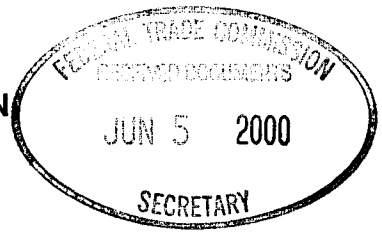

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

MOTION OF RESPONDENT ANDRX CORPORATION FOR LEAVE TO FILE ANNEXED "SUPPLEMENTAL SUBMISSION IN FURTHER OPPOSITION TO COMPLAINT COUNSEL'S MOTION TO STRIKE AFFIRMATIVE DEFENSES"

Pursuant to § 3.22(c) of the FTC Rules of Practice of Adjudicatory Proceedings, respondent Andrx Corporation ("Andrx") respectfully seeks leave to file the attached Supplemental Submission in Further Opposition to Complaint Counsel's Motion to Strike Affirmative Defenses". The grounds for this motion are twofold: (i) although Complaint Counsel's Motion to Strike Affirmative Defenses should solely address matters of pleading, Complaint Counsel itself, as part of its motion, has made assertions about what facts do and do not exist that are refuted by the documents annexed hereto; and (ii) at the time Andrx submitted its opposition to the motion to strike, the documents annexed hereto had not been produced to Andrx. The annexed documents bear directly on the sufficiency of Andrx's pleading of its affirmative defenses.

Complaint Counsel confirmed to us on June 3, 2000, that it does not object to our making this submission (it does reserve the right to respond) and that no claim of confidentiality is being made with respect to these documents by the FTC.

For the foregoing reasons, and without waiver of any claims of confidentiality that Andrx has with respect to the annexed documents or otherwise, Andrx respectfully requests that this Court permit the filing of the annexed supplemental submission or provide Andrx with such other and further relief as this Court deems just and proper.

Dated: June 5, 2000

Respectfully Submitted,

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP

By: 

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Counsel for Respondent Andrx Corporation

ANDRX'S SUPPLEMENTAL SUBMISSION IN FURTHER OPPOSITION TO COMPLAINT COUNSEL'S MOTION TO STRIKE AFFIRMATIVE DEFENSES

Through its brief in opposition to Complaint Counsel's motion to strike Andrx's affirmative defenses, Andrx believes it fully demonstrated that, as a matter of law, Andrx has made sufficient allegations to sustain its pleading of affirmative defenses. Andrx believes it is important for this Court to consider Andrx's arguments and the cases it cites in that opposition rather than Complaint Counsel's characterization of them.

At the time of our opposition (filed 5/19/00), Complaint Counsel was to have already made its initial disclosures as required by FTC Rules § 3.31(b)(2). Complaint Counsel was by then to have responded and produced documents in response to Andrx's comprehensive document demand as well. However, the documents referred to herein were only produced at the end of last week. Those documents refute the statement made by Complaint Counsel, in its proposed reply, that "Complaint Counsel is unaware of any evidence that the FTC was the source of pre-complaint publicity surrounding this matter" (5/26/00 Mem. at 3). The documents provide further demonstration that Andrx should be entitled to pursue the affirmative defenses that Complaint Counsel has moved to strike.

Without attempting to reargue any points of law, we summarize below the context in which these issues arise and then set forth a brief summary of only some of the documents. We append each of the summarized documents to this memorandum. The purpose of this submission is not to demonstrate that Andrx will prevail in its affirmative defenses but simply to demonstrate that its affirmative defenses should not be struck at this early stage of the proceedings.

THE RELEVANT FACTUAL CONTEXT

Several of Andrx's affirmative defenses being challenged by Complaint Counsel arise in the context of the following three series of questions:

First, the complaint in this proceeding alleges no anticompetitive effect flowing from the HMR-Andrx Stipulation. Why has a complaint been served, why have the massive resources of the government been put in motion, and why has Andrx been put to the extraordinary expense of defending itself in these proceedings when the Stipulation is not alleged to have done anything that the FTC is prepared to claim in fact harmed consumers or in fact diminished competition?

Second, certain of the provisions of the Stipulation being challenged have been used by many other companies in the generic drug industry. One such company is Biovail Corporation International ("Biovail"). Yet why has Andrx been singled out? Why not Biovail also, whose conduct has included actual or potential agreements doing the very same thing that Complaint Counsel (incorrectly) complains Andrx did?[1]

Third, it has been determined as a matter of law that during the entirety of the relevant period Biovail could not lawfully have sold a generic version of Cardizen CD, not because of any conduct of Andrx or because of the HMR-Andrx Stipulation but

---

[1] For example, when Biovail entered into an agreement with Elan Corporation plc for Adalat CC, competition for one entire strength of Adalat CC was eliminated, with no challenge or complaint by the FTC. And Biovail met with Andrx representatives on July 20, 1998, and threatened Armageddon unless Andrx knuckled under and gave up its efforts to get its lower-priced generic version of Cardizem CD to consumers. Biovail's threat contemplated the complete elimination of generic competition, yet again the FTC did not and has done nothing. And Biovail misused the Hatch-Waxman Act and filed a frivolous patent infringement suit against Andrx relating to a product in the very market implicated by the FTC's complaint against Andrx here. Biovail Corporation International v. Andrx Pharmaceuticals, Inc., No. 98-8076-CV-WPD (S.D.Fla.). Andrx won after trial, but then Biovail made a trivial change in the labeling of the product (literally, suggesting that the drug could not only be ingested whole but could be sprinkled on applesauce). This has led to a further delay in Andrx getting its lower-priced product to consumers. Yet here again the FTC has done nothing.

because Biovail lacked a safe drug approved by the FDA. Approval did not come until after the expiration of Andrx's period of exclusivity. The Federal District Court for the District of Columbia dismissed with prejudice Biovail's claims of antitrust violations against Andrx. Andrx v. Friedman, 83 F.Supp.2d 179 (D.D.C. 2000). Yet notwithstanding the clear and explicit rejection of any claim that the Stipulation injured Biovail in a way cognizable under the antitrust laws, the complaint in this proceeding embraces Biovail, referring to it repeatedly; and in Complaint Counsel's answers to Andrx's interrogatories, Complaint Counsel refers again repeatedly to Biovail as a party allegedly injured through the operation of the HMR-Andrx Stipulation or entitled to protection. So why is the FTC attempting to promote the private interests of Biovail over those of Andrx?

Several of Andrx's affirmative defenses offer one related series of facts as a partial answer to each of these questions. What lies behind each of these, in part, are improper, illegitimate, and unlawful communications that occurred between the FTC and Biovail. These communications were made by FTC staff members to a former Senior Deputy Director of the Bureau of Competition during a time when it was impermissible to do so. The communications conveyed competitively sensitive information about Andrx and helped Biovail fabricate its claims of injury here — claims then used by the FTC staff itself in complaining about the Stipulation. And the FTC staff, itself or through Biovail, created such public attention over this matter that the Chairman of the FTC was left with no choice, he said, but to authorize an enforcement action (Andrx Mem. In Opp. (5/19/00) at 20). All of this has come to light despite what can fairly be described as

conduct attempting to cover-up this improper activity, as we alleged in the affirmative defenses.

SUMMARY OF *SOME OF* THE RELEVANT DOCUMENTS

1. February 11, 1999, memorandum from the FTC staff to Steve Kaiser of Cleary Gottlieb (copy annexed hereto as Appendix A)

In February 1999 the staff of the FTC was conducting what was by statute a non-public investigation into the HMR-Andrx Stipulation. By that time Andrx had communicated to the staff at least four reasons why the Stipulation was not anticompetitive but in fact was procompetitive. One of those reasons included the highly confidential fact that, given the pendency of the patent infringement litigation against Andrx, Andrx would not have gone to market because of the risks associated with the patent infringement suit. The other of Andrx's explanations were also competitively sensitive in that a potential competitor of Andrx, if learning them, would be in a vastly superior position in determining what Andrx's competitive moves might or might not be in the marketplace. Had Andrx shared this kind of information with an actual or potential competitor, the FTC no doubt would have been extremely unhappy.

By February 1999 George Cary, former Senior Deputy Director of the Bureau of Competition, was working at the law firm of Cleary, Gottlieb, Steen & Hamilton and had been retained by Biovail. His colleague, also representing Biovail, was Steve Kaiser. February 1999 was during the waiting period when Mr. Cary was prohibited from having the communications that we now know he was having.

In the memorandum annexed hereto as Appendix A, under the guise of giving "hypothetical justifications", the FTC staff told Biovail what facts and arguments Andrx was making to the FTC. Among the disclosures was highly sensitive competitive

information about Andrx's thinking, about its risk profile and about whether it would or would not enter the market during the pendency of the patent infringement litigation — litigation that was still ongoing in February 1999. Andrx was never advised that the FTC staff had told Biovail this information, which came to the FTC under a promise of confidentiality as part of the non-public investigation.

2. March 9, 1999, letter from Cleary Gottlieb to the FTC staff (excerpt annexed hereto as Appendix B)

There is no doubt that the "hypotheticals" described the confidential information communicated to the FTC by Andrx and that Biovail's lawyers knew that. Within a month of receiving the memorandum, Cleary Gottlieb wrote a 16-page single-spaced letter to the Commission complaining about the HMR-Andrx Stipulation. The excerpt of that letter annexed hereto as Appendix B addresses each of the four "hypothetical" justifications that were told to Biovail's counsel by the FTC (quoting *verbatim* each of the four justifications). As a result, the FTC could then say (and did say) that potential competitors had complained about the Stipulation, when the very complaint was instigated by the FTC staff itself. There is no disclosure in the March 9 letter that this information had originally come from the FTC. There was never any disclosure to Andrx of the facts either.

3. June 15, 1999, meeting between Andrx and FTC staff

On June 15, 1999, counsel for Andrx met with various FTC staff members and provided additional factual and legal bases why Andrx believed the Stipulation should not be the subject of interest to the FTC. From the documents that follow, it is evident that one or more FTC staff people communicated with Mr. Cary or Mr. Kaiser of Cleary Gottlieb and disclosed this non-public information. It is also clear that the FTC

staffers, certainly including Mr. Balto, requested another submission from Biovail to make it appear that the complaints were coming from the outside.

4. June 22, 1999, communication from Cleary Gottlieb to David Balto enclosing draft of submission (excerpt annexed hereto as Exhibit C)

Although the paper trail is incomplete, we do know that on June 22 Biovail's counsel sent a "draft version of our submission" to Mr. Balto. Former Senior Deputy Director Cary had reviewed at least some of the draft, and his name was used twice in the e-mail communication. We are unaware of any conceivably legitimate reason why the FTC staff is soliciting or receiving a draft from a complaining party. We here have a complaining witness sending a draft of his complaint to the enforcement officer so that the enforcement officer can show the complaining witness how to beef-up the complaint and then rely on the beefed-up complaint to recommend enforcement action. This is blatantly unconstitutional conduct, violating federal law and FTC Regulations and wholly undermining the legitimacy of the non-public investigation.

5. June 23, 1999, communication from Cleary Gottlieb to Mr. Balto (copy annexed hereto as Appendix D)

It is clear from the communications that Mr. Balto then gave additional comments to Biovail's counsel concerning what Biovail should be arguing. Mr. Balto then reviewed in detail a 15-page, single-spaced draft some time between 6:16 p.m. on June 22 and the morning of June 23. This document, sent at 11:43 a.m. on June 23, has Biovail's counsel saying to Mr. Balto, a senior official at the FTC, who should have been engaging in a neutral fact-finding exercise:

> "Dave [Balto]:
>
> "Thank you for your helpful and insightful comments. Could you give me a little more guidance on the Empire

Specialties case you mentioned? I have not been able to locate it.

"Also, as you requested, attached is a MS Word file containing our March letter to Brad [Albert, also an FTC attorney].

"Steve".

6. June 23, 1999, communication from Cleary Gottlieb to Mr. Balto (copy annexed hereto as Appendix E)

Mr. Balto evidently made additional comments to the draft, since this e-mail makes reference to Mr. Balto's comments about Section 7, the Yamaha standard, Section 7 standards, and the "Hoechst/MMD case". In full, the e-mail reads:

"Dave [Balto]:

"In reference to your comments about Section 7, we included in the draft the attached footnote, which I think picks up on Yamaha and the Section 7 standards (as well as the Hoechst/MMD case). We weren't sure if this made it into the version you read (i.e., if the conversion from Word carried the footnotes) or if you thought the passage didn't cover the materials sufficiently or should be in text.

"We'd be interested in your views on this.

"Thanks.

"Steve".

7. June 25, 1999, letter from George Cary and Steve Kaiser to the FTC (excerpt annexed hereto as Appendix F)

This excerpt, of an 17-page, single-spaced letter, indicates clearly Mr. Balto's influence in telling Biovail what to argue back to the FTC. The "Engine Specialties" matter is referred to on page 6 (evidently Mr. Balto told Cleary that the matter was the "Engine Specialties" matter, not the "Empire Specialties" matter). The discussion of Yamaha, the Section 7 standards, and the Hoechst/MMD merger all appear in the letter. We have not yet received any discovery from Cleary, Gottlieb in this action or taken the relevant depositions to know just how much of this letter Mr.

Balto wrote. There is no disclosure in the letter of any prior communication or assistance by Mr. Balto or any other FTC staff member. The entire timing of the letter, it is clear, was due to the FTC's improper communication of the substance of Andrx's presentation to the FTC staff on June 15.

8. June 28, 1999, e-mails to and from Mr. Balto (copy annexed hereto as Appendix G).

Appendix G hereto reflects three e-mails. The first is the June 23 e-mail identified in Appendix D hereto. The second is an e-mail form Mr. Balto to Biovail's counsel. Mr. Balto states: "**great letter! can you e mail me the final version? thanks**". The final communication to be produced to us is one coming just four minutes later from Cleary Gottlieb back to Mr. Balto stating: "**thanks and thank you for your help. Attached is the file.**"

* * *

At no time was Andrx advised of these unlawful communications. At no time was Andrx advised that its confidential information was being shared by the FTC with what the FTC calls a potential competitor of Andrx. And Andrx complained repeatedly to FTC staff counsel and management about the leaks. Andrx was mystified, not knowing where they were coming from. Again and again FTC staff counsel and management advised that searches had been made and that no one had any idea where the leaks were coming from. (Indeed even as recently as the proposed reply on the motion to strike Complaint Counsel uses the phraseology: "*If* Andrx actually has, as it claims, 'hard evidence'" of leaks (emphasis added).)

We will not repeat here the long list of leaks we are already aware of (see Andrx Mem. (5/19/00) at 18-20). It bears important mention, however, that on

September 30, 1999, just three months after the improper June 1999 communications described above, *USA Today* ran two stories about the FTC's non-public investigation. Both disclose non-public information. One describes, as a source, "lawyers involved in the probe". Both quote Mr. Cary extensively.

We believe that the inference is clear form the above and that discovery will show that this leak came directly from the FTC or, at very least, it was a foreseeable and intended consequence of the FTC staff's earlier improper leaks to Biovail. Complaint Counsel has suggested that Andrx itself might be responsible, since a year earlier Andrx had disclosed what the securities laws required it to disclose: that the FTC was conducting a non-public investigation. The short answer is that Andrx never disclosed confidences to a potential competitor, never broke the law, and never fabricated the very public interest that the Commission now claims exists with respect to this matter. The FTC staff did that. As a result of the *USA Today* article Andrx shareholders lost hundreds of millions of dollars of value virtually overnight. The cause of that was the FTC's improper conduct.

The communications summarized above are highly pertinent to providing answers to the three questions posed above. The allegations support Andrx's affirmative defenses that the FTC did not have the requisite reason to believe to commence this proceeding as required by statute. Rather, the complaint is the product of an unlawful effort spurred by a potential competitor of Andrx represented by a former FTC official. This explains why the proceeding was commenced by an Agency interested in competition policy even though there is no alleged anticompetitive effect of the Stipulation being challenged. The commencement of the proceeding went beyond

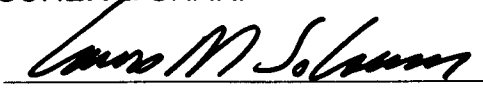
any proper role that the FTC might play, since it merely assists one competitor at the expense of another in a private dispute. This also explains why the FTC is improperly singling out Andrx, who has not been represented by a former FTC official with secret ties to current policymakers at the FTC staff. (Andrx is a relatively small, science-based company that has a track record of getting lower-priced generic products to consumers. Unlike Biovail, it does not have friends in high or formerly-high places.) Finally, these facts support Andrx's affirmative defenses that the FTC is not entitled to any equitable or injunctive relief here, even if Complaint Counsel otherwise proves its claims, given the staff's unconstitutional actions toward Andrx and their patently inequitable behavior.

The suggestion that the disclosure of this wrongdoing would somehow compromise the FTC's ability to conduct non-public investigations cannot be credited. Complaint Counsel's motion to strike Andrx's affirmative defenses should be denied.

Dated: June 5, 2000

Respectfully Submitted,

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP

By: 

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Counsel for Respondent Andrx Corporation

CERTIFICATE OF SERVICE

I, Colin A. Underwood, hereby certify that on June 5, 2000, I caused a copy of the Motion of Andrx Corporation for Leave to File Annexed "Supplemental Submission in Further Opposition to Complaint Counsel's Motion to Strike Affirmative Defenses" to be served upon the following persons by hand:

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

Donald S. Clark, Secretary
Federal Trade Commission
Room 172
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Markus Meier, Esq.
Federal Trade Commission
Room 3114
601 Pennsylvania Ave., N.W.
Washington, D.C. 20580

And upon the following persons by overnight mail:

James M. Spears, Esq.
Shook, Hardy & Bacon, L.L.P
801 Pennsylvania Avenue, N.W.
Suite 800
Washington, D.C. 20004

Peter O. Safir, Esq.
Kleinfeld, Kaplan and Becker
1140 19th St., N.W.
Washington, D.C. 20036

Colin A. Underwood

Fax

Name:	Steve Kaiser
Organization:	Cleary Gottlieb Steen Hamilton
Fax:	(202) 974-1999
Phone:	
From:	Daniel Kotchen, Federal Trade Commission
Date:	February 11, 1999
Subject:	Hypothetical Justifications for Litigation Settlement Agreement Between Pharmaceutical Companies
Pages:	2

Comments:

Steve,

Let me know if you have any questions regarding these justifications. I can be reached at (202) 326-2942. Thanks for your help with this matter.

Dan

HYPOTHETICAL JUSTIFICATIONS FOR, OR DEFENSES TO, A PARTIAL SETTLEMENT IN A PATENT INFRINGEMENT LAWSUIT

1. *Risk-Reduction.* The risks which are inherent in any litigation, are particularly acute in the patent infringement context where nearly 50% of the district court decisions are reversed, in whole or in part, by the Federal Circuit. Given this uncertainty, the parties to the litigation, Company G (generic manufacturer) and Company I (innovator drug manufacturer), would have difficulty predicting the likely outcome and would have an incentive to reduce the risk. Also assume that Company G is a small company with limited revenues and profits.

   Under this scenario, if Company G marketed its product and then was found to infringe Company I's patent, Company G would be faced with enormous liability for damages for Company I's lost profits. Given that Company I's monopoly profits would far exceed Company G's revenues (based on brand name and generic pricing patterns), Company G would likely face financial ruin. Of course, if treble damages were awarded for willful infringement, the likelihood of financial ruin would be significantly increased. In order to reduce or avoid these risks, Company I and Company G may be motivated to enter into an agreement which compensates Company G for not bringing its drug to market until after the resolution of the patent infringement suit.

2. *Avoid Costly Litigation of Preliminary Injunction.* The agreement reaches the same outcome as would a successful preliminary injunction action filed by Company I -- i.e., Company G is unable to market a generic product until resolution of patent infringement suit. Thus, the agreement avoids the costly litigation of the preliminary injunction.

3. *Protect 180-day Exclusivity Right.* Federal laws confers 180 days of market exclusivity as an incentive to induce companies, such as Company G, to make the investment and accept the risk of litigation necessary to bring a generic product to market prior to the expiration of the patents relating to the innovator drug. Company G wanted to ensure that it did not jeopardize this valuable right. If Company G were to bring its product to market before the patent action was resolved, Company I would be entitled to seek a preliminary injunction. Prior to such an injunction taking effect, it is conceivable that Company G would have triggered the 180 days exclusivity period and then be prevented from taking advantage of it.

4. *No Effect on Competition.* The agreement does not block entry of generic competition for two reasons: (1) Company G would not have gone to market because of the risks associated with the patent infringement suit; and (2) No other company is both approved and ready to market a generic product, even in the absence of the agreement.

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Fax

Name: Steve Kaiser
Organization: Cleary Gottlieb Steen Hamilton
Fax: (202) 974-1999
Phone:
From: Daniel Kotchen, Federal Trade Commission
Date: February 11, 1999
Subject: Hypothetical Justifications for Litigation Settlement Agreement Between Pharmaceutical Companies
Pages: 2

Comments:

Steve,

Let me know if you have any questions regarding these justifications. I can be reached at (202) 326-2942. Thanks for your help with this matter.

Dan

Writer's Direct Dial: (202) 974-1554

March 9, 1999

Bradley Scott Albert, Esq.
Federal Trade Commission
Room 3115
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Re: Hoechst-Andrx Agreement

Dear Brad:

Thank you for allowing us the opportunity to present the views of Biovail Corporation International ("Biovail") regarding the competitive effects of the agreement concerning diltiazem between Hoechst AG ("Hoechst") and Andrx Pharmaceuticals, Inc. ("Andrx").

Our understanding is that, in exchange for Andrx agreeing not to bring its FDA-approved generic Cardizem CD product to the market, Hoechst has agreed to pay Andrx $40 million per year. As a result of this agreement, consumers will pay more for Cardizem CD than they otherwise would and Hoechst will continue to enjoy--and share with Andrx--monopoly rents to which it is not entitled. Biovail urges the FTC to take action to end this blatantly illegal agreement and to enable the competition in Cardizem CD that Andrx's introduction of a generic version would have created.

The Legal Environment

The procedures for bringing a new drug to market are governed by the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 *et seq.* (1998) and the related implementing regulations of the Food and Drug Administration ("FDA"). In essence a manufacturer of a prescription drug must convince the FDA that the drug is both safe and effective for its intended use. Such approval can be obtained through a new drug application ("NDA") or an abbreviated new drug application ("ANDA"). Approval for generic drug products most often is obtained

are not "repugnant" to Hatch-Waxman. On the contrary, Hatch-Waxman was enacted to foster competition between branded drugs and their generic equivalents. Its regulatory scheme is designed to create incentives to bring generic drugs to market as quickly as the patents on the corresponding branded drug expire. The antitrust laws further rather than hinder the purposes of Hatch-Waxman by ensuring that competition between manufacturers of branded drugs and their generic equivalents is not lost by collusive agreements between them. Antitrust, therefore, is not "repugnant" but supportive of the regulatory scheme.[11] Implying an exemption to the antitrust laws that would allow pioneer manufacturers to eliminate competition by colluding with generic producers would undercut the very purposes of Hatch-Waxman.

Thus, the Hatch-Waxman Act gives Andrx some discretion as to when it unilaterally decides to trigger the 180 days. Nothing in the statute allows Andrx to conspire with its competitor in exercising this discretion in exchange for a share of the monopoly profits.

4. There is no Legitimate Procompetitive Justification for the Hoechst-Andrx Agreement Not to Compete to Permit the Agreement Under the Rule of Reason

Four hypothetical justifications for the Hoechst-Andrx Agreement might be advanced. None of those justifications, which are taken up in turn below, are sufficient to permit the Hoechst-Andrx Agreement.

a. Risk Reduction

This "justification" rests on Hoechst's desire to avoid the uncertainty inherent in patent litigation. First, the Agreement cannot legitimately be considered a settlement or partial settlement of the underlying patent infringement suit. If it were such a settlement, the payment would be from the alleged infringer, Andrx, to the patent holder Hoechst, not the other way around.

Second, any argument that Hoechst's payments are justified because they remove "uncertainty" about the applicability of Hoechst's patent is specious and circular. Hoechst "right" to monopolize Cardizem CD is wholly dependent on its patent. It cannot use that "right" to extend the monopoly outside its narrow scope.[12] In paying Andrx not to press the issue in

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Ctr. v. Blue Cross, 452 U.S. 378, 390-91 (1981) (rejecting claim of antitrust immunity where defendant failed to establish "clear repugnancy" between application of the antitrust laws to defendant's exclusion of a plaintiff hospital from its payment plan and statutory and regulatory system under which that exclusion was based).

[11] Of course, the FTC has not hesitated to challenge anticompetitive acquisitions and practices by FDA-regulated companies. See, e.g., In re Roche Holding, FTC Docket No. C-3809 (1998); United States v. Summit Technology, Inc., FTC Docket No. 9286 (1998); In re Ciba-Geigy Ltd., FTC Docket No. C-3725 (1997); In re Hoechst AG, FTC Docket No. C-3629 (1995).

[12] See, e.g., United States v. New Wrinkle, Inc., 342 U.S. 371, 378 (1952) ("Patents give no protection from the prohibitions of the Sherman Act to [plans to restrain commerce] when the licenses are used, as here, in the scheme to restrain."); Hartford-Empire Co. v. United States, 323 U.S. 386, 406 (1945) ("Rights conferred by patents

litigation. Hoechst attempts to extend its current monopoly. The only uncertainty removed by the Agreement is that the Hoechst patent does not cover Andrx's product or that it is invalid. Such uncertainty cannot be a justification for the Agreement, which would allow Hoechst to extend the patent monopoly to areas that it does not cover. The lawful (i.e., patent protected) monopoly extends only as far as it can be vindicated as a matter of patent law, and no further. To permit Hoechst to "buy off" a party seeking to determine the limit allows Hoechst to extend its monopoly into and through the area of uncertainty. If it turns out that Hoechst is wrong, then it gains an extension of its monopoly into areas to which it is not entitled. Attempting to do so via a payment to Andrx is thus nothing more than a willful attempt to acquire or extend monopoly power, in violation of Section 2 of the Sherman Act.[13]

The current situation is in stark contrast to one where a potential infringer is paying the patent holder for a license to practice the patent. Such a payment may be procompetitive in that it permits another competitor to enter the market. Here the Hoechst-Andrx Agreement has the opposite effect--it does nothing but keep a competitor off the market. There is simply no way that such a result can be procompetitive.

Third, an argument that the Hoechst-Andrx Agreement is procompetitive because it prevents the infringement in which Andrx otherwise would engage is similarly flawed. If this were Hoechst's actual concern, it could address it by prosecuting the patent infringement lawsuit to judgment, including treble damages. If Hoechst could demonstrate that it would be irreparably injured if Andrx came to market--because, for example, Andrx could not satisfy an eventual judgment--Hoechst would be entitled under 35 U.S.C. § 283 to an injunction *pendente lite* blocking Andrx from marketing its product.[14] Of course, to obtain an injunction, Hoechst would have to show a reasonable likelihood of eventual success on the merits and satisfy the other traditional elements for an injunction.[15] But if Hoechst is right that the Andrx product

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are indeed very definite and extensive, but they do not give any more than other rights a universal license against positive prohibitions. The Sherman law is a limitation of rights--rights which may be pushed to evil consequences and therefore restrained.") (quoting Standard Sanitary Mfg. Co. v. United States, 226 U.S. 20, 49 (1912)); Morton Salt Co. v. Suppiger Co., 314 U.S. 488, 492 (1942) ("[T]he public policy which includes inventions within the granted monopoly excludes from it all that is not embraced in the invention. It equally forbids the use of the patent to secure an exclusive right or limited monopoly not granted by the Patent Office and which it is contrary to public policy to grant.").

13 See United States v. Krasnov, 143 F. Supp. 184, 192-93 (E.D. Pa. 1956) (finding Sherman Act violation when two manufacturers with patents, one of which arguably superseded the other, entered into cross license rather than pursue litigation), aff'd per curiam, 355 U.S. 5 (1957).

14 See, e.g., Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d 1553 (Fed. Cir. 1996) (affirming grant of preliminary injunction); Hybritech Inc. v. Abbott Lab., 849 F.2d 1446 (Fed. Cir. 1988) (noting that "[i]t is well-settled that . . . the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole").

15 See, e.g., Bio-Technology General Corp., 80 F.3d at 1558; Hybridtech, 849 F.2d at 1451.

infringes its patent, Hoechst should have no trouble vindicating its legitimate rights in this manner. If it is wrong, then its has no right to exclude Andrx. In any event, as in the Intel case currently before the FTC, Hoechst must vindicate its right in court, not through a collusive anticompetitive agreement or other anticompetitive practices. See In re Intel Corp., FTC Docket No. 9288 (June 8, 1998) (Complaint).

Requiring Hoechst to run the risks inherent in attempting to vindicate its patent rights in court rather than paying Andrx not to challenge those rights is a well-established principle of antitrust law. There is nothing in the intellectual property laws that permits collusive agreements in the guise of litigation settlements and, in fact, it is well established that such settlements can not cover otherwise collusive behavior. For example, in United States v. Singer Manufacturing Co., 374 U.S. 174 (1962), the United States sued the Singer Manufacturing Co. ("Singer") alleging that Singer had conspired with two of its European competitors to exclude Japanese manufacturers from the United States market for zig-zag sewing machines. Part of that conspiracy was effectuated by the parties, putatively for the reason of avoiding protracted litigation, entering into cross-licensing agreements under which they agreed not to sue each other and to allow each to practice the other's patents. Id. at 177-80. The Supreme Court found that the purpose of the cross-licensing agreements was not to settle any dispute between the parties but rather to exclude competition and that they therefore violated the antitrust laws. Id. at 192-93.[16] Similarly here, it is clear from the fact that the patent holder is paying the infringer that the "settlement" is intended to eliminate competition, not to vindicate a patent claim. Avoiding "protracted litigation" or "litigation risk" is therefore not a defense.

The danger that agreements in the context of patent disputes would harm competition was highlighted by Assistant Attorney General Joel Klein in a speech in 1997 to the American Intellectual Property Law Association on the relationship of antitrust law to intellectual property law. There Klein discussed the danger that settlements of patent infringement suits are often merely a cover for anticompetitive behavior:

> Based on our experience, we think [the risk of anticompetitive intellectual property licensing agreements] is probably greatest in the context of settling infringement litigation. The stakes are high, particularly if the dispute involves a market with a small number of competitors to begin with or a particularly broad or fundamental intellectual property claim. The defendant may be facing the possibility of continuing in business only at the sufferance of the plaintiff; for the plaintiff, the

[16] See also Duplan Corp. v. Deering Milliken, Inc., 540 F.2d 1215, 1221 (5th Cir. 1976) (recognizing that, under Singer, "the collusive termination of patent litigation might constitute a violation of the Sherman Act" if the parties in entering into settlement had anticompetitive intent).

> litigation may determine its ability to decide who it will or won't allow to compete. Consequently, settlements are often based on consideration that lead parties to give up rights that they might well vindicate if they went to the mat. And when intellectual property rights are at stake, the consequences of those compromises can align the settlers' interests against the interests of consumers.

Klein Speech, at 4. Here, of course, there is no legitimate settlement of a patent claim at all. Hoechst has not agreed to allow Andrx to come to market in violation of its patents in exchange for a payment from Andrx. The risks that the Assistant Attorney General recognized of competitors aligning their interests against consumers are therefore even more clear in the Hoechst-Andrx Agreement. In such circumstances, the antitrust laws require that any legitimate patent rights be vindicated through litigation rather than through collusive agreements.

b. Avoid Costly Litigation of Preliminary Injunction

Under the facts of the Hoechst-Andrx Agreement, this rationale is dismissible on its face. Hoechst has agreed to pay Andrx $40 million per year to keep the Andrx generic product off the market. It is inconceivable that litigating a preliminary injunction will cost anything close to $40 million. Any incremental litigation expenses associated with Hoechst's seeking a preliminary injunction in an otherwise ongoing patent litigation would be minuscule compared to the payments it is making to Andrx.

More generally, the argument assumes that Hoechst has a legitimate patent right that Andrx would infringe by marketing its generic Cardizem CD product. If that is the case, accelerating the pace of the litigation, rather than slowing it as the Agreement apparently will do, would be the appropriate course.

c. Protect the 180-day Exclusivity Right

As we understand it, this hypothetical justification is that Andrx, in bringing its product to market, will trigger its 180-day exclusive period, which would continue to run even if Hoechst successfully obtained a preliminary injunction against Andrx. Andrx thereby would lose the value of the 180-day period.

This argument fails because the trial judge in the underlying patent infringement case has numerous tools to prevent such a result. First, under Federal Rule of Civil Procedure 16(b)(2), the court can require the parties to notify each other of motions they intend to file and require that any motion for preliminary relief be filed by a certain date. The defendant can therefore know very early in the case whether a preliminary injunction will be filed, and can go to market immediately if no such motion is scheduled or immediately upon the expiration of the relevant deadlines with no risk to the exclusivity period. This is but one of the numerous options

available to the court in ensuring that such an inequitable result does not occur. Given the broad discretionary powers that trial courts have in shaping equitable relief, it is inconceivable that Andrx would face this dilemma.[17]

Perhaps more fundamentally, there is no legitimate reason why Hoechst would set such a "booby trap." Hoechst has every incentive not to let the 180-day exclusivity period run so as to preclude other competitors. That is, after all, one of the anticompetitive consequences it has purchased for its $40 million per year. Hoechst presumably would, therefore, bring an injunction as early as possible to prevent this very result rather than risking starting the 180-day clock and facing the entry of other new competitors.

d. No Effect on Competition

This argument depends on two facts, the first of which is untrue and the second of which is untrue and irrelevant. First, it is simply not credible that Andrx would not have gone to market even without the payment. If true, why would Hoechst agree to make the payment? And why would Andrx have expended considerable sums in preparing to go to market, including expenditures related to product development and approval? In any event, the antitrust laws require Andrx to make the decision of whether to come to market unilaterally, not in collusion with its only potential competitor in exchange for a share of its monopoly rents. Indeed, even if Andrx decided unilaterally that the risks of infringement were too great to risk going to market, the Agreement is still anticompetitive because without it, Andrx could have sold its "place in line" to another drug company--such as Biovail--rather than entering into a collusive agreement with Hoechst.

The second factual assumption is that no other company is both approved and ready to market a generic product. Although this is literally true, it is only true because of the joint actions of Hoechst and Andrx. In particular, Purepac Pharmaceutical Company ("Purepac") received "tentative approval" from FDA for its product in October 1998. But for Andrx "sitting on" its 180-day exclusivity right and Hoechst guaranteeing Andrx will stay there for $40 million per year, Purepac's tentative approval would become final in June 1999, after the expiration of the 30-month waiting period caused by Hoechst's suing Purepac for patent infringement. Biovail, which Hoechst did not sue and which thus does not face a similar 30-month delay, also has a product that will receive tentative approval and at that point only will be blocked by Andrx's 180-day exclusivity period. Thus, in addition to removing Andrx from the market (which it could have entered in July 1998), the Hoechst-Andrx Agreement shortly will prevent two other strong competitors--Purepac and Biovail--from entering as well.

Further, any argument that the parties' agreement not to compete is permitted under the antitrust laws because Andrx would not have competed anyway is specious. As

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[17] See generally Lemon v. Kurtzman, 411 U.S. 192, 200-01 (1973) (discussing court's broad power to fashion equitable remedies).

discussed above. Andrx has expended considerable sums in developing its product and in seeking FDA approval. It clearly intended to compete. And its agreement with Hoechst is nothing more than an allocation of the market to Hoechst--a *per se* violation of the Sherman Act.[18] Even if one were to consider the Agreement under the rule of reason, the Agreement is the sort of naked restraint that courts have found to create a presumption of anticompetitive effect. For example, in NCAA v. Board of Regents, 468 U.S. 85 (1984), the Supreme Court found illegal under the antitrust laws agreements between the NCAA and member institutions regarding the number of college football games to be broadcast. In dismissing the defendant's contention that the plaintiff had failed to prove anticompetitive effect, the Court observed that "when there is an agreement not to compete in terms of price or output, no elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement." Id. at 109.[19]

In short, antitrust dictates that the market be free of such collusive agreements and that independent economic actors unilaterally make decisions about whether to compete or what prices to charge.

Hoechst's Conduct is Part of a Pattern of Monopolization

Any doubt as to Hoechst's true motives is allayed by Hoechst's attempts in 1997 to induce Biovail to enter into a similarly anticompetitive agreement. Under the arrangement proposed at that time, Biovail would not bring its generic Cardizem CD product to market before July 1999 in exchange for Hoechst: (1) refraining from suing Biovail for patent infringement; and (2) agreeing to advance substantial, non-refundable funds to Biovail, putatively for the completion of the development and approval of a product licensed to Biovail by Hoechst. Hoechst told Biovail that a necessary condition would be Biovail's agreeing not to reach its own agreement with Andrx that would have the effect of accelerating the approval of a generic version of Cardizem CD. Hoechst's stated motive in seeking Biovail's agreement was to delay the loss of its Cardizem CD monopoly until mid-1999, at which time it would have other products on the market that would reduce its dependence on Cardizem CD sales.

Hoechst's proposal to Biovail was motivated by the same anticompetitive intent which led it to enter into the Hoechst-Andrx Agreement. Both were simply unlawful attempts by Hoechst to stifle competition between Cardizem CD, other diltiazem products, and generic equivalents.

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[18] See Palmer v. BRG of Georgia, 498 U.S. 46, 49 (1990) (finding *per se* violation of Sherman Act where potential competitor in bar review courses agreed with provider of such courses not to enter geographic markets outside Georgia).

[19] See also FTC v. Indiana Fed'n of Dentists, 476 U.S. 447, 457-66 (1986) (finding illegal under the rule of reason horizontal agreement among dentists not to provide x-rays to insurance companies to enable those companies to evaluate patients' claims).

From: Steven J. KAISER <SKaiser@cgsh.com>
To: HQ.DCMAIL2(DBALTO)
Date: Tue, Jun 22, 1999 6:16 PM
Subject: Hoechst/Andrx

Dave:

Attached is a draft version of our submission. Although George has not reviewed some of the revisions and it is therefore possible that we will want to change a thing or two, we wanted to get this draft to you as soon as possible.

Please call me or George if you have any questions; if you have trouble reading or printing the attached, let me know and I can have a clean copy messengered to you.

Steve Kaiser

CC: gsc <gsc%Leg%CGSHDC@cgsh.com>

Writer's Direct Dial: (202) 974-1920
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DRAFT OF 6/22/99
June ___, 1999

David A. Balto, Esq.
Federal Trade Commission
Office of Policy & Evaluation
600 Pennsylvania Avenue, N.W.
Washington, D.C.

Re: Hoechst-Andrx Agreement Not to Compete

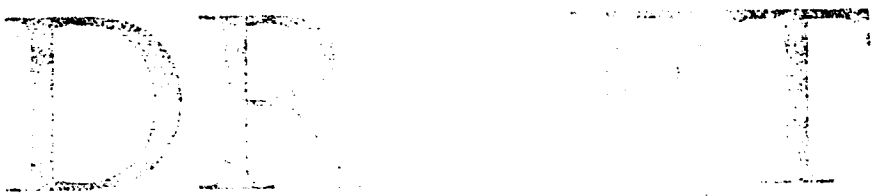
Dear David:

This letter supplements our letter of March 19, 1999. In our earlier letter, we argued that the agreement between Hoechst and Andrx (the "Agreement") was nothing more than an agreement not to compete, and therefore violated the antitrust laws. This conclusion is clear on the face of the Agreement, which explicitly recites that Andrx is to receive $40 million *per year* only so long as it refrains from competing, which payments stop the moment it enters the market. In the face of this obviously anticompetitive agreement, the burden of demonstrating off-setting procompetitive benefits is quite high. We showed in our earlier letter that this burden was not even close to being satisfied by the proffered justifications because those rationales conferred no countervailing benefits on consumers, but only benefited the parties. We showed, for example, that the Agreement could not be considered a settlement of a patent litigation for two straightforward reasons: first, the patent litigation was not resolved by the Agreement at all; and second, the money was flowing the wrong way – from the *patent holder* to the *infringer*. The other proffered justifications, when stripped to their core, merely amount to the obvious: Hoechst's rationale is to avoid the "uncertainty" inherent in having the validity of its patent monopoly challenged; and Andrx would prefer to reap a share of Hoechst's monopoly rents

We hope this letter is helpful to you and your colleagues as you continue to investigate the Hoechst-Andrx Agreement. If we can be of further assistance, please do not hesitate to contact us.

Very truly yours,

George S. Cary
Steven J. Kaiser



From: Steven J. KAISER <SKaiser@cgsh.com>
To: HQ.DCMAIL2(DBALTO)
Date: Wed, Jun 23, 1999 11:43 AM
Subject: Hoechst/Andrx

Dave:

Thank you for your helpful and insightful comments. Could you give me a little more guidance on the Empire Specialties case you mentioned? I have not been able to locate it.

Also, as you requested, attached is a MS Word file containing our March letter to Brad.

Steve

From: Steven J. KAISER <SKaiser@cgsh.com>
To: HQ.DCMAIL2(DBALTO)
Date: Wed, Jun 23, 1999 2:34 PM
Subject: Hoechst/Andrx -- Section 7

David:

In reference to your comments about Section 7, we included in the draft the attached footnote, which I think picks up on Yamaha and the Section 7 standards (as well as the Hoechst/MMD case). We weren't sure if this made it into the version you read (i.e., if the conversion from Word carried the footnotes) or if you thought the passage didn't cover the material sufficiently or should be in text.

We'd be interested in your views on this.

Thanks.

Steve

Footnote 11:

In assessing likelihood of entry in the Section 7 context, courts consider a firm's expressions of interest, economic incentives, capacity, and ability to enter the market unilaterally. See, e.g., Yamaha Motor Co. v. FTC, 657 F.2d 971 (8th Cir. 1981) (examining criteria including interest, incentive and capacity to evaluate potential competition); see also Republic of Texas Corp. v. Board of Governors of the Fed. Reserve Sys., 649 F.2d 1026, 1044 (5th Cir. 1981) (listing factors to consider in assessing reasonable probability of entry as anticipated profitability of independent entry versus other forms of entry, and evidence specific to applicant demonstrating a preference for independent entry); Areeda & Hovenkamp Supplement ¶ 1121e (citations omitted) ("[R]ecent cases have noted expressions of interest; incentives, including the availability of attractive profits, and the utility of a full product line; past entries into related geographic or product markets; the ability to enter, including access to the necessary capital and familiarity with the relevant technology. . . .").

The mere existence of a patent dispute over the product at issue has never been a bar to Section 7 relief. For example, when the FTC reviewed Hoechst's merger with Marion Merrel Dow ("MMD"), the FTC concluded that competition in once-a-day diltiazim would be substantially lessened as a result of the merger. Hoechst AG; Proposed Consent Agreement With Analysis to Aid Public Comment, 60 Fed. Reg. 49609 (1995); see also Hoechst Settles FTC Challenges of Reducing Competition for Four Drugs in Connection with MMD Merger, FTC Press Release (Sept. 18, 1995). In particular, the FTC cited the loss of competition between MMD's Cardizem CD and potential entry by a diltiazim product ("Tiazac") that a Hoechst-Biovail joint venture was developing. Tiazac was in the FDA approval process, but had not yet received approval. MMD had sued the Hoechst-Biovail joint venture, alleging that Tiazac infringed patents held by MMD. As part of the remedy for the anticompetitive effects of the merger, the FTC insisted that Hoechst-MMD dismiss its patent infringement suit regarding Tiazac and agree not to bring future patent litigation against Biovail over the product.

In concluding that the Hoechst-MMD merger was likely to substantially lessen competition in once-a-day diltiazim, the FTC necessarily concluded that the Hoechst-Biovail joint venture was a potential competitor to MMD under the "reasonably probable" standard of the Guidelines, notwithstanding the uncertainty created by the patent infringement suit. In essence, the Commission's decision stands for the proposition that there is competitive benefit to retaining the independence of the protagonists, and that the possibility of competition should not be thwarted by the parties through merger. The same conclusion should hold here in respect of a collusive agreement between Hoechst and Andrx.

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June 25, 1999

Bradley S. Albert, Esq.
Federal Trade Commission
Room 3115
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Re: Hoechst-Andrx Agreement Not to Compete

Dear Brad:

This letter supplements our letter of March 19, 1999. In our earlier letter, we showed that the agreement between Hoechst and Andrx (the "Agreement") was nothing more than an agreement not to compete, and therefore violated the antitrust laws. This conclusion is clear on the face of the Agreement, which explicitly recites that Andrx is to receive $40 million *per year* only so long as it refrains from competing, which payments stop the moment it enters the market. In the face of this obviously anticompetitive agreement, the burden of demonstrating offsetting procompetitive benefits is quite high. We showed in our earlier letter that this burden was not even close to being satisfied by the proffered justifications because those rationales conferred no countervailing benefits on consumers, but only benefited the parties. We showed, for example, that the Agreement could not be considered a settlement of a patent litigation for two straightforward reasons: first, the patent litigation was not resolved by the Agreement at all; and second, the money was flowing the wrong way – from the *patent holder* to the *infringer*. The other proffered justifications, when stripped to their core, merely amount to the obvious: Hoechst's rationale is to avoid the "uncertainty" inherent in having the validity of its patent monopoly challenged; and Andrx would prefer to reap a share of Hoechst's monopoly rents rather than having to compete or adjudicate whether its product violates Hoechst's patent. Like all cartel agreements, both justifications have obvious benefits to the conspirators and neither involves integrative efficiencies or consumer benefits.

This letter responds to specific questions and issues that since have been posed to us. In particular, we demonstrate below that, regardless of the analysis employed – whether it be *per se*, truncated rule of reason, or full-blown rule of reason – the Agreement cannot be justified either by claims that Hoechst and Andrx were not competitors or that the Agreement is procompetitive. Indeed, the Agreement is the type of restraint of trade that the antitrust laws condemn and that the FTC should take action to remedy.

I. The Agreement Between Hoechst and Andrx Not to Compete is an Agreement Between "Competitors."

You asked what the legal standard is for judging whether Hoechst and Andrx are "competitors" or "potential competitors." By any reasonable formulation of those terms, Hoechst and Andrx are competitors. Using the terminology of the Intellectual Property Guidelines,[1] the

[1] DOJ/FTC Intellectual Property Guidelines (hereinafter "Guidelines") § 3.3.

This was also the conclusion in Engine Specialties, Inc. v. Bombadier Limited. In Engine Specialties, a manufacturer of minicycles entered into a "joint venture" agreement with a manufacturer of snowmobiles that, among other things, required the snowmobile manufacturer not to enter the minicycle business in North America. In a clear analogy to the instant case, the potential entrant had developed a minicycle product with which it was intending to enter the marketplace. It threatened the incumbent with such entry.[17] Concerned that its product would not succeed in the marketplace, however, it instead entered into an agreement with the established manufacturer, part of which allocated territorial markets among the two parties.[18] The court rejected the parties' argument that they were not potential competitors for purposes of Section 1.[19] It found that the relevant inquiry was whether the potential competitor had the "necessary desire, intent, and capability to enter the market" at the level of the existing competitor.[20]

Although it is difficult to generalize as to whether "objective" or "subjective" factors predominate in the analysis, it matters little here.[21] The facts surrounding the Agreement speak for themselves that entry by Andrx – or by another firm using Andrx's place in line – was "reasonably probable" (or, put differently, that Andrx had the "necessary desire, intent and capability") in June 1998. In preparing to enter, Andrx had spent millions of dollars on research, development, and technology, all of which would have been wasted had it not done so.[22] Such entry was sufficiently likely that Hoechst was willing to pay $90 million to head it off. Both parties believed entry was "reasonably probable." Andrx filed a Paragraph IV certification that

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16 605 F.2d 1 (1st Cir. 1979), cert. denied, 449 U.S. 890 (1980).

17 Id. at 3-4.

18 See id. at 10-11.

19 Id. at 11.

20 Id. at 9.

21 In the Section 7 context, both objective and subjective factors are relevant. See infra note 26.

22 Cf. Transource Int'l, Inc. v. Trinity Indus., Inc., 725 F.2d 274, 280 (5th Cir. 1984) (finding that parties to an agreement were not potential competitors where one party "lacked the financial ability to enter the market at the same level" as the other).

its product was not infringing – presumably risking criminal liability for a knowingly false representation – evidencing its belief that there was no patent conflict preventing entry. (Indeed, if it is the case that Andrx made the Paragraph IV Certification in bad faith, knowing that it would prevent entry of competing generic Cardizem CD products, that act alone could be viewed as a violation of Section 2 of the Sherman Act by Andrx.) Andrx has not amended its application by withdrawing the Paragraph IV Certification and replacing it with a Paragraph III Certification applicable to an infringing application. (ANDAs with Paragraph III Certifications do not carry with them the 180-day exclusivity period.) In fact, to this day Andrx continues to assert that its original formula is non-infringing.[23] Moreover, Andrx had cleared the FDA approval process as of July 1998. While Andrx tells the FTC that no reasonable firm would enter under the cloud of an infringement suit and risk patent damages, it cannot explain why a sophisticated market participant like Hoechst would bet $90 million on the "reasonable probability" that Andrx would in fact enter.[24] And the parties cannot explain why the payments were triggered by FDA approval or why they were set to cease on Andrx's first marketing of its product. Finally, if Hoechst did not realistically contemplate that Andrx would have entered the market, why did it include in the Agreement a provision building in retroactive "increases [to the amounts paid for Andrx's compliance if Andrx prevailed in the patent infringement litigation] . . . representing an agreed-upon amount of profits that Andrx would have earned had it begun selling its product upon receiving FDA approval"?[25] The only answer is that Hoechst and Andrx were attempting to split between them the increased prices that their illegal collusion would cause.

In short, all of the marketplace evidence supports the conclusion that Andrx would have entered after receipt of FDA approval. All of Andrx's public statements support the conclusion that Andrx believed that its product did not infringe, and that therefore there was little risk in coming to market. Hoechst obviously believed as much, as demonstrated by its payment of $40 million a year to avoid this result. This evidence clearly satisfies the "reasonably probable" test of the Guidelines. Requiring more would change that standard to one of certainty beyond a reasonable doubt, which the government could never sustain. The agencies have never followed such a standard, and it would be bad public policy to do so now.[26]

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23 Andrx Say Hoechst Settles Cardizem Suit, Reuters, June 9, 1999, available online at http://biz.yahoo.com/rf/990609/2i.html.

24 Critical to this point is the fact that Hoechst needed nothing from Andrx to market its product. Rather, all it received for its payment of $40 million per year (and now $90 million overall) to Andrx was Andrx's agreement not to enter the market.

25 Andrx Enters Into Agreement With HMR Concerning Its Generic Version of Cardizem CD, Andrx Corporation Press Release (Sept. 25, 1997) (emphasis added).

26 The same conclusion obtains in the Section 7 context. In assessing likelihood of entry for purposes of Section 7, courts consider a firm's expressions of interest, economic

The FTC should resist the argument that the parties' patent litigation effectively prevents Hoechst and Andrx from being considered actual or perceived potential competitors in the context of Section 1 of the Sherman Act. Such a position would allow parties to patent infringement lawsuits free reign to enter into manifestly anticompetitive agreements – fixing prices, allocating territories, and so forth – with virtual impunity, no matter how thin the patent

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incentives, capacity, and ability to enter the market unilaterally. See, e.g., Yamaha Motor Co. v. FTC, 657 F.2d 971 (8th Cir. 1981) (examining criteria including interest, incentive and capacity to evaluate potential competition), cert. denied, 456 U.S. 915 (1982); see also Republic of Texas Corp. v. Board of Governors of the Fed. Reserve Sys., 649 F.2d 1026, 1044 (5th Cir. 1981) (listing factors to consider in assessing reasonable probability of entry as anticipated profitability of independent entry versus other forms of entry, and evidence specific to applicant demonstrating a preference for independent entry); Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1121c (1997 Supp.) (citations omitted) ("[R]ecent cases have noted expressions of interest: incentives, including the availability of attractive profits, and the utility of a full product line; past entries into related geographic or product markets; the ability to enter, including access to the necessary capital and familiarity with the relevant technology. . . .").

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drugs in the United States – are entitled to enforcement of the antitrust laws here. Moreover, the facts of this case are relatively straightforward and well established. Future cases may not present such a clean pattern.

In consideration of all of this, we once again urge the FTC to pursue the described remedies on behalf of consumer users of Cardizem CD.

* * *

We hope this letter is helpful to you and your colleagues as you continue to investigate the Hoechst-Andrx Agreement. If we can be of further assistance, please do not hesitate to contact us.

Very truly yours,

George S. Cary
Steven J. Kaiser

Cc: William J. Baer
David A. Balto
Richard A. Feinstein
Willard K. Tom

From: Steven J. KAISER <SKaiser@cgsn.com>
To: HQ.DCMAIL2(DBALTO)
Date: Mon, Jun 28, 1999 9:58 AM
Subject: Re: Hoechst/Andrx -- Section 7

Thanks and thank you for your help. Attached is the file.

Steve

---------- Original Text ----------

From: David Balto <DBALTO@FTC.GOV>, on 6/28/99 9:54 AM:

great letter! can you e mail me the final version? thanks

>>> Steven J. KAISER <SKaiser@cgsn.com> 6/23/99 2:34 PM >>>
David:

In reference to your comments about Section 7, we included in the draft the attached footnote, which I think picks up on Yamaha and the Section 7 standards (as well as the Hoechst/MMD case). We weren't sure if this made it into the version you read (i.e., if the conversion from Word carried the footnotes) or if you thought the passage didn't cover the material sufficiently or should be in text.

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Thanks.

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