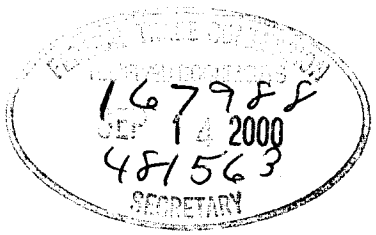


UNITED STATES OF AMERICA

BEFORE FEDERAL TRADE COMMISSION

In the Matter of

HOECHST MARION ROUSSEL, INC., a corporation,

CARDERM CAPITAL L.P., a limited partnership,

and

ANDRX CORPORATION, a corporation.

Docket No. 9293

RESPONDENT ANDRX CORPORATION'S "STATEMENT OF THE CASE" REPORTING ON VARIOUS MATTERS

Pursuant to the Court's Scheduling Order, respondent Andrx Corporation ("Andrx") submits this statement of the case reporting on compliance with discovery and settlement negotiations and identifying legal and factual matters to be decided by the Administrative Law Judge.[1]

Introduction

The Complaint in this proceeding focuses on a Stipulation pendente lite, which arose out of then-ongoing patent infringement litigation brought by Hoechst Marion Roussel, Inc. ("HMR") against Andrx in federal court in the Southern District of Florida, captioned Hoechst Marion Roussel, Inc. v. Andrx Pharmaceuticals, No. 96-

[1] We also have reviewed Aventis Pharmaceuticals, Inc.'s Statement of the Case, which, in substance, sets forth many of the issues to be tried. By this submission, we are endeavoring not to duplicate Aventis' submission.

06121 (the "Patent Action"). The Patent Action was brought under the complex and interconnected series of statutes known as the Hatch-Waxman Act, formally, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, codified at 21 U.S.C. §355(j). The statute was enacted to coordinate patent law, drug law, and competition policy with respect to generic pharmaceuticals in the United States. In the context of that statutory and regulatory scheme, the Stipulation was lawful and pro-competitive in both purpose and effect. Reviewing the very Stipulation and very conduct at issue here, the Federal District Court for the District of Columbia held that, pursuant to the applicable statutory and regulatory scheme, Andrx's conduct was "permit[ted]" and "protect[ed]." Andrx Pharmaceuticals, Inc. v. Friedman, 83 F.Supp.2d 179, 185-186 (D.D.C. 2000). The Stipulation served to advance competition, not hinder it.

In challenging a Stipulation that terminated over a year ago, Complaint Counsel presses a Complaint short on specifics. Nowhere, for example, does (nor can) Complaint Counsel describe how consumers were harmed as a result of respondents' conduct. Nor does (or can) Complaint Counsel identify a single competitor excluded from or delayed in entering the market by the Stipulation. Tellingly, the Complaint does not allege that the Stipulation actually restrained trade; rather, it alleges that the Stipulation had the "tendency or capacity" to do so (Cmplt., ¶ 29) -- whatever that means. That, however, fundamentally misstates Complaint Counsel's burden, which is not to demonstrate that respondents' conduct merely had a theoretical "tendency or capacity" or "was likely" to restrain trade but that it, in fact, had a concrete anti-competitive effect -- a showing Complaint Counsel cannot make, and fails even to plead that it can.

In any event, even if an alleged potential or capacity to restrain trade was enough for finding wrongdoing -- and it is not -- there are only two possible means by which the Stipulation might have done so: first, if Andrx itself remained out of any market because of the Stipulation; or second, if others were kept out by it. Thus, at the bare minimum, Complaint Counsel will need to prove that Andrx would have marketed sooner but for the Stipulation or that the Stipulation precluded others from entering the market and that these effects were not intended by Congress in enacting the Hatch-Waxman Act. Complaint Counsel will not be able to show any of this. Independent of the Stipulation, Andrx would not have marketed its generic product in the face of HMR's patent claims (and the risk of substantial damages) and Andrx otherwise confronted serious manufacturing obstacles with the product. Nor did any purported competitor have the ability to bring a generic product to market during the period that the Stipulation was operative.

Another reason Complaint Counsel's case fails is that the Stipulation being challenged constitutes activity protected from antitrust scrutiny because it was incidental to litigation. The Stipulation, fairly characterized, was equivalent to a stipulated preliminary injunction, allowing the parties to bypass the time, expense, and risks of having to litigate a preliminary injunction application; as such, it is activity protected under the Noerr-Pennington doctrine.

In addition, Andrx intends to establish a number of additional defenses at the trial of this matter. Among other things, the FTC reviewed the Stipulation before it went into effect and did not object to it. Indeed, Complaint Counsel waited until the Stipulation ceased to apply and the Court in the Patent Action could no longer approve it

before raising any challenge. In light of such laches on its part, the FTC should be precluded from obtaining the relief sought in its pleading. Andrx also intends to prove that Andrx finds itself here because of a perversion in the FTC process initiated by a company, Biovail Corporation International ("Biovail"), who claims to be a competitor. Biovail first co-opted the former Senior Deputy Director of the Bureau of Competition, hiring him as its outside counsel to petition his former colleagues at the FTC at a time when doing so violated federal statutes, FTC regulations, and common sense notions of conflict of interest. Biovail then coupled that improper engagement with improper dealings with members of the FTC staff.

A. Status of Compliance with Discovery

Complaint Counsel enjoys the advantage of already having obtained all the discovery it needs during the FTC staff's two-and-a-half year pre-Complaint investigation into this matter, during which time it received all of the documents and testimony it sought from Andrx plus information from well in excess of sixty other parties. Recognizing that such an exhaustive effort cannot be duplicated in the time allotted for discovery, respondents have sought to narrowly tailor their discovery requests both to Complaint Counsel and non-parties.

Regrettably, Complaint Counsel has taken an obstructionist approach to discovery, which, in turn, has encouraged non-parties -- including Biovail and others working in collaboration with Complaint Counsel -- to do the same. Not only have respondents so far been deprived of any opportunity to depose any representative of Biovail -- which is Complaint Counsel's "star witness" -- but Complaint Counsel went so far as to join in a motion by Biovail to quash subpoenas directed to it. In addition, the

Food and Drug Administration, which played a role central to this matter, has refused to produce any documents (or even a log of privileged documents) in response to a subpoena authorized by this Court.

In response to Complaint Counsel's arguments, this Court determined not to compel Complaint Counsel to produce, out of the FTC's files, "other agreements" containing so-called "ancillary restraints" similar to provisions in the Stipulation at issue here, because respondents could obtain those documents directly from non-parties without raising the issue of governmental privileges. Nonetheless, respondents have been thwarted so far in their efforts to do so because non-parties have raised bogus objections concerning confidentiality -- even after respondents agreed to an extreme strengthening of the protective order in place -- and have refused to produce responsive materials.

To date, Andrx has served subpoenas on approximately thirty-five non-party entities (not counting the multiple individuals at the entities who received subpoenas.) However, fewer than half have produced any documents and no depositions of individuals noticed by respondents have occurred.

B. Status of Settlement Discussions

No discussions with Andrx concerning the settlement of this matter are ongoing. Andrx remains willing to confer with Complaint Counsel in good faith regarding a negotiated resolution of this matter.

C. Identification of Legal and Factual Issues

Complaint Counsel's case must be subject to a rule of reason analysis. See, e.g., State Oil Co. v. Khan, 522 U.S. 3 (1997) ("most antitrust claims" involve "whether the questioned practice imposes an unreasonable restraint on competition"). In

particular, courts evaluating restraints involving intellectual property rights, such as here, consistently evaluate those restraints under the rule of reason, after considering the actual effect of the alleged restraints on competition. E.g., B. Braun Medical, Inc. v. Abbott Laboratories, Inc., 124 F.3d 1419, 1427 n.4 (Fed. Cir. 1997) ("By virtue of its patent rights . . ., Braun has the right to exclude competition altogether in each of these markets. Therefore, the restricted sale does not constitute a per se illegal horizontal restraint."); E.I. Du Pont de Nemours & Co. v. Berkley & Co. Inc., 620 F.2d 1247, 1274 (8th Cir. 1980) (only where "patent is invalid as improperly issued and the patentee has illegally received exclusionary rights he would not otherwise have" is there any basis for antitrust violation).[2]

At this point in the proceeding, Complaint Counsel has not clarified its case in significant respects[3] and respondents have been unable to obtain meaningful (let

[2] While Complaint Counsel has referred to a decision in the Multidistrict Litigation, in which Andrx and HMR are parties, pending in U.S. District Court for the Eastern District of Michigan, finding the HMR/Andrx Stipulation to be a "per se" violation of the Sherman Act § 1, that single decision is taken out of context. Not only is the Michigan court's decision neither binding nor controlling in this proceeding, but it is at this moment being challenged: the very district court judge who entered that opinion has now certified it for interlocutory appeal to the Sixth Circuit. Complaint Counsel, in fact, consistently has treated this case as a rule of reason matter, consistent with the way it is pleaded. See, generally, the FTC's Release by Richard G. Parker, Director, Bureau of Competition, Federal Trade Commission, March 16, 2000; and, generally, Transcript of Initial Pretrial Conference, April 24, 2000, at pp. 11, 21 and 37.

[3] Recognizing the need to amplify the nature of its charges, Complaint Counsel stated, during the initial conference before the Court on April 24, 2000, that it was prepared to provide a statement more fully describing its case. 4/24 Tr. at 19. According to Complaint Counsel: "we would be willing to do that to try to clarify some of the issues. Again if your Honor finds that to be useful, we would be prepared to do that, and I would propose possible some time in June to do that." However, Complaint Counsel has not done that. In addition, this Court has ordered Complaint Counsel to provide supplemental interrogatory responses, if any, by October 2, 2000 -- which we do not yet have. See Order on Respondent Andrx's Motion to Compel Complaint Counsel to Respond to Interrogatories (dated August 18, 2000).

alone comprehensive) discovery. As a result, Andrx is not able to provide a definitive identification of legal and factual matters for determination in this proceeding. Nonetheless, based on Andrx's present understanding of Complaint Counsel's allegations, the legal and factual issues include the following:

1. Issues Concerning Whether the Alleged Conduct Resulted In Substantial Anti-competitive Conduct

To establish a violation Section 5 of the Federal Trade Commission Act, Complaint Counsel bears the burden to demonstrate that the alleged anti-competitive conduct, which is the operation of the Stipulation here, had a substantial negative effect on competition. E.g., United States v. Arnold, Schwinn & Co., 388 U.S. 365, 374 (1967). Complaint Counsel cannot satisfy that burden for various reasons, including that it will need to prove that Andrx's generic product, prior to its reformulation, did not infringe HMR's valid patents. The holder of a patent is expressly allowed to restrict the territory in which a licensee may practice the patent. 35 U.S.C. § 261. The exercise of that right cannot give rise to liability under the antitrust laws. Dunlop Co. Ltd. v. Kelsey-Hayes Co., 484 F.2d 407, 417-18 (6th Cir. 1973). In addition, Complaint Counsel will be unable to satisfy its burden because, in light of HMR's patent claims, it was reasonable for Andrx not to market its product irrespective of the Stipulation -- and the evidence adduced will show that Andrx, apart from the Stipulation, would not have marketed under the circumstances. Andrx also confronted serious manufacturing obstacles impacting its ability to market a generic product. Because Andrx had an independent, rational basis for waiting to market, no antitrust violation can be established. See, e.g., Hodges v. WSM, Inc., 26 F.3d at 36, 38 (6th Cir. 1994) (no antitrust violation where

"[p]laintiff would have suffered the same injury without regard to the allegedly anti-competitive acts") (quoting).

As for other competitors, no manufacturer other than Andrx had final FDA approval to market a generic Cardizem® CD until well after the Stipulation, by its terms, ceased to operate. Although Complaint Counsel has referred to Faulding Inc. and Biovail, Faulding is not relevant because it admitted that its product infringed the HMR patents. See Complaint Counsel's Response to Aventis' First Request for Admissions, Response No. 56. It therefore had no right to market its generic product. As for Biovail, it was unable to secure even tentative FDA approval for its product on a timely basis because of medical and scientific issues surrounding its formulation. Indeed, even after Biovail finally received tentative approval in October 1999, well after the Stipulation terminated, the FDA continued to accept and consider material relating to whether or not Biovail's product was safe enough to substitute for Cardizem® CD. Biovail did not receive final marketing approval until December 23, 1999, which was after the Stipulation was no longer operative and expiration of Andrx's 180 days of statutory exclusivity.

2. Issues Concerning Whether the Stipulation Resulted In Pro-Competitive Benefits

Even assuming that a substantial negative effect on competition can be established (which it cannot), Complaint Counsel has the further burden to demonstrate that the alleged anti-competitive restraints ancillary to the Stipulation do not outweigh the substantial pro-competitive benefits of the Stipulation. E.g., National Collegiate Athletic Ass'n v. Board of Regents of University of Oklahoma, 468 U.S. 85, 113 (1984). Here, the evidence will prove that the pro-competitive effects are manifest. Among other

things, the Stipulation provided funds that enabled Andrx, at the time only five years in existence and relatively cash poor, to defend itself in the Patent Action, reformulate its product, and get its generic product to market earlier (plus obtain license rights, among other things). In any event, the Stipulation did not impose any outright prohibition against Andrx marketing its generic product -- if Andrx did so, it at most would need to return certain funds.

3. The Provisions At Issue Were Ancillary and Necessary for Pro-Competitive Purposes

The Complaint fails and the relief sought is barred because they focus on provisions of the Stipulation that were, if anything, ancillary to that agreement's primary purposes, that had no demonstrable effect on the parties' behavior, and that were necessary to ensure that the parties could not evade their obligations under the Stipulation. Similar ancillary restraints are typically found in agreements and are necessary to achieve the pro-competitive benefits such agreements.[4] In the context of what other entities in the industry are doing, the provisions in the Stipulation being challenged are ancillary and independently necessary to implement the Congressional intent in passing the Hatch-Waxman Act. Indeed, the evidence will show that there essentially is no other way to implement the purpose of the Hatch-Waxman Act.

[4] For example, such so-called "restraints" are found in the March 31, 1998, agreement between Abbott Laboratories and Zenith Goldline Pharmaceuticals, an agreement as to which the Commission has publicly indicated that it will take no action because it believes the agreement to be lawful. Indeed, the evidence will show that the very entity on which Complaint Counsel heavily relies, Biovail, has itself engaged in such restraints.

4. Issues Concerning Existence of Alleged Conspiracy to Monopolize and Scope and Definition of Alleged Market

To establish its conspiracy to monopolize claim, Complaint Counsel has the burden to demonstrate the elements of a conspiracy to monopolize. However, the elements of a conspiracy cannot be established here. Complaint Counsel also must demonstrate the existence of a relevant market, properly defined in legal and economic terms. United States v. E.I. DuPont de Nemours & Co., 351 U.S. 377, 391-92 (1956). The alleged once-a-day diltrazem market is artificially narrow, and other products compete with Cardizem® CD in a broader market.

5. Purpose and Intent of the Stipulation

Complaint Counsel alleges that the Stipulation was anti-competitive in "purpose or effect," "intent," "tendency," and "capacity." Cmplt., ¶ 29, 31, 38. Contrary to those contentions, Andrx intends to prove that the Stipulation, in both purpose and effect, hastened competition, hastened the termination of the Patent Action, and hastened Andrx's ability to bring a generic product to market that HMR agreed did not infringe on its patents. It did so consistent with the Hatch-Waxman Act and the applicable regulatory regime. In light of the risks the parties reasonably sought to manage given the Patent Action, the Stipulation, in short, was pro- competitive in design and nature.

6. Issues Concerning Whether Stipulation Is Protected Activity

Under the Noerr-Pennington doctrine, conduct incidental to litigation is protected from antitrust scrutiny. See Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc. 365 U.S. 127 (1961); United Mine Workers of America v. Pennington, 381 U.S. 657 (1965). Providing the same remedy as a stipulated preliminary injunction, the Stipulation required the parties to maintain the status quo pending resolution of the case,

the presumption is that such activity is exempt from antitrust liability. Complaint Counsel will be unable to show that the conduct is exempt from immunity, either because the litigation was a sham or the settlement was a sham. Professional Real Estate Investors, Inc., v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56-57 (1993). Indeed, Complaint Counsel does not even make any allegation of a sham. To the contrary, the evidence will demonstrate that both HMR and Andrx litigated the Patent Action vigorously.

7. Issues Concerning Various Defenses

Andrx intends to establish at trial a number of defenses, including, among other things, the following.

a. The conduct challenged in the Complaint does not violate the law because Andrx's actions are fully consistent with the Hatch-Waxman Act and the regulations promulgated thereunder, as the court specifically held in Andrx Pharmaceuticals, Inc. v. Friedman, 3 F.Supp.2d at 185-86 (D.D.C. 2000). The Complaint and the relief sought therefore are barred because the claims asserted and the relief sought are contrary to and preempted by the Hatch-Waxman Act.

b. The FTC should be estopped from pressing this case or should be severely circumscribed in obtaining any relief because of equitable considerations. For example, the FTC first investigated the Stipulation in 1997 and then advised Andrx's counsel that the matter was closed. The FTC concedes it had prompt notice of the Stipulation. See Complaint Counsel's Response to Aventis' First Request for Admissions (5/15/00), Response No. 26. The FTC thereafter waited almost two years before resuming an investigation into the Stipulation. In reliance on the completion of the initial

investigation, Andrx was prejudiced because it proceeded to operate under the Stipulation. The FTC waited until after the Patent Action settled before challenging the Stipulation, and now apparently contends that the Stipulation is not protected from antitrust scrutiny since the judge did not approve it.

c. Beyond the issue of laches, the FTC's unclean hands and other inequitable conduct involves, among other things, questions pertaining to the FTC's selective enforcement and its dealings with Biovail and leaking confidential information during the non-public investigation. As part of the effort to assist the former Senior Deputy Director and his client, various members of the FTC staff engaged in numerous leaks of confidential information to Biovail, into the public domain, and elsewhere during the investigation concerning the Stipulation. These leaks were in clear violation of the FTC's rules and procedures. The leaks created an atmosphere in which the Commission concededly felt compelled to file charges. We intend to prove that, since the FTC staff along with Biovail, by way of improper leaks and other misconduct, improperly created the very publicity pressuring the FTC to take action here, there was no legitimate basis for the bringing of this action.

d. Under Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), two of the elements that are essential for any Commission proceeding are (1) that "reason to believe" exists that the defendants have violated the law; and (2) that a proceeding "would be to the interest of the public." The case law makes clear that decisions about "public interest" and "reason to believe" are subject to review. See Federal Trade Commission v. Klesner, 280 U.S. 19 (1929) (Brandeis, J.); Moretrench Corp. v. Federal

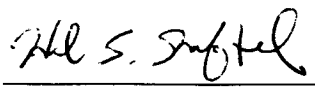
Trade Commission, 127 F.2d 792, 795 (2d Cir. 1942) (Hand, J.) (The Supreme Court in Klesner "did indeed decide that the public interest in the controversy was a justiciable issue"); Block Drug Company, Inc., 1976 FTC LEXIS 552 (February 6, 1976) *4 ("As a matter of proper pleading, respondents should not be denied the opportunity of demonstrating the lack of public interest"); American Family Publishers, Inc., 1991 FTC LEXIS 177 *1 (May 6, 1991) (denying motion to strike affirmative defense "pertaining to the alleged lack of public interest in the prosecution of this Complaint"). Here, Complaint Counsel will not be able to establish the prongs relating to either public interest or reason to believe.

e. Other defenses pertain to the public policy in favor of private settlements. The Stipulation was a proper settlement of the preliminary injunction aspect of the patent dispute. As is well-settled, settlement of disputed patent litigation alone cannot violate the antitrust laws. See, e.g., Duplan Corp. v. Deering Milliken, Inc., 540 F.2d 1215, 1220 (4th Cir. 1976); Procter & Gamble Co. v. Paragon Trade Brands, Inc., 61 F.Supp.2d 102, 108 (D. Del. 1996); Polo Fashions, Inc. v. Fashion Associates, Inc., 1986 WL 1176. *3 (S.D.N.Y. 1986). "Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the

nature of which is often inordinately complex and time consuming." Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir.), cert. denied, 429 U.S. 862 (1976).

Dated: September 13, 2000
New York, New York

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP

By 

Louis M. Solomon
Hal S. Shaftel
Colin A. Underwood
Michael S. Lazaroff
45 Rockefeller Plaza
New York, New York 10111
(212) 956-3700
Attorneys for Defendant
Andrx Pharmaceuticals, Inc.