.3d at 809 ("Although it is true that the first to file an ANDA is permitted to delay marketing as long as it likes, the statutory scheme does not envision the first applicant's agreeing with the patent holder of the pioneer drug to delay the start of the 180-day exclusivity period.").

Respondents may well be able to show at trial that there was no concerted agreement to preserve the exclusivity period or manipulate the start date, that Upsher-Smith's eligibility for the 180-day exclusivity period was a consequence of Upsher-Smith's unilateral action in attaining first filer status, and that the exclusionary effect was by operation of federal law. Or, Complaint Counsel may be able to prove that, by purely private conduct and agreement, the parties intended to delay other generic manufacturers' entry into the market by delaying the start of the 180-day exclusivity period. Such acts would not be immune from antitrust liability under Noerr-Pennington. The facts alleged in the Complaint, if taken as true, and the reasonable inferences therefrom sufficiently allege concerted action which states a claim for which relief may be granted. Accordingly, these allegations will not be dismissed.

2. Status of law on the 180 day exclusivity period

Schering also argues that the Complaint misstates the governing FDA regulations as it alleges that "at all time relevant herein, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked." Schering argues that under the

FDA regulations in effect at the time of the settlement, Upsher-Smith may have lost all exclusivity rights and all rights to block third party generics when it settled its case.

Complaint Counsel admits that "FDA's implementation of this exclusivity has varied over the course of time covered by the complaint." Complaint Counsel's Response to Schering's Motion for Partial Dismissal of the Complaint at p. 20. Complaint Counsel asserts: (1) at the time of Schering's agreement, there was uncertainty about whether Upsher-Smith would retain its right to 180 days of market exclusivity after the settlement; (2) this lack of certainty - and the possibility that Upsher-Smith might not be entitled to the exclusivity unless it successfully defended the patent suit - created an incentive for Schering to enter its January 1998 agreement with AHP; and (3) subsequent court decisions eliminated the uncertainty and confirmed Upsher-Smith's right to the 180-day exclusivity period.

Although it is apparent, based on the court decisions and FDA rulings referred to in the parties' pleadings, that the law on the 180 day exclusivity period has been in flux, whether or not FDA approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked is a disputed factual question which will not be resolved through a motion to dismiss.

VI. CONCLUSION

For the above stated reasons, Schering's and Upsher-Smith's motions to dismiss the Complaint are DENIED.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: October 31, 2001

Federal Trade Commission

Headquarters
600 Pennsylvania Avenue, NW Washington, DC 20580

FAX Number:

Facsimile Transmittal Sheet

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