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 STATEMENT OF THE CASE

In accordance with the Scheduling Order entered on April 26, 2000, complaint counsel submit this statement of the case: (1) identifying the legal and factual matters to be decided at trial; (2) reporting on compliance with discovery; and (3) reporting on the status of settlement discussions.

I. Introduction

This case involves a straightforward application of well-established antitrust principles that prevent competitors from entering into agreements not to compete. In this case, respondents Hoechst Marion Roussel, Inc., and Andrx Pharmaceuticals, Inc., two competing drug manufacturers, entered into a written agreement in which Hoechst agreed to pay Andrx at least $40 million a year -- and as much as $100 million a year -- to delay marketing a generic version

of Hoechst's lucrative branded prescription drug, Cardizem CD. Specifically, in return for payments of at least $10 million per quarter, Andrx agreed:

- Not to market its generic version of Hoechst's Cardizem CD;
- Not to market any other generic or bioequivalent version of Cardizem CD; and
- Not to relinquish any of its rights granted by the Food and Drug Administration, which had the intended effect of preventing all other pharmaceutical manufacturers from marketing a generic version of Cardizem CD in competition with Hoechst.

At the time the respondents entered into the agreement in September 1997, Cardizem CD -- a once-a-day formulation of the chemical compound diltiazem, which is used in treating high blood pressure (hypertension) and chronic chest pain (angina) -- was Hoechst's top-selling prescription drug, with sales of over $700 million per year.

It is well documented in the economic literature and well known to pharmaceutical companies like Hoechst and Andrx, that when generic versions of a branded drug enter the market and compete with the branded drug, generics quickly take significant market share from the branded drug. And generics do so at substantially lower prices, saving consumers literally billions of dollars a year. Indeed, within the first full year of generic entry, branded drugs lose an average of 44% of their market share to generics, and the generics cost consumers on average 25% less than the branded drug at retail prices. As additional generic versions of a drug enter the market over time, the price of the generic drugs continue to fall, sometimes decreasing to less than 50% of the branded price. The consumer's gain is the branded drug company's loss.

Andrx was the first generic competitor to challenge Hoechst's lucrative Cardizem CD franchise by filing with the Food and Drug Administration an Abbreviated New Drug

Application (ANDA) in 1995, which was required to obtain approval to market a generic version of Cardizem CD. In response, Hoechst promptly sued Andrx for patent infringement, which, by law, triggered a statutory 30-month stay of the FDA's approval of Andrx's generic product.

In the patent lawsuit, Hoechst alleged that Andrx's generic version of Cardizem CD violated what is known as the '584 patent, a patent covering the rate of dissolution of diltiazem in the human body. (The patent covering the diltiazem chemical compound was no longer valid and not at issue in the patent suit.) Respondent Carderm Capital L.P. is the owner of the '584 patent, and Hoechst is Carderm's exclusive licensee.

In the lawsuit, Andrx consistently maintained that its generic version of Cardizem CD did not infringe the '584 patent. This position was predicated primarily on the fact that the dissolution profile of Andrx's generic Cardizem CD product fell well outside the dissolution rate specified in the '584 patent. Andrx also took the position that the '584 patent was not valid. Andrx vigorously defended the patent infringement suit, and it informed its shareholders that it was confident in its patent position vis-a-vis Hoechst. Andrx also informed the court presiding over the patent litigation that it intended to manufacture and sell its generic version of Cardizem CD as soon as it received FDA approval. Additionally, Andrx certified to the FDA on at least three occasions that its generic product did not infringe the '584 patent or any other patents covering Cardizem CD, and that, in any event, any such patents were invalid.

Hoechst, in light of the competitive threat from generic entry, informed its shareholders in 1997 that generic competition to Cardizem CD could occur as early as 1998, and that this could have a "material adverse effect on Cardizem CD sales and could have a material adverse effect on the operating profits of the Group." To reduce or eliminate this threat to its profits, Hoechst

approached Andrx in mid-1997 regarding the possibility of entering into an agreement concerning Andrx's generic Cardizem CD product. Over the course of several months, the two parties negotiated and ultimately signed an agreement not to compete that was a "win-win" for both companies.

For Andrx, the agreement served as a means to maximize its profits. Under the agreement, Andrx would be paid for the time it stayed off the market (from July 1998 to the end of the patent litigation) at a guaranteed rate of $40 million a year *even if it ultimately lost the patent litigation* and $100 million a year if it ultimately won the patent litigation. Additionally, if it won the patent suit, Andrx would still profit from its right to 180 days of marketing exclusivity prior to other generic entry. (As the first generic manufacturer to challenge the Cardizem CD patents, Andrx enjoyed a statutory right of 180 days of marketing exclusivity against all other generic manufacturers seeking FDA approval to sell generic Cardizem CD.) Although the law with respect to the 180-day exclusivity right was uncertain due to various legal challenges at the time Hoechst and Andrx entered their agreement, both companies were confident that the FDA would award Andrx this valuable right.

For Hoechst, the agreement, by guaranteeing the delay of generic competition to Cardizem CD, also served to protect its profits. First, in return for large payments from Hoechst, Andrx refrained from launching: (a) the product at issue in the patent litigation, or (b) any other generic version of Cardizem CD, even if Hoechst had no basis for alleging that the other products infringed a patent covering Cardizem CD. Second, because Andrx also agreed not to relinquish its right to 180 days of marketing exclusivity, Hoechst was able to forestall the threat of generic competition to Cardizem CD from other companies, such Faulding, Inc. and Biovail Corporation,

both of which also had filed ANDAs with the FDA seeking approval to market generic versions of Cardizem CD in 1997. Consequently, Hoechst was able to enjoy large profits from Cardizem CD without the threat of generic competition eroding its market share.

As expected, Andrx received final FDA approval to market its generic version of Cardizem CD in July 1998, at which time Andrx (absent the agreement) could have begun marketing its product. It was also at this time that Hoechst, in accordance with the agreement, began making non-refundable payments of $10 million per quarter to Andrx. These quarterly payments were made to Andrx until June 1999, when -- under pressure of the FTC's investigation of the agreement as well as class action law suits challenging the agreement -- Hoechst and Andrx terminated their agreement, and Andrx finally went to market with a reformulated product. In all, Hoechst successfully protected its lucrative Cardizem CD franchise from July 1998 to June 1999, by paying Andrx almost $90 million for staying off the market.

Thus, the evidence in this case will show that:

- Hoechst and Andrx were acutely aware of the dramatic, negative impact that the entry of generic Cardizem CD would have on Hoechst's $700 million-a-year Cardizem CD franchise. In fact, internal Hoechst forecasts projected that a generic version of Cardizem CD sold at 70% of the branded price would capture approximately 40% of Cardizem CD's sales within the first year, and even a one year delay in generic entry would preserve more than $350 million in Hoechst's gross sales.

- At the time Hoechst and Andrx entered into their agreement not to compete, Cardizem CD accounted for approximately 70% of all once-a-day diltiazem products sold in the United States.

- Andrx did not believe that its generic product infringed the '584 patent; it certified this to the FDA on a number of occasions; it announced publicly, and to the federal district court presiding over the patent dispute, its intention to manufacture and sell its generic Cardizem CD product immediately upon receiving final FDA approval; and it took steps to do so.

- The agreement harmed competition by eliminating Andrx's incentives: (1) to compete with Hoechst in July 1998 after it received final approval from the FDA to market its generic Cardizem CD product; (2) to compete with Hoechst even after it developed a reformulated product whose diltiazem dissolution rate was even more significantly different from the '584 patent; and (3) to relinquish its 180-day FDA-granted marketing exclusivity period, the intended effect of which was to prevent all other pharmaceutical manufacturers from marketing a generic version of Cardizem CD in competition with Hoechst.

- By eliminating Andrx's incentives to bring its generic Cardizem CD product to market, American consumers were denied access to lower cost generic alternatives to Cardizem CD.

- Hoechst and Andrx terminated the agreement almost a year after Andrx had received final FDA approval to market its generic product, under pressure from the Federal Trade Commission's investigation and related private litigation.

- Hoechst paid Andrx almost $90 million for delaying the launch of Andrx's generic version of Cardizem CD.

Respondents may try to entangle the Court in various tangential legal and factual inquiries in an attempt to avoid the consequences of their illegal agreement. For example, the fact that Hoechst has the rights to one or more patents relating to Cardizem CD does not determine the legality of the agreement, nor does it require Your Honor to adjudicate the patent claims. The anticompetitive restraints in the agreement here went well beyond mere assertion of patent claims, by, for example, prohibiting Andrx's sale of non-infringing products and barring Andrx from relinquishing its 180-day exclusivity right.[1] And the courts have made it clear that antitrust violations -- including *per se* violations -- may arise in the context of patent claims.[2]

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[1] *Duplan Corp. v. Deering Milliken, Inc.*, 444 F. Supp. 648, 684 (D.S.C. 1977) ("if an agreement transcends what is necessary to protect the use of the patent or the patent monopoly it may be found to violate the antitrust laws").

[2] *See, e.g., United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963) (patent settlement agreements between the Singer and its Italian and Swiss competitors were violations of the

Moreover, Hoechst's obligation under its agreement to pay Andrx (the putative patent infringer) at least $40 million per year not to market a competing product arises solely because of the agreement, not from Hoechst's patent rights. A patent gives the patent holder the right to exclude others from making, using, offering to sell, or selling the claimed apparatus or method for the life of the patent. These are rights that a patent holder may legitimately assert, but only after carrying its burden of demonstrating infringement. When the respondents entered their agreement not to compete, however, the scope and validity of the Cardizem CD patents was uncertain. Indeed, if Hoechst had conclusively demonstrated Andrx's infringement and firmly established its right to eliminate competition from Andrx, Hoechst would not have found it necessary to pay Andrx almost $90 million not to compete.

Similarly, the fact that Andrx was entitled to make a *unilateral* decision to delay marketing its generic product, does not give it the right -- under the Hatch-Waxman Act or any other law -- to enter into an agreement with a competitor to collusively decide when to start competing. As the U.S. District Court for the Eastern District of Michigan observed in the private class action case challenging the agreement between Hoechst and Andrx, "there are many things a defendant can do unilaterally without offending the antitrust laws that it cannot do collusively."[3]

Sherman Act); *United States v. Masonite Corp.*, 316 U.S. 265 (1942) (agreements between patent holder and its competitors were *per se* illegal).

[3] *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 618, 648 n. 16. *See also* 105 F. Supp. 2d at 658 ("Even though the Hatch-Waxman Amendments may authorize very specific unilateral conduct and a specific, limited restraint of trade, they do not authorize agreements to restrain trade"); *id.* at 663 ("The fact that the Hatch-Waxman Amendments permit defendant Andrx to unilaterally do what it cannot do collusively does not serve to immunize Defendants' conduct from the antitrust laws").

Ultimately, this case involves a straightforward application of well-established antitrust principles. The fundamental issue presented is whether respondents' agreement not to compete and to share the monopoly profits -- at the expense of consumers -- violates the antitrust laws.

II. Legal and Factual Matters to Be Decided

The U.S. District Court for the Eastern District of Michigan, evaluating the very agreement between Hoechst and Andrx at issue in this case, held that this agreement "constitutes a restraint of trade that has long been held to be illegal *per se* under established Supreme Court precedent."[4] The court went on to find that:

> On its face, the Agreement: (1) restrained Andrx from marketing its generic version of Cardizem CD in July 1998 when the FDA approval was expected and

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Andrx relies heavily on language in *Andrx v. Friedman*, 83 F. Supp. 2d 179 (D.D.C. 2000), *appeal docketed, sub nom., Andrx Pharmaceuticals, Inc. v. Biovail Corp. Int'l,* No. 00-5050 (D.C. Cir. February 7, 2000), but that case merely held that Biovail lacked standing to mount an antitrust challenge to the agreement between Hoechst and Andrx. The opinion contains language suggesting that any injury to Biovail is more directly caused by the existence of the exclusivity scheme of Hatch-Waxman than the agreement, but the court did not find that the agreement was immune from challenge by *any* plaintiff. To the contrary, the court stated that "there are other, more direct victims of Andrx's alleged violation," and that "[t]hose most directly affected by such a violation would be the consumers forced to pay artificially high prices for Cardizem." Id. at 186. It is precisely those consumer interests that our case seeks to vindicate.

[4] *In re Cardizem Antitrust Litigation*, 105 F. Supp. 2d 682, 685 (E.D. Mich. 2000). On August 15, 2000, the district judge granted Hoechst's and Andrx's motion for certification to the Sixth Circuit Court of Appeals, pursuant to 28 U.S.C. § 1292(b), concerning, among other things, the district court's ruling that the September 1997 agreement constitutes a *per se* violation of federal antitrust law. *See In re Cardizem Antitrust Litigation*, No. 99-md-1278 (E.D. Mich.) (Order No.16 Granting Defendant's Motion for Certification and Amending Orders No. 12 and 13 so as to Add this Court's Certification of the Two Legal Issues Identified in this Order No. 16) (August 15, 2000) (finding that although "in this Court's mind the likelihood of reversal is not great, substantial grounds for difference of opinion with respect to the Court's holding is evidenced by the lengthy briefing by all parties and the lengthy opinion by this Court"). The Sixth Circuit has yet to decide whether to accept this interlocutory appeal.

> obtained; (2) restrained Andrx from marketing other bioequivalent or generic versions of Cardizem CD which were not at issue in the pending [Hoechst]/Andrx patent case . . . and (3) restrained Andrx from relinquishing or otherwise compromising its right to the 180-day period of exclusivity it obtained under the Hatch-Waxman Amendments. The [Hoechst]/Andrx Agreement thus inhibited rather than enhanced generic competition for Cardizem CD and allocated the entire United States market for Cardizem CD and its bioequivalents to [Hoechst] during the life of that Agreement. By restricting generic competition, the Agreement also allowed [Hoechst] to maintain or fix the price of Cardizem CD at non-competitive price levels.[5]

Finally, the federal district court evaluated and rejected each of Hoechst's and Andrx's purported defenses.[6]

Complaint counsel could well rely solely on the facts presented to, and the law found by, the federal district court, but we intend to prove not only that the agreement between Hoechst and Andrx to collusively decide when to start competing is illegal *per se*, but that it also constitutes: (1) an unreasonable restraint of trade under the rule of reason; (2) a conspiracy to monopolize; (3) an attempt to monopolize; and (4) an unfair method of competition.

Accordingly, the legal and factual issues to be tried in this case include the following:

1. Whether Hoechst and Andrx are corporations, and Carderm is a partnership, within the meaning of Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, so as to confer FTC jurisdiction over these entities. (Although it does not appear that respondents intend to seriously dispute that they come within the jurisdiction of the FTC, each has denied the FTC's jurisdiction in their respective Answers to the Complaint.)

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[5] *Id.* at 699.

[6] *Id.* at 700-06. *See also In re Cardizem Antitrust Litigation*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) (evaluating and rejecting Hoechst's and Andrx's defenses).

2. Whether the agreement between Hoechst and Andrx not to compete constitutes a *per se* illegal market allocation in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C.§ 45. To reach such a conclusion -- under controlling law, including *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990) and *United States v. Topco Associates, Inc.*, 414 U.S. 801 (1973) -- this Court will need to find that:

a. There was an agreement between Hoechst and Andrx. (It does not appear that respondents intend to seriously dispute that they entered into the written agreement of September 24, 1997 that is the subject of this action.)

b. The agreement between Hoechst and Andrx occurred in or affected interstate commerce. (Although it does not appear that respondents intend to seriously dispute that their general business activities or that their pharmaceutical sales, including Hoechst's sales of Cardizem CD and Andrx's sales of generic Cardizem CD, occur in or affect interstate commerce, each has denied this in their respective Answers to the Complaint.)

c. The agreement between Hoechst and Andrx was anticompetitive on its face; that is, it is the type of agreement that always or almost always tends to raise price or reduce output.

3. Whether the agreement between Hoechst and Andrx not to compete is an unreasonable restraint of trade in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C.§ 45. To reach such a conclusion -- under controlling law, including *FTC v. Indiana Federation of Dentists,* 476 U.S. 447 (1986), *NCAA v. Board of Regents,* 468 U.S. 85 (1984), *Broadcast Music, Inc. v. Columbia Broadcasting Systems, Inc.*, 441 U.S. 1 (1979), and *National Society of Professional Engineers v. United States,* 435 U.S. 679 (1978) -- this Court will need to find that:

a. There was an agreement between Hoechst and Andrx.

b. The agreement between Hoechst and Andrx occurred in or affected interstate commerce.

c. The agreement between Hoechst and Andrx had actual or likely anticompetitive effects or was likely to create or facilitate Hoechst's exercise of market power in the market for once-a-day diltiazem products.

d. The agreement's harmful effects on competition were not outweighed by any benefits to competition.

4. Whether the agreement between Hoechst and Andrx not to compete constitutes a conspiracy to monopolize in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C.§ 45. To reach such a conclusion -- under controlling law, including *United States v. Yellow Cab Co.*, 332 U.S. 218 (1947) -- this Court will need to find that:

a. There was an agreement (conspiracy) between Hoechst and Andrx.

b. Hoechst and Andrx engaged in overt acts in furtherance of the conspiracy.

c. Hoechst and/or Andrx had specific intent to monopolize the market for once-a-day diltiazem products.

5. Whether the agreement between Hoechst and Andrx not to compete constitutes attempted monopolization in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C.§ 45. To reach such a conclusion -- under controlling law, including *Spectrum Sports, Inc. v. McQuillan,* 506 U.S. 447 (1993) -- this Court will need to find that:

a. Hoechst engaged in anticompetitive conduct.

b. Hoechst had specific intent to monopolize the market for once-a-day diltiazem products.

c. Hoechst had a dangerous probability of achieving or maintaining monopoly power in the market for once-a-day diltiazem products.

6. Whether the agreement between Hoechst and Andrx not to compete constitutes an unfair method of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C.§ 45. To reach such a conclusion -- under controlling law, including *FTC v. Cement Institute,* 333 U.S. 683 (1948) and *United States v. W. T. Grant Co.,* 345 U.S. 629 (1953) -- this Court will need to find that even if the agreement did not have direct anticompetitive effects because the respondents terminated it under pressure from the FTC, had the agreement remained unchecked, it would have had such effects, and absent putting the respondents under order, there exists a cognizable danger of recurrent violation.

III. Compliance with Discovery

Complaint counsel has fully complied with all discovery requests to date from the respondents in accordance with this Court's various orders governing discovery. The remainder of this section discusses respondents' compliance with our discovery requests.

A. Written Discovery

On May 3, 2000, we issued to respondents our first request for the production of documents. Although we have received some documents, we still have not received complete responses from either Hoechst or Andrx.

B. Deposition Discovery

On July 21, 2000, we issued initial deposition notices to Andrx and Hoechst. In response to this notice, respondents neither made their witnesses available for deposition nor proposed alternative dates. Over the next several weeks, we attempted to discuss informally with respondents the deposition scheduling of respondents' employees and agents, including those

identified on the July 21 notice as well as additional witnesses that we identified later in correspondence and in a subsequent deposition notice. Despite these efforts, almost two months later, no depositions of respondents' witnesses have been scheduled, and indeed, respondent Andrx has not even proposed a single date for the deposition of any of their witnesses. In addition, respondents have informed us they will not make available for deposition in this proceeding any individual whose testimony was taken during the pre-complaint investigation, more than a year ago. We are meeting today (September 13, 2000) with respondents and hope to resolve these outstanding discovery issues.

C. Expert Discovery

Respondents' expert witness lists collectively identify four individuals who expect to testify solely on patent issues. Nonetheless, despite repeated requests,[7] respondents still have not produced -- more than 5 months into discovery -- basic documents from the patent suit, including summary judgment motions, as well as deposition transcripts and exhibits. Respondents' failure to respond timely to these requests seriously prejudices our ability to prepare any expert rebuttal to the patent issues which respondents apparently intend to raise.

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[7] These documents are responsive to at least six separate outstanding discovery requests, including: (1) request 4 of our first request for production of documents issued to Hoechst on May 3, 2000; (2) requests 2 and 7 of our first request for production of documents issued to Andrx on May 3, 2000; (3) requests 4, 5 and 6 of our *subpoena duces tecum* issued to Eric D. Isicoff, Esq. on July 14, 2000; (4) requests 4, 5 and 6 of our *subpoena duces tecum* issued to Gerald J. Houlihan, Esq. on July 14, 2000; (5) requests 4, 5 and 6 of our *subpoena duces tecum* issued to Thomas V. Heyman, Esq. on July 14, 2000; and (6) requests 4, 5 and 6 of our *subpoena duces tecum* issued to James V. Costigan, Esq. on July 14, 2000. In our letters of July 6, and August 25, 2000, we outlined the deficiencies in the pre-complaint productions of patent-related documents. Moreover, during negotiations following the August 3, 2000 hearing on Complaint Counsel's Second Motion to Compel Andrx, Andrx agreed to expeditiously produce these documents from the patent litigation.

IV. Status of Settlement Discussions

To date, we have had separate preliminary discussions with both Hoechst and Andrx concerning the possibility of settlement.

V. Conclusion

As discussed above, complaint counsel will prove that the agreement not to compete entered into by Hoechst and Andrx in September 1997 is not only illegal *per se*, but that it also constitutes an unreasonable restraint of trade under the rule of reason; a conspiracy to monopolize; an attempt to monopolize; and an unfair method of competition in violation of Section 5 of the Federal Trade Commission Act. Accordingly, at the end of these proceedings we will ask that Your Honor enter a cease-and-desist order prohibiting Hoechst, Carderm, and Andrx from entering into similar agreements in the future, and providing such other relief as is necessary to protect American consumers from any future recurrence of these illegal acts.

Respectfully submitted,

Markus H. Meier
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Daniel A. Kotchen

Counsel Supporting the Complaint

Dated: September 13, 2000

CERTIFICATE OF SERVICE

I, Robin L. Moore, hereby certify that on September 13, 2000, I caused a copy of the Complaint Counsel's Statement of the Case to be served upon the following persons by Federal Express and facsimile.

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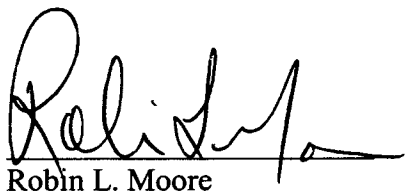

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