

**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

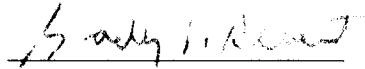
TO: The Honorable D. Michael Chappell  
Administrative Law Judge

**COMPLAINT COUNSELS' MOTION FOR LEAVE TO FILE  
REPLY IN SUPPORT OF MOTION TO STRIKE**

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 Reply Memorandum in Support of Motion to Strike Certain Affirmative Defenses. Complaint counsel have moved to strike certain affirmative defenses set forth in respondents' answers because they are nothing more than smoke screens. As a matter of law they are not defenses to the charges of the complaint. They should be stricken now so as to avoid the diversion of time and attention from getting to trial on the only real issue here -- whether respondents, by exchanging large sums of money for an agreement not to compete, have violated the antitrust

laws. Respondents' filings confirm the need to focus this case on the relevant 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: May 26, 2000

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BEFORE FEDERAL TRADE COMMISSION**

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a limited partnership,	)	
	)	
and	)	
	)	
ANDRX CORPORATION,	)	
a corporation.	)	
	)	

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

IT IS HEREBY ORDERED that complaint counsels' motion for leave to file Reply Memorandum in Support of Motion to Strike is GRANTED.

\_\_\_\_\_  
D. Michael Chappell  
Administrative Law Judge

Dated: May \_\_\_\_, 2000

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BEFORE FEDERAL TRADE COMMISSION**

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and	)	
	)	
ANDRX CORPORATION,	)	
a corporation.	)	
	)	

TO: The Honorable D. Michael Chappell  
Administrative Law Judge

**COMPLAINT COUNSEL'S REPLY MEMORANDUM IN  
SUPPORT OF MOTION TO STRIKE CERTAIN AFFIRMATIVE DEFENSES**

Complaint counsel have moved to strike certain affirmative defenses set forth in respondents' answers because they are nothing more than smoke screens. As a matter of law they are not defenses to the charges of the complaint. They should be stricken now so as to avoid the diversion of time and attention from getting to trial on the only real issue here – whether respondents, by exchanging large sums of money for an agreement not to compete, have violated the antitrust laws. Respondents' filings confirm the need to focus this case on the relevant issues. Andrx candidly admits its intention to blame the FTC staff for the consequences of what complaint counsel submits was a patently illegal agreement. Andrx Opp. at 3. For the reasons set forth below and in our moving papers, we respectfully urge Your Honor to confine this case to the antitrust issues by striking affirmative defenses that have no legal relevance.

First, complaint counsel's motion to strike defenses that challenge the sufficiency of the Commission's pre-complaint mental deliberations is grounded in well-settled law and decades of Commission precedent.<sup>1</sup> As stated in Exxon Corporation:

It has long been settled that . . . [o]nce the Commission has resolved the[] questions [of whether there is a reason to believe a violation has occurred and a proceeding would be in the public interest] and issued a complaint, the issue to be litigated is not the adequacy of the Commission's pre-complaint information. . . but whether the alleged violation has in fact occurred.

83 F.T.C. 1759, 1760 (Order Denying Reconsideration, June 4, 1974).<sup>2</sup> Striking these defenses is necessary – even at this early stage – because it will avoid an inappropriate broadening of the case to issues irrelevant to this proceeding. This hearing is about whether respondents' conduct

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<sup>1</sup> The defenses falling into this category are: (1) those challenging the Commission's "reason to believe" and "public interest" determinations (Andrx Def. Nos 7, 8, 18, and 19; HMR Def. No. 2; Carderm Def. No. 2); (2) selective prosecution defense (Andrx Def. No. 12); and (3) equitable defenses (Andrx Def. No.17).

<sup>2</sup> Even the cases cited by respondents confirm that this Court has no authority to review the Commission's pre-complaint deliberations. TRW Inc., 88 F.T.C. 544 (1976) (the *Commission*, not the ALJ, may review its "reason to believe" and "public interest" determinations and only "in the most extraordinary circumstances") (emphasis added); Pepsico, Inc., 83 F.T.C. 1716 (1974) (same); see also, Crush Int'l Ltd., 80 F.T.C. 1023 (1972) ("the examiner is considered to be without authority to rule" on the Commission's discretion on "whether or not a proceeding would be in the public interest.").

Andrx's other cases state only that the Commission may reconsider its "public interest" determination where circumstances have changed after the Commission issued its complaint. As no one alleges any such changed circumstances since the complaint was issued, these cases also are irrelevant. See, e.g., Denver Chemical Mfgr. Co., Docket No. 5755 (March 25, 1954) (granting *complaint counsel's* motion to dismiss because respondent modified conduct after the issuance of the complaint to comply with the law) (emphasis added); Wildroot Co., Docket No. 5928, at \*6 (June 30, 1953) (dismissing because respondent ceased illegal conduct in response to newly adopted industry-wide standards after the issuance of the complaint).

in agreeing not to compete with one another, as charged in the complaint, violates Section 5 of the FTC Act (see Exxon Corp., 83 F.T.C. at 1760), not an Andrx sideshow about the FTC staff's pre-complaint investigation and the Commission's pre-complaint mental deliberations.

*Pre-Complaint Publicity:* No fewer than 20 times in its Opposition, Andrx accuses the FTC staff of misconduct during the pre-complaint investigation, and it has made similar allegations in its Answer and during the Scheduling Conference before this Court. See, e.g., Andrx Answer, at 18-21. Andrx had the opportunity to raise this issue with each Commissioner before issuance of the complaint in this matter. Having failed, Andrx now wants Your Honor to second-guess the Commission's unanimous determinations that it had a "reason to believe" a violation had occurred and that a proceeding would be in the "public interest." This classic tactic by a defendant facing defeat on the merits – calling into question the motives and conduct of the prosecution in order to divert the Court and the parties from the task at hand – should be rejected. In the end, if the complaint charges cannot support the Commission's "public interest" and "reason to believe" determinations (as respondents allege), they should have no trouble showing these deficiencies to the Court by sticking to the antitrust merits, and without resorting to this diversionary attack on the mental deliberations of the Commission.

In any event, complaint counsel is unaware of any evidence that the FTC was the source of pre-complaint publicity surrounding this matter. If Andrx actually has, as it claims, specific "hard evidence" linking the publicity to FTC staff's improper disclosure of information, it should present this evidence to the Inspector General of the Federal Trade Commission, whose

responsibility it is to investigate such matters.<sup>3</sup>

*Selective Enforcement:* Andrx's "selective enforcement" affirmative defense (no. 12) poses significant discovery concerns. Relying on this defense, Andrx already has sought to pry into various open and closed Commission non-public law enforcement investigations. In response to these requests, complaint counsel informed Andrx that it intends to rely solely on documents that were or should have been produced in FTC File Number 981-0368 (the one that lead to issuance of the complaint in this case);<sup>4</sup> and further that all documents produced in any investigation besides FTC File Number 981-0368 are privileged or confidential under 15 U.S.C. §§ 46(f), 57b-2(b), and 18a(h), as well as 16 C.F.R. § 4.10(d). If any respondent who alleges selective prosecution may have access to the confidential and sensitive information obtained in any related investigation, the Commission's ability to conduct non-public investigations and

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<sup>3</sup> So far, Andrx has merely cited a number of newspaper articles that contain information available to numerous sources, besides the FTC staff, including:

- Third parties who had been contacted by Commission staff during its pre-complaint investigation;
- Plaintiffs, lawyers, or other individuals involved in the many private class action lawsuits filed against Andrx and HMR concerning the same HMR/Andrx Stipulation and Agreement at issue in this proceeding; and
- Andrx and HMR, both of whom had publicly acknowledged the existence of the FTC investigation in securities-related filings and press releases, as early as October 1998.

<sup>4</sup> The only exception concerns a document that HMR withheld – on claim of privilege – in the Andrx/HMR investigation, FTC File No. 981-0368, but which was produced in an earlier investigation conducted by one of the FTC's merger divisions (not the Health Care Division as Andrx states). As we indicated in our 4/27/00 Protective Order Motion, we believe HMR's production of the document, which it asserts was inadvertent, waives any privilege claim. Thus, we believe this document should have been produced in this matter.

obtain information voluntarily with assurances of confidential treatment would be severely compromised.<sup>5</sup> Surely, Andrx would complain if a respondent in a separate, unrelated FTC matter was seeking access to Andrx's non-public materials.

Second, complaint counsel moved to strike certain antitrust immunity defenses that are legally insufficient in this proceeding. For example, Andrx contends it is immune from antitrust scrutiny on the ground that its decision not to market its competing generic version of Cardizem CD prior to resolution of the patent infringement suit is consistent with federal food and drug law. See Andrx Def. No. 2. But whether a unilateral decision to refrain from marketing would have been legal is irrelevant, because the complaint challenges an agreement with HMR whereby Andrx was paid up to \$100 million a year (a) not to compete with any generic version of Cardizem CD, including ones that did not infringe any HMR patent, and (b) to foreclose the entry of other third-party competitors by agreeing not to relinquish its marketing exclusivity right. As recognized by a federal district court in private litigation involving the same agreement at issue here, Andrx's defense ignores a basic antitrust principle: "In antitrust cases such as this, the only difference between legal and illegal conduct is the existence of an agreement to do the same thing the parties could have done unilaterally and thus legally." In Re Cardizem CD Antitrust Litigation, File No. 99-md-1278 at 57 (Memorandum Opinion Denying Defendant's Motions to Dismiss, E.D. Mich. May 11, 2000). None of the cases cited by Andrx address agreements to restrain trade. In each of those cases, either the alleged antitrust offender acted unilaterally to

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<sup>5</sup> Even the cases relied on by respondent denied the type of industry-wide discovery sought here. See, e.g., Revlon, Inc., 1990 FTC Lexis 336 (Sept. 28, 1990).



withhold licenses or the authority to compete resided explicitly in the hands of regulators.<sup>6</sup> Here, Andrx's authority to compete was in its own hands as of July 1998, when it received FDA approval of its generic version of Cardizem CD. By agreement with HMR, however, it decided to receive multi-million dollar payments, rather than compete.

Third, complaint counsel's motion narrowly targets only those defenses that are deficient under this Court's Dura Lube standard, leaving in 24 of the 37 affirmative defenses raised in respondents' answers. Rather than ignoring the "overall statutory and regulatory framework" as Andrx contends (Andrx Opp. at 4), our motion leaves undisturbed respondents' numerous affirmative defenses that go to the operation and application of the patent laws and federal regulations.<sup>7</sup> Indeed, complaint counsel agrees with Andrx that it is important to place the Hoechst/Andrx agreement to delay marketing of Andrx's generic product in the context of the Hatch-Waxman and FDA implementing regulations, which were intended to increase the availability of cheaper, generic versions of drugs to the American public. See generally Mylan Pharmaceuticals, Inc. v. Shalala, 81 F. Supp. 2d 30, 32-33 (D.D.C. Jan. 4, 2000). Likewise, we expect to litigate and prevail on respondents' Noerr-Pennington defenses, which also were not

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<sup>6</sup> See, e.g., City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 266 (3d Cir. 1998) (No competitive injury existed where electric utility could not compete because it lacked the necessary regulatory certificate to deliver power in the relevant market); Schuylkill Energy Resources, Inc. v. Pennsylvania Power & Light Co., 113 F.3d 405, 415 (3d Cir.), cert denied, 522 U.S. 977 (1997) (Finding no antitrust injury because plaintiff, a supplier to a regulated monopoly, was neither a competitor nor a consumer in the relevant market); United States v. Westinghouse Electric Corp., 648 F.2d 642, 648 (9<sup>th</sup> Cir. 1981) (dismissing claim where patent holder acts unilaterally in selecting licensees).

<sup>7</sup> See, e.g., Andrx Def. No. 3 (Hatch-Waxman preemption); HMR Def. No. 14 (same); Carderm Def. No. 14 (same); Andrx Def. No. 4 (Patent Act preemption); HMR Def. Nos 5, 6, 7 (patent laws); Carderm Def. Nos 5, 6, 7 (patent laws).

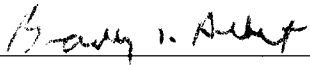
## CERTIFICATE OF SERVICE

I, Bradley S. Albert, hereby certify that on May 26, 2000, I caused a copy of the Complaint Counsels' Motion For Leave to File Reply Memorandum in Support of Motion to Strike Certain Affirmative Defenses, and the Reply Memorandum in support thereof, to be served upon the following persons via facsimile and overnight delivery.

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Bradley S. Albert



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

Bureau of Competition

May 26, 2000

**VIA HAND DELIVERY**

Hon. D. Michael Chappell  
Administrative Law Judge  
Federal Trade Commission  
Room 104  
600 Pennsylvania Avenue, N.W.  
Washington, D.C. 20580

Re: In the Matter of Hoechst Marion Roussel, Inc., Carderm  
Capital L.P., and Andrx Corporation, FTC Docket No. 9392

Dear Judge Chappell:

On behalf of complaint counsel, I have enclosed two copies of our Motion for Leave to File a Reply in Support of Motion to Strike and the Reply Memorandum. Per your Scheduling Order, I have also provided two copies of In Re Cardizem CD Antitrust Litigation, File No. 99-md-1278 (Memorandum Opinion Denying Defendant's Motions to Dismiss, E.D. Mich. May 11, 2000), which is referenced in our memorandum and not reported in any digest or on Lexis.

Sincerely,

A handwritten signature in cursive script that reads "Bradley S. Albert".

Bradley S. Albert  
Counsel Supporting the Complaint

cc: James M. Spears (w/o attachment)  
Peter O. Safir (w/o attachment)  
Louis M. Solomon (w/o attachment)