

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

TO: The Honorable D. Michael Chappell
Administrative Law Judge

COMPLAINT COUNSEL’S MOTION FOR LEAVE TO FILE
SUPPLEMENTAL REPLY MEMORANDUM IN SUPPORT OF
MOTION TO STRIKE CERTAIN AFFIRMATIVE DEFENSES

Pursuant to Rule 3.22(c) of the Federal Trade Commission Rules of Practice for Adjudicatory Proceedings, complaint counsel respectfully requests leave to file the attached Supplemental Reply Memorandum in Support of Motion to Strike Affirmative Defenses. Complaint counsel have moved to strike certain affirmative defenses set forth in respondents’ answers because they are nothing more than smokescreens. On June 5, 2000 Andrx filed yet another document opposing complaint counsel’s motion. As Andrx’s filing states, both complaint counsel and Andrx contemplated an opportunity for complaint counsel to reply to Andrx’s latest filing, which again confirms Andrx’s plan to turn this case into an inquiry of

alleged misdeeds by FTC staff before the Commission issued the complaint. It is time to put an end to Andrx's sideshow and get on to the antitrust issues. Complaint counsel respectfully submits that the attached reply memorandum will assist Your Honor in doing so.

Respectfully Submitted,



Markus H. Meier
Bradley S. Albert

Counsel Supporting the Complaint

Bureau of Competition
Federal Trade Commission
Washington, D.C. 20580

Dated: June 12, 2000

**UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION**

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| In the Matter of |) | |
| |) | |
| HOECHST MARION ROUSSEL, INC., |) | |
| a corporation, |) | |
| |) | |
| CARDERM CAPITAL L.P., |) | Docket No. 9293 |
| a limited partnership, |) | |
| |) | |
| and |) | |
| |) | |
| ANDRX CORPORATION, |) | |
| a corporation. |) | |
| _____ |) | |

**ORDER GRANTING LEAVE TO FILE
SUPPLEMENTAL REPLY IN SUPPORT OF MOTION TO STRIKE**

IT IS HEREBY ORDERED that complaint counsel's motion for leave to file Supplemental Reply in Support of Motion to Strike Certain Affirmative Defenses is GRANTED.

D. Michael Chappell
Administrative Law Judge

Dated: June ____, 2000

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of

HOECHST MARION ROUSSEL, INC.,
a corporation,

CARDERM CAPITAL L.P.,
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and

ANDRX CORPORATION,
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Docket No. 9293

TO: The Honorable D. Michael Chappell
Administrative Law Judge

**Complaint Counsel's Supplemental Reply Memorandum in
Support of Motion to Strike Certain Affirmative Defenses**

This case is about Hoechst paying its most dangerous competitor, Andrx, more than \$89 million not to compete. That is a blatant antitrust violation, as the U.S. District Court for the Eastern District of Michigan recently ruled. Before the court was the same anticompetitive agreement between Hoechst and Andrx that is at issue in this case. Granting the private plaintiffs' motion for partial summary judgment, the court held that the agreement "constitutes a restraint of trade that has long been held to be illegal *per se* under established Supreme Court precedent."¹

¹ See *In re Cardizem Antitrust Litigation*, No. 99-md-1278 (E.D. Mich.) (Memorandum Opinion and Order Granting Plaintiffs' Motions for Partial Summary Judgment, at p. 1) (June 6, 2000).

Andrx's chosen defense is to attempt to turn this case into an inquiry of alleged misdeeds by FTC staff before the Commission issued the complaint. Besides speaking volumes about the weakness of Andrx's case on the merits, the company's latest smokescreen -- an accusation that FTC staff provided Biovail with "competitively sensitive information about Andrx" -- is false, is contradicted by Andrx's own public statements, and, in any event, is irrelevant to the anticompetitive conduct being challenged here.

It is time to put an end to Andrx's sideshow and get on to the antitrust issues. Granting complaint counsel's motion to strike will advance this goal substantially.

1. The Documents Submitted by Andrx Do Not Contain Any Evidence that FTC Staff Improperly Disclosed Confidential, Non-Public Information

When FTC staff receive a complaint from a third party, staff investigates both the factual basis of a complaint and the legal theory asserted by the complainant. Staff frequently poses questions to a third-party complainants, just as it does to the targets of an investigation, to test whether various facts, actual or hypothesized, and certain cases or legal arguments are consistent with the possibility that a violation of the antitrust laws has occurred.² The communications identified by Andrx revealed no confidential information of Andrx or any other party. They are not relevant to the issue here -- whether the agreement between Andrx and Hoechst violates the antitrust laws -- and should not divert attention from the fundamental issue of this case.

² In testing the factual basis for the third party complaints, FTC staff frequently use hypothetical examples and other methods to avoid revealing confidential information. FTC rules contemplate, however, that sometimes confidential information must be, or is inadvertently, revealed. So long as any such disclosure is in furtherance of the FTC investigative process, no violation of FTC rules occurs. FTC Operating Manual, Ch. 16.9.3.4.

a. The February 1999 Facsimile to Biovail Does Not Contain Any Confidential, Non-Public Information

Contrary to Andrx's assertions, FTC staff did not reveal any confidential information of Andrx in its February 1999 facsimile to Biovail's counsel. The document reflects simply an effort by FTC staff to probe the merits of certain hypothetical legal arguments relating to agreements such as the one at issue in this case. Andrx is well aware that its arguments in defense of its agreement not to compete with Hoechst were not confidential: it had already advanced them in considerable detail on the public record in on-going private litigation.

Before entering into its September 1997 agreement not to compete with Hoechst, Andrx maintained that it intended to bring its generic version of Cardizem CD to market upon receiving final approval from the Food and Drug Administration:

Andrx has filed an ANDA requesting permission to sell its once-a-day diltiazem formulation. Andrx intends to manufacture and sell its once-a-day diltiazem composition as soon as it receives FDA approval.³

In July 1998, however, in the context of on-going litigation, Andrx changed its position and asserted the self-serving claim that it would not have gone to market after receiving final FDA approval, even without its agreement with Hoechst.⁴ In a brief filed publicly in support of a motion to dismiss an antitrust counterclaim brought by Biovail in *Andrx Pharmaceuticals, Inc. v.*

³ Defendant's Memorandum of Law in Opposition to Plaintiff's Motion to Dismiss Declaratory Judgment Counterclaims on the '497 and '689 Patents (June 2, 1997) at 6, *Hoechst Marion Roussel, Inc. v. Andrx*, No. 96-06121 (S.D. Fla. dismissed June 1999).

⁴ Andrx's suggestion that Biovail's complaint "was instigated by the FTC staff itself" (Supp. Sub. at 5) is likewise contradicted by the public record. Biovail had charged that the Hoechst-Andrx agreement was illegal in two separate legal proceedings initiated well before it submitted its March 1999 letter to FTC staff. See *Biovail Corp. Int'l v. Hoechst*, 49 F. Supp. 2d 750 (D.N.J. 1999), and *Andrx Pharmaceuticals, Inc. v. Friedman*, 83 F. Supp. 2d 179 (D.D.C. 2000).

Friedman, Andrx made this and various other arguments that it would have Your Honor believe were “highly confidential” seven months later, in February 1999.⁵

When FTC attorneys framed a series of hypothetical questions to Biovail’s counsel in February 1999, the hypotheticals did not refer to any specific on-going investigation, did not name any parties, and did not indicate whether any of the assertions made had any basis in fact. The hypotheticals were structured to question what legal relevance, if any, a number of arguments had to the applicable antitrust analysis. Third-party complainants in FTC investigations often provide FTC staff with their views on the legal basis for the Commission action that they seek, and staff often questions them regarding their legal arguments. Thus, even if Andrx had not already made its arguments public, the February 1999 fax would still be proper.

Andrx’s true objection to the probing hypothetical questions posed by FTC staff is not that the questions revealed confidential information, but that the answers are so damaging to Andrx. The first part of the fourth hypothetical questioned whether there is any legal significance to a claim that -- even had it not been paid by the dominant competitor to agree to

⁵ Statement of Points and Authorities in Support of Andrx Pharmaceuticals, Inc.’s Motion to Dismiss Biovail Corporation International’s Counterclaim (July 10, 1998) at 4, 16, 18, 19, *Andrx Pharmaceuticals, Inc. v. Friedman*, 83 F. Supp. 2d 179 (D.D.C. 2000), *appeal docketed*, No. 00-5050 (D.C. Cir. 2000). For example, Andrx’s brief contains the following statements:

- Andrx is a defendant in a patent infringement action that could result in hundreds of millions of dollars in potential damages. That is why Andrx is not marketing its product (emphasis in original) (p. 4);
- Andrx decided to avail itself of its statutory right not to enter the market until HMRI’s suit is finally resolved. It did so in order to preserve the value of its period of exclusivity (p. 16).

stay off the market -- a generic manufacturer nevertheless would have decided unilaterally not to enter. That is precisely the question answered so resoundingly by Judge Edmunds in holding that Andrx's argument is insufficient as a matter of law to avoid liability:

Whether Andrx's prior unilateral decision, as opposed to the HMRI/Andrx Agreement, caused it to stay off the market after it had obtained FDA approval and the 30-month Hatch-Waxman waiting period had expired is not at issue here. . . . Rather than Andrx's unilateral decisions, the conduct at issue here is Andrx's bilateral agreement with HMRI, its horizontal competitor, that unambiguously allocates the entire market for Cardizem CD and its bioequivalents to HMRI for as long as the Agreement remained in effect.⁶

b. The Kaiser-Balto E-Mails Do Not Show that FTC Staff Improperly Disclosed Any Confidential, Non-Public Information Either

Andrx's supplemental submission attaches copies of four e-mails between Steven Kaiser of the Cleary, Gottlieb law firm and David Balto, FTC Assistant Director for Policy and Evaluation. According to Andrx, "it is evident" from these communications that FTC staff disclosed to Biovail's counsel non-public information received from Andrx. (Supp. Sub. at 5-6). But Andrx points to no confidential, non-public information disclosed in the e-mails. Rather, its claim of improper disclosures rests on the fact that Biovail's counsel happened to submit a letter to FTC staff a few weeks after a meeting between Andrx and FTC staff. In the letter, Biovail's counsel state that they were asked to address certain legal issues not covered in their prior submission to the FTC. As we have already noted, however, it is perfectly proper for FTC staff to ask third parties for their views.

Andrx devotes the balance of its discussion of the e-mails to an argument that Mr. Balto helped Biovail "beef-up [its] complaint" to the FTC. Mr. Balto apparently made suggestions to

⁶ *In re Cardizem CD Antitrust Litigation*, slip op. at 35-36.

Mr. Kaiser regarding legal cases to address in Biovail's legal analysis. Andrx does not explain how it was harmed by such suggestions, nor does it suggest that the legal analysis was incorrect. At most, Andrx might argue that these communications suggest bias on Mr. Balto's part. Even assuming *arguendo* that were true, however, such bias on the part of one staff member would not be a defense to the allegations in the complaint. As the Commission has stated: "Bias presents an issue only when it undermines the independence of the Commission's decisionmaking process."⁷ There is simply no plausible argument that any of Mr. Balto's suggestions could have tainted the Commission's determination to issue the complaint.

2. The Alleged Staff Leaks Also Have No Relevance to this Proceeding

Even if Andrx's allegations of staff leaks were true, they are not a defense to the complaint. Indeed, they have no relevance to the Commission's determination to issue the complaint. As the Commission observed in *Toys "R" Us*, "we see no reason why leaks to the press by the staff would affect a Commission determination that there was reason to believe a violation had occurred or that a Commission proceeding was in the public interest."⁸ As we have previously pointed out, an inquiry into alleged staff leaks is a matter for the FTC Inspector General, not this adjudicative proceeding.

⁷ *Tyson's Corner Regional Shopping Center*, 82 F.T.C. 1459, 1462 (1973). It is clear from the context, that use of term "Commission" in *Tyson's Corner* means the five Commissioners acting in their capacity as a reviewing authority rather than the FTC as a whole. Cf. *Cinderella Career and Finishing Schools, Inc. v. FTC*, 425 F.2d 583, 586 (D.D.C. 1970) (drawing a distinction between the "Commission" meaning the entire FTC, including the Commissioners, administrative law judges, and staff, etc., and the "Commission" meaning the five FTC Commissioners sitting as a reviewing body).

⁸ FTC Dkt. No. 9273 (September 25, 1997) at 169, *appeal docketed*, No. 98-4107 (7th Cir. argued May 1999).

Andrx's sorry attempt to concoct a link between supposed FTC staff leaks and the Commission's decision-making -- by claiming that in a pre-complaint conversation FTC Chairman Pitofsky confessed that he felt compelled to support the complaint in this matter because of publicity about the Commission's investigation -- is perhaps the most egregious example of Andrx's tactics in this case. It would be inappropriate for complaint counsel or the Chairman himself to engage in a public discussion about what was said at the non-public meeting in question. But the suggestion that a respected antitrust scholar and experienced government official would tell a potential respondent that he was being manipulated by publicity about the investigation is absurd.

* * * * *

As set forth above, Andrx's various responses to complaint counsel's motion to strike certain affirmative defenses confirms the need to focus this case on the antitrust issues. We respectfully ask that our motion to strike certain affirmative defenses be granted in its entirety.

Respectfully Submitted,



Markus H. Meier
Bradley S. Albert

Counsel Supporting the Complaint

Bureau of Competition
Federal Trade Commission
Washington, D.C. 20580

Dated: June 12, 2000

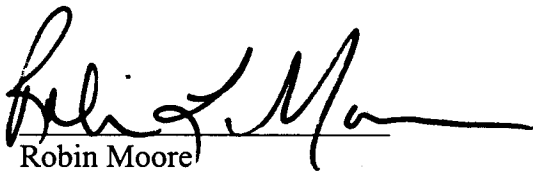
CERTIFICATE OF SERVICE

I, Robin Moore, hereby certify that on June 12, 2000, I caused a copy of the Complaint Counsel's Motion for Leave to File Supplemental Reply Memorandum in Support of Motion to Strike Certain Affirmative Defenses, order granting leave, and the supplemental reply memorandum to be served upon the following persons via facsimile and overnight delivery.

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