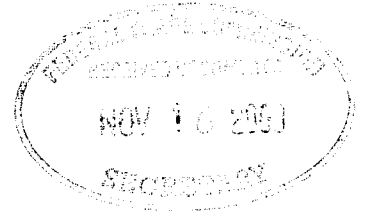


UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION



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

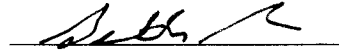
To: The Honorable D. Michael Chappell  
Administrative Law Judge

**COMPLAINT COUNSEL'S MOTION IN LIMINE TO  
PRECLUDE RESPONDENTS' INTRODUCTION OF EVIDENCE  
OFFERED TO SHOW PATENT INFRINGEMENT**

Complaint counsel move that this Court preclude respondents from entering evidence for the purpose of showing that any Andrx product infringed Hoechst's patent, on the ground that such evidence is irrelevant and would unduly delay the course of this proceeding, and should therefore be excluded under Section 3.43(b) of the Commission's Rules of Practice. In particular, we seek an order excluding evidence that is relevant only to show the likely outcome of the patent litigation. In addition, the testimony of certain experts offered by respondents – specifically, Hoechst's expert Mr. Methvin and Andrx's expert Dr. Banakar – should be excluded as their testimony is both irrelevant and improper.

Therefore, and as more fully discussed in the memorandum accompanying this motion, complaint counsel request that Your Honor issue an order to this effect.

Respectfully submitted,



Markus H. Meier

Elizabeth Hilder

Suzanne Michel

Seth C. Silber

Counsel Supporting the Complaint

Bureau of Competition

Federal Trade Commission

Washington, D.C. 20580

Dated: November 16, 2000

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TO: The Honorable D. Michael Chappell  
Administrative Law Judge

**MEMORANDUM IN SUPPORT OF  
COMPLAINT COUNSEL'S MOTION IN LIMINE TO  
PRECLUDE RESPONDENTS' INTRODUCTION OF EVIDENCE  
OFFERED TO SHOW PATENT INFRINGEMENT**

This case involves a written agreement between Hoechst and Andrx (the Stipulation and Agreement) in which Hoechst agreed to pay Andrx at least \$40 million a year, and possibly as much as \$100 million a year, to delay marketing a generic version of Hoechst's lucrative prescription drug, Cardizem CD. Respondents entered into the agreement in the course of a patent infringement lawsuit brought by Hoechst against Andrx. Respondents settled the lawsuit in June 1999, before the district court decided the case.

Respondents intend to ask this Court to decide in this antitrust case the hypothetical question whether, if the parties had continued their lawsuit, Andrx ultimately would have been found to have infringed Hoechst's patent. They intend to offer testimony from expert witnesses on how the court would have ruled, along with the lengthy record from the patent

litigation. If necessary, we are prepared to offer an expert witness in rebuttal, the author of a leading treatise on patent law, who has reviewed the record in the patent suit and will testify that in his opinion Andrx likely would have prevailed had the litigation continued.<sup>1</sup> Ultimately, resolution of this hypothetical determination would involve testimony from several expert witnesses and a review of the voluminous pleadings from the patent litigation.

We submit, however, that Your Honor should not go down that road. This Court need not decide this hypothetical infringement question because a determination on infringement is not necessary to determine whether the Stipulation and Agreement violates the antitrust laws, whether evaluated under a per se or a rule of reason analysis.

The scope of the agreement (for example, the bar on relinquishing market exclusivity rights) went well beyond merely keeping out Andrx's allegedly infringing product. Even a showing of infringement would not justify an agreement that far exceeds the asserted patent claim. Thus, there is no support for respondents' suggestion that this Court must reach a hypothetical decision on the merits of the parties' infringement dispute in order to determine whether this agreement is unlawful. Even if respondents could show that Hoechst would likely have prevailed in the patent infringement suit had it not been abandoned, that would not be a defense. Finally, Hoechst's arguments about the strength of its case avoid the "\$40 million question:" if it was so clear that Andrx's entry would have been foreclosed by a preliminary injunction, then why did Hoechst find it necessary to pay Andrx \$40 million a year?

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<sup>1</sup> If Hoechst's patent expert (Mr. Methvin) is precluded from testifying, we will not offer our patent expert (Prof. Adelman) as a witness.

Accordingly, we move that this Court preclude respondents from entering evidence for the purpose of showing that any Andrx product infringed Hoechst's patent, on the ground that such evidence is irrelevant and would unduly delay the course of this proceeding, and should therefore be excluded under Section 3.43(b) of the Commission's Rules of Practice.<sup>2</sup> In particular, we seek an order excluding evidence that is relevant only to show the likely outcome of the patent litigation. In addition, the testimony of certain experts offered by respondents – specifically, Hoechst's patent attorney "expert" (Mr. Methvin) and Andrx's expert who testifies on what *Hoechst* could have done to demonstrate infringement (Dr. Banakar) – should be excluded as their testimony is both irrelevant and improper.

#### **I. The Patent Litigation.**

The patent suit was "hotly contested" (Hoechst Statement at 4). Hoechst and Andrx filed several dispositive motions with the district court in Florida, including:

- Andrx's Motion to Dismiss for Lack of Subject Matter Jurisdiction;
- Andrx's Motion for Summary Judgment of Non-Infringement;
- Hoechst's Motion for Summary Judgment of Infringement;
- Andrx's Motion for Summary Judgment of Patent Invalidity; and

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<sup>2</sup> Rule 3.34(b) states, in pertinent part, that "[e]vidence, even if relevant, may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or if the evidence would be misleading, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."

- Andrx's Motion for Summary Judgment and Sanctions for Fraud Upon the United States Patent Office.<sup>3</sup>

The central issue contested in the patent litigation was whether any Andrx product infringed the '584 patent either literally or under the doctrine of equivalents.<sup>4</sup> The '584 patent claims the delayed release beads of a once-a-day diltiazem product that dissolve at a specified rate under specified conditions. The parties focused in particular on whether Andrx's SR2 delayed release bead satisfied the claim element requiring that the bead release from 0-45% of its total diltiazem after 18 hours of measurement. Andrx asserted that its product did not infringe the '584 patent, and if the patent were construed so broadly as to make the Andrx product infringe, then the patent was invalid.

In its Motion for Summary Judgment of Non-Infringement, Andrx argued that its SR2 bead could not infringe because it released "not less than 55%" of its diltiazem at 18 hours, an amount that clearly falls outside the claim range of 0-45%. (Motion at 7-8). In support of this

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<sup>3</sup> Copies of the reports, pleadings, and other materials referenced in this motion are not attached as most of these materials contain confidential information. Two courtesy copies of these materials, however, have been provided to the Court. The voluminous exhibits to the pleadings have not been included, but will be provided to the Court upon request.

<sup>4</sup> An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims. The second step is comparing the properly construed claims to the device or method accused of infringing. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Claim interpretation is a question of law. *Id.* When there is no dispute as to the properties of the accused product, the question of infringement is resolved by the legal issue of claim interpretation. *See Southwall Technologies v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). To infringe under the doctrine of equivalents, the accused product must contain each claim element or its equivalent. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). An accused product is equivalent to a claimed element if the differences between the two are "insubstantial." *Id.* at 39-40.

argument, Andrx submitted the affidavit of its President, Dr. Chih-Ming Chen, who explained how he modified the dissolution of the delayed release beads to “insure that Andrx’s once-a-day diltiazem formulation always avoids infringement” of the ‘584 patent.<sup>5</sup> Andrx reasserted that its product did not infringe Hoechst’s patent in later court filings – including the Stipulation and Order filed in June 1999 that led to the dismissal of the patent infringement case.

Hoechst now seeks to persuade this Court that the patent court would have resolved each dispositive motion in its favor, largely through the “expert” testimony of a patent attorney, Gaynell C. Methvin. The motions listed above and their supporting exhibits and affidavits (submitted as exhibits to Mr. Methvin’s report), total more than one thousand pages. The exhibits to Mr. Methvin’s report also include roughly another thousand pages of material representing discovery in the patent litigation.

For its part, Andrx now attempts to back-pedal from the position it consistently took until this case began. Dr. Umesh Banakar – an expert testifying on behalf of *Andrx* – will offer his opinion as to what Andrx’s patent adversary *Hoechst* “could likely have” done during the patent litigation to demonstrate that Andrx infringed.<sup>6</sup> Notably, Andrx apparently does not intend to offer the two legal opinions that it obtained from patent counsel around the time of the

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<sup>5</sup> Affidavit of Chih-Ming Chen in Support of Defendant’s Motion for Summary Judgment on the Issue of Non-Infringement (“Chen Affidavit”) at 6-8.

<sup>6</sup> See Banakar Report at 5.

Stipulation and Agreement – which Andrx has represented stated clearly that the Andrx product did not infringe the Hoechst patent<sup>7</sup> – having thus far withheld those opinions as privileged.

The testimony of Mr. Methvin and Dr. Banakar, and the voluminous pleadings and exhibits from the patent litigation, are unnecessary to this proceeding. As we discuss below, this Court need not determine the hypothetical outcome of the patent litigation.

We note as well that it is impossible for this Court to determine how the courts would have ultimately resolved the patent dispute. Even if Your Honor were willing to assess the relative merits of the parties' various summary judgment motions, there is no way of predicting how the case might have been resolved had the court concluded that there were disputed facts requiring a trial, let alone what would have happened on appeal. One key reason for this is that the alleged infringer, Andrx, no longer has the desire or incentive to defend its product. Hoechst and Andrx are no longer adversaries in patent litigation, but instead are co-respondents in the present action and co-defendants in numerous private antitrust suits.

**II. This Court's Determination Whether the Stipulation and Agreement Violates the Antitrust Laws Does Not Require a Determination on Patent Infringement.**

Antitrust law and intellectual property law share the common goal of promoting innovation and enhancing consumer welfare. The intellectual property laws provide incentives for innovation by establishing enforceable property rights for the creators of new and useful products. The antitrust laws promote innovation and consumer welfare by prohibiting certain

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<sup>7</sup> See Andrx Bates Nos. 009683-4.



actions that may harm competition.<sup>8</sup> The common goal is furthered and a balance between the two bodies of law is achieved by treating intellectual property similarly to other property when conducting an antitrust analysis.

The Patent Act supports this treatment of patent rights. It gives a patent owner the right to exclude others from making, using or selling the claimed invention. 35 U.S.C. § 154. An intellectual property owner's rights to exclude are similar to the rights enjoyed by owners of other forms of private property. In particular, the Patent Act provides that "[s]ubject to the provisions of this title, patents shall have the attributes of personal property." 35 U.S.C. § 261; *see also Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985).

As with other forms of private property, certain types of conduct involving patent rights violate the antitrust laws. For example, the Supreme Court has emphasized the limits on actions that a patentee may undertake in exercising its patent rights, stating:

A patentee has the exclusive right to manufacture, use, and sell his invention. The heart of his legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without his consent. The law also recognizes that he may assign to another his patent, in whole or in part, and may license others to practice his invention. But there are established limits which the patentee must not exceed in employing the leverage of his patent to control or limit the operations of the licensee.

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<sup>8</sup> Department of Justice & Federal Trade Commission Antitrust Guidelines for the Licensing of Intellectual Property § 1 (1994), *reprinted in* 4 Trade Reg. Rep. (CCH) 20,733 at 13,132, § 1 (April 11, 1995) ("*IP Guidelines*"). *See also* Willard K. Tom & Joshua A. Newberg, "Antitrust and Intellectual Property: From Separate Spheres to Unified Field," 66 *Antitrust L.J.* 167 (1997).

*Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 135 (1969) (citations omitted).<sup>9</sup>

The same general antitrust principles apply to conduct involving intellectual property that apply to conduct involving any other form of tangible or intangible property. *IP Guidelines* § 2.1. Intellectual property is thus neither particularly free from scrutiny under the antitrust laws, nor particularly suspect under them. *Id.* This basic principle of balancing intellectual property law and antitrust law governs the antitrust analysis of the relationship of Hoechst's patent rights to the legality of the respondents' agreement.

**A. The Stipulation and Agreement Went Beyond Merely Excluding Andrx's Allegedly Infringing Product.**

Hoechst and Andrx entered into a horizontal agreement intended to insulate Hoechst's highly profitable \$700 million a year Cardizem CD franchise from any generic competition for an indefinite period of time. Andrx agreed (i) not to market *any* generic once-a-day diltiazem product whether or not Hoechst had a good faith basis for claiming infringement; and (ii) not to relinquish its right to Hatch-Waxman exclusivity. In return for accepting these restraints, Andrx was generously compensated.

Thus, the agreement on its face went beyond binding Andrx not to enter the market with the allegedly infringing product that was the subject of the patent litigation in which the parties were engaged. The plain language of the agreement barred Andrx from selling *any* generic version of Cardizem CD, not merely an infringing product. And the ban on waiving exclusivity rights meant that no other firm could be approved by the FDA to market a generic version of Cardizem CD, even potential entrants with clearly non-infringing products.

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<sup>9</sup> See also *Sears, Roebuck & Co., v. Stiffel Co.*, 376 U.S. 225, 230 (1964) ("the patent monopoly may not be used in disregard of the antitrust laws") (citations omitted).

Even if Hoechst could show that Andrx would have lost the patent case, this would not justify restraints on the entry of other generic products, whether those of Andrx or other generic companies. A hypothetical resolution of the Hoechst-Andrx patent litigation would merely demonstrate that the product that was the subject of the litigation infringed. It would not establish that other generic versions of Cardizem CD also infringed Hoechst's patent. Indeed, Hoechst has not contended or offered to prove that its patent was so broad and iron-clad that any generic version of Cardizem CD would necessarily infringe its patent.<sup>10</sup>

Since the restraints contained in the agreement clearly fall beyond the scope of any asserted patent rights, an assessment of whether Andrx would have lost the infringement lawsuit is plainly irrelevant. The patent laws provide no protection for restraints that exceed the patent grant. *See Sears, Roebuck & Co.*, 376 U.S. at 230; *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942).

**B. The Stipulation and Agreement Is Not Immunized By the Patent Laws.**

The Stipulation and Agreement is an agreement that Andrx will not enter the market in exchange for a payment of money. Such agreements not to compete – especially as here, where the alleged infringer receives payments from the patent owner in return for staying off the market – are particularly suspect under the antitrust laws, because they “always or almost always tend to restrict competition and decrease output.” *Northwest Wholesale Stationers, Inc. v. Pacific Stationary & Printing Co.*, 472 U.S. 284, 289-90 (1985). As stated in the opinion of the

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<sup>10</sup> The patent on the active chemical ingredient of Cardizem CD, diltiazem, had already expired by the time Andrx sought FDA approval. As was noted above, the patent at issue in the litigation related solely to the controlled release aspect of the drug. This patent, which expires in 2012, has not served as a broad bar to generic entry.

U.S. District Court for the Eastern District of Michigan concerning this same agreement, the Stipulation and Agreement “is a straightforward horizontal market allocation agreement and thus fits within the category of business practices which have long been held illegal per se under section 1 of the Sherman Act.”<sup>11</sup>

Even as to the Andrx product that was the subject of the litigation, Hoechst’s contention that the product would have been found to infringe is not a defense to the charge that its agreement with Andrx unreasonably restrained competition. There is no basis to suggest – and indeed Hoechst does not appear to be claiming – that Andrx failed to launch its FDA-approved product in July 1998 because it was acceding to Hoechst’s clearly superior patent. Both Hoechst and Andrx have agreed that this was a vigorously contested, bona fide dispute about infringement.<sup>12</sup> As was noted above, Andrx consistently maintained until the Commission brought the present action that its product did not infringe Hoechst’s patent.

Instead, Hoechst appears to be suggesting that any restraint on Andrx’s competition through its initial product would not be anticompetitive because it would amount to unlawful competition by an infringing product. It is clear, however, as a matter of law that

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<sup>11</sup> *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 682, 701 (E.D. Mich. 2000). See also *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (finding that market allocation “agreements are anticompetitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other”).

<sup>12</sup> Hoechst’s own statement of the case characterizes the patent litigation as “hotly contested and vigorously pursued.” (Hoechst Statement at 4). Mr. Methvin states “this litigation was in every aspect bona fide and hard fought.” (Methvin Report at 15). Andrx’s experts have stated in their reports that Andrx had a plausible claim of non-infringement and the “parties could not know” the outcome of the litigation (Putnam Report at 3-4), and that “a bona fide patent dispute existed at the time of the Interim Settlement Agreement” (Elhauge Report at 16).

Hoechst's lawsuit creates no presumption of infringement. While patents are presumed *valid* until proven otherwise, that is not the case with respect to questions of *infringement*. Instead, the patentee bears the burden of establishing infringement.

Hoechst's statement of the case assumes that Andrx's original formulation infringed the patent.<sup>13</sup> Andrx's statement of the case goes even further, suggesting that we bear the burden to "prove that Andrx's generic product, prior to its reformulation, did not infringe HMR's valid patents." (Andrx Statement at 7).<sup>14</sup> Respondents cannot simply presume that the Andrx product infringes. "It is axiomatic that the patentee bears the burden of proving infringement." *Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1364 (Fed. Cir. 2000) (holding patentee did not present sufficient evidence to prove infringement). Nor does bringing a patent infringement suit against an ANDA filer, as Hoechst brought against Andrx, alter the patentee's burden.<sup>15</sup>

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<sup>13</sup> See e.g., Hoechst Statement at 4 ("HMR has every right to enforce its patents.").

<sup>14</sup> Any attempt by Andrx to concede infringement during this proceeding is completely disingenuous. Dr. Chih-Ming Chen, the president of Andrx, submitted in sworn statements during the patent litigation that he modified the dissolution of the delayed release beads to "insure that Andrx's once-a-day diltiazem formulation always avoids infringement" of the '584 patent. (Chen Affidavit at 6-8). Now, in the present proceeding, Andrx has retained an expert whose report sets forth an opinion on how *Hoechst* could have demonstrated infringement. See Banakar Report at 5 ("HMR could likely have produced competently performed test results indicating that the Andrx 'not less than 55% at the eighteenth hour' delayed release beads directly infringed the claims of the '584 patent.").

<sup>15</sup> See *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1567 (Fed. Cir. 1997) ("The plain language of the [Hatch-Waxman] statute does not alter a patentee's burden of proving infringement . . . As is well-established for infringement actions brought under § 271, a patentee seeking relief under § 271(e)(2) must prove by a preponderance of the evidence that what is to be sold will infringe. That burden is not shifted under § 271(e)(2).").

Thus, unless and until Hoechst had proved that the Andrx product infringed, there was no basis for any assumption that the Andrx product infringed. And no court ever reached the infringement question, because the parties abandoned the litigation, with Andrx receiving a “victory payment” as part of the final settlement. Despite the fact that the patent court never reached a determination on infringement, Hoechst maintains that it is entitled to have this Court delve into the unresolved infringement dispute.

However, the patents laws do not grant immunity from the antitrust laws. While Hoechst obtained certain rights concerning the ‘584 patent (including rights to enforce that patent), this case is not about Hoechst’s unilateral exercise of those rights. Rather, it is about the concerted action by respondents in entering into the Stipulation and Agreement in September 1997.<sup>16</sup> Because it is this concerted action that is challenged here, this Court’s *post hoc* determination on infringement does not justify or provide a defense. This Court, therefore, should not entertain respondents’ attempt to try a hypothetical patent case, as this Court’s determination on infringement is irrelevant to any decision on whether the Stipulation and Agreement violates the antitrust laws.<sup>17</sup>

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<sup>16</sup> *Id.* (“[r]ather than Andrx’s unilateral decisions, the conduct at issue here is Andrx’s bilateral agreement with HMRI”); *see also Lee-Moore Oil Co. v. Union Oil Co.*, 599 F.2d 1299, 1302 (4<sup>th</sup> Cir. 1979) (holding that when an antitrust plaintiff alleged damages resulting from the defendant’s concerted refusal to deal, “the fact that [defendant] might have caused the same damages by lawful [unilateral] cancellation of the contract is irrelevant”).

<sup>17</sup> Respondents contend that the Stipulation and Agreement is a settlement that “facilitated” resolution of the patent dispute, and thus should be protected from a *per se* analysis. *See e.g.*, Hoechst Statement at 20-21. Introduction of voluminous evidence on the hypothetical question of whether Hoechst would have won the case is irrelevant to this issue.

Horizontal agreements between parties to a patent dispute are not exempt from the antitrust laws, even where there is no resolution of patent issues. The U.S. District Court for the Eastern District of Michigan found the Stipulation and Agreement *per se* illegal without reaching a determination on whether Andrx infringed Hoechst's patent. Similarly, the Supreme Court found in *Singer* that patent settlement agreements between Singer and its Swiss competitors violated the Sherman Act, without resolving the underlying patent dispute. As Professor Hovenkamp explains:

[A]lthough a declaration of invalidity was a possible outcome of the dispute between Singer and the Swiss firm, it was not the only possible outcome, and *there was no finding by any court or the Patent Office that the patents were in fact invalid*. The crux of the complaint was that by pooling their claims and defending validity jointly against the Japanese, rather than vis-a-vis one another, the defendant and his fellow participants violated the Sherman Act.<sup>18</sup>

Here, there was a good faith dispute between the parties at all times relevant to this case, a dispute whose outcome was impossible to predict with certainty. The fact that a patentee like Hoechst might *later* demonstrate that the product at issue did infringe its patent provides no defense to the antitrust violation that occurred at the time the competitors entered a collusive agreement, when the patent issues were subject to a bona fide dispute. Thus, even if Hoechst could demonstrate in this proceeding that the Andrx product likely infringed the '584 patent, the act of entering into the Stipulation and Agreement still violates the antitrust laws. Accordingly, there is no need for this Court to rule on the patent issues.

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<sup>18</sup> 11 H. Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION, ¶ 2043 at 240 (1999) (emphasis added).

Moreover, Hoechst's assertion that the Stipulation and Agreement merely constitutes a valid exercise of its patent rights is premised on case law that simply demonstrates that certain *unilateral conduct* is lawful under the antitrust laws. For example, Hoechst cites to the recent Federal Circuit opinion in *In re Independent Serv. Orgs. Antitrust Litig.* where that court observed that the defendant "was under no obligation to sell or license its patent parts and did not violate the antitrust laws by refusing to do so."<sup>19</sup> *In re Independent Serv. Orgs.*, however, simply states that a patent holder may unilaterally exercise its right to exclude others from making, using, or selling products infringing its patent by refusing to license or sell to other parties. Thus, that opinion and other similar cases involving *unilateral* conduct cited by Hoechst merely stand for the proposition that a patent holder may seek to enforce its patent rights through lawful unilateral acts.<sup>20</sup>

**C. A Hypothetical Determination of Infringement is Irrelevant to a Rule of Reason Analysis of the Stipulation and Agreement.**

In deciding the present motion, it is irrelevant whether this Court examines the agreement under a per se or rule of reason analysis. A rule of reason analysis takes into account a restraint's likely or probable effects. *Board of Trade of City of Chicago v. United States*, 246 U.S. 231, 238 (1918).<sup>21</sup> The Commission's complaint alleges that the Stipulation and Agreement

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<sup>19</sup> 203 F.3d 1322, 1328 (Fed. Cir. 2000) (cited by Hoechst in its Statement of the Case at 20, n. 23).

<sup>20</sup> See Hoechst Statement at 20, n. 23 (citing additional cases concerning unilateral attempts by patent holders to enforce their patent rights).

<sup>21</sup> See also *Levine v. Central Fla. Medical Affiliates*, 72 F.3d 1538, 1552 (11<sup>th</sup> Cir. 1996) ("rule of reason analysis is concerned with the actual or likely effects of defendants' behavior");  
(continued...)



eliminated Andrx's incentives to compete with Hoechst prior to conclusion of the patent litigation. This effect on Andrx's incentive to compete was *immediate* and continued through the life of the patent litigation. A determination by this Court – years after respondents entered into their agreement – on the probable outcome of that litigation today bears no relationship to what Andrx may have believed in 1998 concerning whether it should launch its product at the time it entered the Stipulation and Agreement, or to how the Stipulation and Agreement influenced Andrx's incentives to enter the market. The probable outcome of the patent litigation, as determined by this Court today, is irrelevant to whether the Stipulation and Agreement altered Andrx's incentives to enter the market during the life of the litigation.

Beyond the immediate effects on Andrx's incentives to compete, the Stipulation and Agreement's likely would have delayed Andrx's entry prior to a court determination on the patent issue and prevented entry by other generic manufacturers, thereby depriving consumers of access to lower priced Cardizem CD. Under pressure from the Commission's investigation and numerous private class action suits, Hoechst and Andrx chose to terminate the Stipulation and Agreement in June 1999. Absent this termination, the agreement would likely have delayed the entry of Andrx's generic Cardizem product and other generic applicants. Any determination on infringement is irrelevant to looking at these likely effects, as there was no such determination at the time of termination. Moreover, the "likely effects" would have occurred only prior to final

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<sup>21</sup> (...continued)

*Balmoral Cinema, Inc. v. Allied Artists Pictures Corp.*, 885 F.2d 313, 315 (6<sup>th</sup> Cir. 1989) (a rule of reason determination inquires into "the purposes of the restraint and its likely effect on competition in the market in question").

court determination of the patent issues. Therefore, this Court need not reach a determination on infringement to find a violation under a rule of reason analysis.

**III. Expert Testimony Relevant Solely to the Hypothetical Outcome of the Patent Litigation Should Be Excluded.**

Based on the foregoing, the Court should exclude any evidence that is relevant only to the likely outcome of the patent litigation. As a result, the Court should exclude:

- The testimony of Hoechst's patent expert, Mr. Methvin. Mr. Methvin is a patent attorney, and will offer his opinion on whether Hoechst would have prevailed in the patent litigation. (Methvin Report at 7.)
- The testimony of Andrx's pharmaceutical expert, Dr. Umesh Banakar. To the extent respondents wish to use this testimony as support for the probable outcome of the patent litigation, it is irrelevant to this antitrust case. Dr. Banakar expects to testify that "HMR could likely have produced competently performed test results indicating that Andrx's 'not less than 55% at the eighteenth hour' delayed release beads directly infringed the claims of the '584 patent." (Banakar Report at 5).
- Any testimony that assumes the outcome of the patent litigation. For example, Andrx's witness Einer Elhauge, offered as an expert in antitrust law and economics, expects to testify that Hoechst "likely could have obtained" a preliminary injunction in the patent litigation. (Elhauge Report at 19).

**IV. The Testimony of Hoechst's Patent Expert Mr. Methvin and Andrx's Expert Dr. Banakar Should Also Be Excluded on Other Grounds.**

**A. Mr. Methvin Will Offer Opinion Testimony on Matters of Law, and His Testimony Is Therefore Inadmissible.**

Even if this Court decides that the hypothetical outcome of the patent litigation is relevant to this case, the testimony of Hoechst's patent expert, Mr. Methvin, should be excluded. Mr. Methvin will testify that Hoechst likely would have won the patent litigation on summary judgment. In other words, he will testify that Andrx infringed the '584 patent *as a matter of law*, and that the '584 patent was valid *as a matter of law*. Such testimony constitutes inadmissible

legal opinion. If this Court wishes assistance in understanding the summary judgment briefs filed during the patent litigation, the proper mode for that assistance is through attorney argument, not the testimony of patent attorneys posing as unbiased “experts.”

Attorneys’ testimony on legal issues is generally prohibited because it is the judge’s province alone to determine the relevant legal standards governing a case. *Burkhart v. Washington Metro. Area Transit Auth.*, 112 F.3d 1207, 1213 (D.C. Cir. 1997). “It is axiomatic that the judge is the sole arbiter of the law and its applicability.” *Specht v. Jensen*, 853 F.2d 805, 807 (10<sup>th</sup> Cir. 1988) (en banc). “In no instance can a witness be permitted to define the law of the case” because such testimony usurps the function of the court. *Id.* at 810. Mr. Methvin’s testimony is improper because “a lawyer may not testify as an expert to purely legal matters.” *United States v. Cross*, 2000 U.S. Dist. LEXIS 13177, \*3 (S.D. Ind. 2000).

The fact that respondents are attempting to insert a patent infringement determination into this antitrust case does not alter this basic principle of evidence law. “[I]t is inappropriate and unnecessary to allow expert testimony on issues of [patent] law.” *Ely v. Manbeck*, 17 U.S.P.Q.2d 1252, 1254, 1990 WL 267419, \*1 (D.D.C. 1990) (precluding expert testimony containing “any exposition or opinion as to the legal issues in the case or patent law generally”).<sup>22</sup> Notably, Hoechst also offered the testimony of Mr. Methvin in the private antitrust litigation pending in the U.S. District Court for the Eastern District of Michigan concerning the Stipulation and Agreement. *In re Cardizem CD Antitrust Litigation*, 105 F. Supp.

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<sup>22</sup> See also *Nutrition 21 v. United States*, 930 F.2d 867, 871 n.2 (Fed. Cir. 1991) (“[a]n expert’s opinion on the ultimate legal conclusion is neither required nor indeed ‘evidence’ at all.”); *Paradigm Sales v. Weber Marking Sys.*, 880 F. Supp. 1247, 1255 (N.D. Ind. 1995) (excluding testimony by patent attorney expert on the issue of infringement).

For example, in *Utah Med. Prods., Inc. v. Clinical Innovations Assocs., Inc.*, 79 F. Supp. 2d 1290 (D. Utah 1999), the court granted the defendant's motion for summary judgment that its medical catheter did not infringe the plaintiff's patent. In doing so, it excluded the testimony of the patentee's patent attorney expert on the issues of claim construction and infringement. The court stated that "such legal opinions attempt to define the legal parameters which in this case should be left to the Court and to the jury." 79 F. Supp. 2d at 1316 (citing *Specht*, 853 F.2d at 807-10).<sup>25</sup> When patent law experts have been allowed to testify, they have testified only on relevant background information concerning the procedures for prosecuting a patent before the Patent and Trademark Office. *Buckley*, 2000 WL 1528750 at \*3.<sup>26</sup>

Accordingly, Mr. Methvin's testimony on issues of law – including the proper interpretation of the '584 patent's claims, whether any Andrx product infringed that patent, whether the '584 patent satisfied the standards of patentability, and all other issues that Hoechst and Andrx are asking this Court to decide as a matter of law – is inadmissible and should be excluded.

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<sup>25</sup> See also *Biomedical Polymers, Inc. v. Evergreen Indus.*, 976 F. Supp. 98 (D. Mass. 1997) (striking affidavit of patent law expert from motion for summary judgment on infringement).

<sup>26</sup> See also *VISX, Inc.*, FTC Docket No. 9286 (Initial Decision, May 27, 1999) at 13 (patent attorney expert witness called by complaint counsel testified regarding procedures of the Patent and Trademark Office) ("available at <http://www.ftc.gov/os/adjpro/d9286/index.htm>").

**B. The Testimony of Dr. Banakar is Irrelevant Even to an Assessment of the Likely Outcome of the Patent Case.**

As discussed above, evidence offered by respondents to demonstrate infringement is irrelevant to this Court's analysis of the Stipulation and Agreement. But the testimony of Dr. Banakar on behalf of *Andrx* – offering his opinion on what *Hoechst* could have done to demonstrate infringement – is also dubious and clearly irrelevant even if this Court believes it is appropriate to make a hypothetical determination on whether the patent court would have found in *Hoechst*'s favor on infringement.

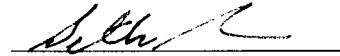
Dr. Banakar worked for *Andrx*, not *Hoechst*. He had no involvement in *Hoechst*'s presentation to the patent court, and he offers no basis to conclude that his opinions as a consultant to *Andrx* have any bearing on what *Hoechst* would have done.

Furthermore, Dr. Banakar never submitted an affidavit in support of any motion on the merits of the patent litigation. His observations and testimony were not in evidence before the district court. Accordingly, his testimony here on *Andrx*'s potential infringement liability merely amounts to *Andrx*'s effort to walk away from its long-standing position that its product did not infringe. This strained attempt to show what its adversary in the patent litigation might have done to demonstrate infringement should be rejected. This opinion is totally irrelevant to an assessment of the district court's likely judgment in the patent case, and should be excluded.

\* \* \* \* \*

For the reasons discussed above, complaint counsel's motion in limine should be granted in its entirety.

Respectfully Submitted,



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Seth C. Silber  
Counsel Supporting the Complaint

Dated: November 16, 2000

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

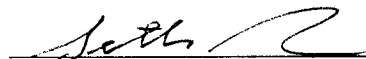
## CERTIFICATE OF SERVICE

I, Seth C. Silber, hereby certify that on November 16, 2000, I caused a copy of the Complaint Counsel's Motion in Limine to Preclude Respondents' Introduction of Evidence Offered to Show Patent Infringement (and the Memorandum in Support of) to be served upon the following persons via hand delivery or facsimile and overnight delivery.

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