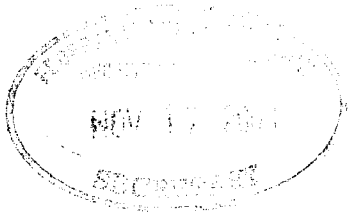
UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



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

RESPONDENT HOECHST MARION ROUSSEL, INC.'S MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OR ARGUMENT THAT THE STIPULATION AND AGREEMENT IS ILLEGAL *PER SE*

Respondent Hoechst Marion Roussel, Inc. ("HMR") moves this Court *in limine* to order that Complaint Counsel, their witnesses, and all other persons involved in this case on their behalf, be instructed not to directly or indirectly, during opening or closing statements, interrogation of witnesses, arguments or objections, or at any other time during the trial of this matter, present any argument or evidence to support a claim that the agreement or actions challenged in these proceedings may or does constitute a *per se* violation of law.

LAW AND ARGUMENT

The Complaint issued by the Commission expressly alleges that the Stipulation and Agreement between HMR and Andrx "had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition and consumers by preventing or discouraging the entry of competition" (Compl. ¶ 29). The Commission acknowledged that the Stipulation and Agreement included procompetitive features (*see* Compl. ¶¶ 25, 35), but claimed that

since these features "did not offset the anticompetitive effects" alleged in the Complaint the Stipulation was "not justified by any countervailing efficiencies." (Compl. ¶¶ 34, 35.) The Commission's balancing of alleged anticompetitive effects and procompetitive efficiencies incorporates the very essence of a Rule of Reason theory of liability.[1/]

Notwithstanding the clear language of the Complaint, Complaint Counsel recently asserted that they intended to introduce evidence and argue that the HMR/Andrx Stipulation and Agreement "constitutes a *per se* illegal market allocation in violation of the Federal Trade Commission Act." (Complaint Counsel's Statement of the Case, at 8-10.) In order to buttress their *per se* theory of liability, Complaint Counsel submitted an expert report of Richard G. Frank. In his report, Mr. Frank opined that the Stipulation and Agreement constitutes "an attempt to divide the market between the parties in time" and was not a "risk mitigation agreement" subject to the Rule of Reason. It is thus apparent Complaint Counsel intends to depart from the proceedings authorized by the Commission in the Complaint and present evidence and testimony in support of a claim that the Stipulation is a market allocation in *per se* violation of the law.

The Court should prohibit Complaint Counsel from claiming or presenting any evidence or argument that the Stipulation is a *per se* unlawful market allocation. To do otherwise would permit Complaint Counsel to proceed on a theory that the Commission determined not to plead, would effectively amend the Commission's Complaint *sub silentio* and would permit

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1/ *See, e.g., California Dental Ass'n v. FTC,* 224 F.3d 942, 947 (9th Cir. 2000) ("The rule-of-reason analysis consists of three components: (1) the persons or entities to the agreement intend to harm or restrain competition; (2) an actual injury to competition occurs; and (3) the restraint is unreasonable as determined by balancing the restraint and any justifications or pro-competitive effects of the restraint," quoting *American Ad Mgmt. v. GTE Corp.,* 92 F.3d 781, 789 (9th Cir. 1996)); *Smith v. Pro Football, Inc.,* 593 F.2d 1173, 1183 (D.C. Cir. 1979) (under the rule of reason, "the 'anticompetitive evils' of the challenged practice must be carefully balanced against its 'procompetitive virtues' to ascertain whether the former outweigh the latter," and a "restraint is unreasonable if it has the 'net effect' of substantially impeding competition").

Complaint Counsel to improperly act on its own in a matter reserved exclusively to the Commission's discretion.[2/]

The Commission, as the administrative agency charged with enforcement of the antitrust laws, was clearly well aware of the merits of proceeding under a Rule of Reason theory as opposed to a *per se* theory of liability and determined, in the exercise of its discretion, to proceed under the Rule of Reason.[3/] The Commission -- not Complaint Counsel -- is invested with the authority to bring a *per se* claim, and the Commission -- not Complaint Counsel -- is the only entity authorized to alter the underlying theory of the Complaint.[4/] Accordingly, Complaint Counsel must not be allowed to present evidence or argument which deviates from the theory of the case adopted by the Commission without first obtaining the Commission's consent and this Court's approval.

In other cases, when attempts have been made to alter the theory on which a case has been authorized, such attempts have been foreclosed. In *Electrical Bid Registration Serv. of Memphis, Inc.*, 107 F.T.C. 240, 1986 FTC Lexis 61, at *12 (Feb. 12, 1986), the Commission, in language similar to that employed in this case, alleged respondents' bidding practices for construction contractors were "unreasonable, because their anticompetitive effects are not outweighed by any procompetitive effects" (¶ 15). In the trial of the case, however, Complaint

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2/ *Capitol Records Distributing Corp.*, 58 F.T.C. 1170 (1961) ("The Commission reserves to itself the discretionary determination of when there is reason to believe the law has been violated and when the public interest requires the institution of a proceeding, as well [as] the authority to frame the charges.").

3/ *See Ford Motor Co.*, 94 F.T.C. 564, 1979 FTC Lexis 225, at *79-80 (Sept. 21, 1979) ("The Commission was well aware of the potential complexities of a Section 19 proceeding as opposed to Section 5 restitution when it issued this complaint, and as far as I am concerned, the statement that it might apply to the courts for consumer redress under Section 19 forecloses complaint counsel's last minute change of theory.").

4/ *See Champion Home Builders Co.*, 99 F.T.C. 397 (1982) ("Where a proposed amendment alters the 'underlying theory' of the original complaint, . . . the Commission must make the determination whether to amend the complaint because only the Commission is authorized to determine whether there is reason to believe that the law has been violated and whether a proceeding on those amended charges would be in the public interest."); *accord Century 21 Commodore Plaza, Inc.*, 89 F.T.C. 238 (1977); *Cavanaugh Communities Corp.*, 87 F.T.C. 143 (1976); *Coca-Cola Co. of the Southwest*, 1988 FTC Lexis 164, at *3 (Oct. 25, 1988) (describing power "to amend the complaint altering the theory of the original complaint" as "a matter lying in the administrative discretion of the Commission").

Counsel asserted a *per se* theory of liability. The Commission tribunal hearing the case refused to apply a *per se* theory of liability finding that the complaint stated a Rule of Reason case and required the parties to put on evidence of anticompetitive effects and procompetitive benefits.

In that case, the Tribunal acknowledged that application of a Rule of Reason standard "would represent a departure from earlier bid depository decisions . . . in which the approach taken by the courts was one of virtual per se condemnation of the practice as either a price-fixing conspiracy or a group boycott" *Id.* at *80-81. Nevertheless, the Tribunal determined that the complaint issued by the Commission constrained it to apply a Rule of Reason standard:

> It is clear, however, from the plain language of the complaint that this case is grounded on the theory that the mere fact that prices are tampered with in the sense that price negotiation is limited, does not resolve the question of legality, and . . . complaint counsel must show actual or probable anticompetitive effects from the challenged practice while respondents are to be given an opportunity to demonstrate procompetitive benefits.

Id.

Here, the plain language of the complaint is grounded on the theory that the procompetitive features of the Stipulation and Agreement (Compl. ¶¶ 25, 35) were not offset by the anticompetitive effects alleged in the Complaint (Compl. ¶¶ 34, 35). Nowhere within the four corners of the complaint does the Commission either state or imply a *per se* theory of liability.

There can be no doubt that the Commission knows how to allege a *per se* violation. Moreover, when it does so, its allegations are in clear and unequivocal terms. For instance, in *Ernesto L. Ramirez Torres, D.M.D.,* 1998 FTC Lexis 101, at *2-3, 6-8 (Sept. 16, 1998), the complaint explicitly charged a group of dentists, who constituted a majority of the dentists practicing in several Puerto Rican municipalities, with entering into certain "agreements, combinations, and conspiracies to set the prices and other terms and conditions under which they would participate in

Puerto Rico's program to provide medical, pharmaceutical, and dental services to the indigent" (¶ 3) and engaged in a "concerted refusal to deal" with that program in an effort to enforce the terms of their agreement (¶ 9). As the Commission's analysis in aid of public comment correctly noted, the Commission's complaint specifically invoked *per se* liability as a term of art, and clearly stated a cause of action under a *per se* theory of liability.

Similarly, in *Summit Communications Group, Inc.*, 1995 FTC Lexis 193, at *4-7 (Apr. 28, 1995), the Commission alleged competing cable television providers "reached an understanding concerning how the two companies should handle future situations . . . where both companies were attempting to serve the same apartment complex or housing subdivision in the dual franchise area" by allocating such potential customers among the two companies (¶¶ 7, 9) and thereby "agree[ing] not to compete in the dual franchise area" (¶ 12). The Commission's statement, made contemporaneously with the issuance of the complaint, specifically highlighted allegations "that the respondents . . . entered into a market allocation agreement" that "is per se illegal."[5/]

There are no *per se* liability terms of art contained in the complaint in this case. Nor is there a specific allegation of an unlawful *per se* market allocation. Instead, the Commission included in the complaint terms such as "procompetitive impact," "countervailing efficiencies," "anticompetitive effects," and "competitively less significant." These are terms of art implicating a Rule of Reason analysis - not terms of art alleging *per se* liability.

Moreover, statements made by the Commission to Respondent's counsel as well as a press release made by the Commission contemporaneous with the issuance of the complaint further demonstrate, and are entirely consistent with, the Commission's intent to proceed under a Rule of

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5/ *Id.* at *24-25. This understanding of the complaint was further confirmed by the terms of the parties' consent order, which prohibited respondents, *inter alia,* from entering into any understanding "[t]o allocate or divide markets, customers, contracts, or territories for Cable Television Services in any part of the Relevant Geographic Area" (Consent Order ¶ II.A). *Id.* at *17.

Reason theory of liability. As noted in the Declaration of James M. Spears (attached hereto as Exhibit 1), Chairman Pitofsky advised that the complaint, if voted out, would proceed under the Rule of Reason. The press release issued by the Commission announcing the complaint also evinces the Commissions's view that a full hearing on the Stipulation and Agreement was required to "shape the appropriate parameters of permissible conduct in this area."[6/]

Indeed, it does not appear that the Commission has changed its view that these types of agreements must be analyzed under the Rule of Reason. Commenting on provisions in an agreement similar to the Stipulation and Agreement at issue here, Commissioner Leary recently stated that a *per se* analysis is improper and that these types of agreements must be analyzed under the Rule of Reason.[7/]

Clearly, Respondent will be unfairly prejudiced if Complaint Counsel is permitted to unilaterally change the underlying theory of this case at this late date. Moreover, it would be manifestly unfair to Respondent if, at the end of the day, the Commission were to disregard the final determinations of this Court because the case proceeded under an unauthorized legal theory and remand the case for retrial under the standard which had, in fact, been authorized by the Commission to begin with.

Since the Commission authorized a case under the Rule of Reason theory and the Commission -- not Complaint Counsel -- has the sole authority to amend its theory of the case,

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6/ *See* FTC Press Release, *FTC Charges Drug Manufacturers with Stifling Competition in Two Prescription Drug Markets*, at 4 (Mar. 16, 2000) (quoting unanimous statement of the Commission noting that the Complaint follows closely on the heels of "the first government antitrust enforcement action" concerning application of "the complicated provisions of the Hatch-Waxman Act" and that "the development of a full factual record in the [Hoechst/Andrx] administrative proceeding" is desirable "to shape further the appropriate parameters of permissible conduct in this area, and guide other companies and their legal advisors"), attached hereto as Exhibit 2.

7/ *See Antitrust Issues in Settlement of Pharmaceutical Patent Disputes,* Prepared Remarks of Thomas B. Leary, Commissioner, Federal Trade Commission, delivered at the Sixth Annual Health Care Antitrust Forum, Northwestern University School of Law, Chicago, Illinois, November 3, 2000 (attached hereto as Exhibit 3).

Respondent respectfully submits that Complaint Counsel should not be allowed to claim or introduce evidence or argument in support of a claim that the Stipulation and Agreement is illegal *per se.*

WHEREFORE, Respondent Hoechst Marion Roussel respectfully prays that the Court grant this motion in its entirety and enter an order barring Complaint Counsel from making any claim in this proceeding or presenting any evidence or argument that the challenged Stipulation and Agreement is illegal *per se.*

Dated: November 16, 2000

Respectfully Submitted,

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ATTORNEYS FOR RESPONDENT
AVENTIS PHARMACEUTICALS INC.

EXHIBIT 1

UNITED STATES OF AMERICA
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

DECLARATION OF JAMES M. SPEARS IN SUPPORT OF HOECHST MARION ROUSSEL, INC.'S MOTION *IN LIMINE* REGARDING *PER SE* EVIDENCE

I, James M. Spears, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am a partner with the law firm of Shook Hardy & Bacon L.L.P., counsel for respondent Hoechst Marion Roussel, Inc. ("HMR").

2. On October 13, 1999, representatives of HMR, including myself, met with Richard Parker, Director of the Bureau of Competition to discuss the status of the underlying investigation, FTC File. 981-0368. During the course of that meeting Mr. Parker stated that the facts of this case did not present a situation that would warrant the assertion of a *per se* theory of liability.

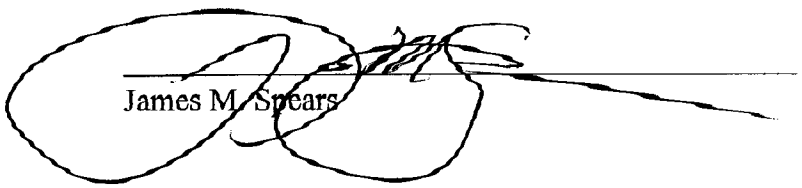
3. On or about January 24, 2000, I spoke telephonically with Mr. Parker regarding his recommendation that the Commission proceed with Part III litigation following the conclusion of their investigation. During this call, Mr. Parker reiterated his position that while some individuals in the Bureau had recommended the case proceed under a *per se* theory of liability, that both he and Chairman Robert Pitofsky were of the view that the case should proceed under the Rule of Reason.

4. On February 25, 2000, representatives of HMR, including myself, met with Robert Pitofsky, Chairman of the Federal Trade Commission to discuss the Commission's review of the recommendation to pursue administrative litigation. During the course of that meeting, Chairman Pitofsky stated that it was his view that the facts would not support a *per se* theory of liability and that any case would proceed under the Rule of Reason standard.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in Washington, D.C., on November 16, 2000.

Respectfully Submitted,



James M. Spears

EXHIBIT 2

Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

For Release: March 16, 2000

FTC Charges Drug Manufacturers with Stifling Competition in Two Prescription Drug Markets

Complaint Filed Against Hoechst Marion Roussel, Inc. and Andrx Corp.; Proposed Settlement Reached with Abbott Laboratories and Geneva Pharmaceuticals, Inc.

Complaints Charge Multi-Million-Dollar Arrangements Were Designed to Keep Generic Versions of Cardizem CD and Hytrin Off the Market

The Federal Trade Commission today charged two drug makers, Hoechst Marion Roussel (now Aventis) and Andrx Corporation, with engaging in anticompetitive practices in violation of Section 5 of the FTC Act, alleging that Hoechst, the maker of Cardizem CD, a widely prescribed drug for treatment of hypertension and angina, agreed to pay Andrx millions of dollars to delay bringing its competitive generic product to market. The Commission also announced a proposed settlement with two other drug makers, Abbott Laboratories and Geneva Pharmaceuticals, Inc., resolving charges that the companies entered into a similar anticompetitive agreement in which Abbott paid Geneva substantial sums to delay bringing to market a generic alternative to Abbott's brand-name hypertension and prostate drug, Hytrin.

"The financial arrangements between the branded and generic manufacturers were designed to keep generic versions of Cardizem CD and Hytrin off the market for an extended period of time," said Richard Parker, Director of the FTC's Bureau of Competition. "These types of agreements have the potential to cost consumers hundreds of millions of dollars each year, Parker noted. He further explained that "the proposed consents with Abbott and Geneva will provide immediate guidance to the drug industry and the antitrust bar with regard to these kinds of arrangements, and the Hoechst-Andrx complaint will allow the Commission to further consider the issues as it examines the arrangement in that case in light of a record developed during an administrative hearing."

Under legislation commonly known as the Hatch-Waxman Act, a company can seek approval from the Food and Drug Administration (FDA) to market a generic drug before the expiration of a patent relating to the brand name drug upon which the generic is based. Pursuant to this Act, the first company to file an Abbreviated New Drug Application (ANDA) with the FDA has the exclusive right to market the generic drug for 180 days. No other generic can gain FDA approval until this 180-day period expires. The purpose of the exclusivity period is to encourage generic entry.

To begin the FDA approval process, the generic applicant must: 1) certify in its ANDA that the patent in question is invalid or is not infringed by the generic product (known as a "paragraph IV certification"); and 2) notify the patent holder of the filing of the ANDA. If the

patent holder files an infringement suit against the generic applicant within 45 days of the ANDA notification, FDA approval to market the generic drug is automatically stayed for 30 months, unless, before that time, the patent expires or is judicially determined to be invalid or not infringed. This 30-month automatic stay allows the patent holder time to assert its patent rights in court before a generic competitor is permitted to enter.

Hoechst-Andrx Complaint Allegations

Hoechst sells Cardizem CD, a once-a-day diltiazem product used to treat hypertension and angina -- chronic, severe chest pain due to a reduction in blood flow to the heart. The Hoechst product accounts for approximately 70 percent of all once-a-day diltiazem products sold in the United States. In September 1995, Andrx filed its ANDA with the FDA to manufacture and distribute a generic version of the drug, and, as the first to file, was entitled to the 180-day exclusivity right. Hoechst promptly sued Andrx for patent infringement, which triggered the 30-month stay on FDA approval of Andrx's ANDA. This 30-month period expired in July 1998.

In September 1997, the FTC's complaint alleges, Hoechst and Andrx entered into an agreement in which Andrx was paid to stay off the market. Under the agreement, Andrx would not market its product when it received FDA approval, would not give up or transfer its 180-day exclusivity right, and would not even market a non-infringing generic version of Cardizem CD.

In exchange, Hoechst paid Andrx $10 million per quarter, beginning in July 1998, when Andrx gained FDA approval for its product. The agreement also stipulated that Hoechst would pay Andrx an additional $60 million per year from July 1998 to the conclusion of the lawsuit if Andrx prevailed.

According to the FTC, the agreement acted as a bottleneck that prevented any other potential competitors from entering the market because: 1) Andrx would not market its product and thus its 180 days of exclusivity would not begin to run; and 2) other generics were precluded from entering the market because Andrx agreed not to give up or transfer its exclusivity.

According to the complaint, Hoechst's agreement with Andrx had the "purpose or effect, or the tendency or capacity" to restrain trade in the market for once-a-day diltiazem and in other narrower markets. Entry of a generic into the market immediately would have introduced a lower-cost alternative and would have started the 180-day waiting period.

The complaint alleges that the agreement between Hoechst and Andrx constituted an unreasonable restraint of trade; that Hoechst attempted to preserve its monopoly in the relevant market; that Hoechst and Andrx conspired to monopolize the relevant market; and that the acts and practices are anticompetitive and constitute unfair methods of competition, all in violation of Section 5.

Abbott-Geneva: Complaint Allegations

Hytrin is the brand-name for terazosin HCL, a prescription drug marketed and sold by Abbott Laboratories. This drug is used to treat hypertension and benign prostatic hyperplasia ("BPH" or enlarged prostate). Both hypertension and BPH are chronic conditions affecting millions

of Americans each year, many of them senior citizens. According to the complaint, Abbott paid Geneva $4.5 million per month to keep Geneva's generic version of Hytrin off the U.S. market. This agreement also resulted in a significant delay in the introduction of other generic versions of Hytrin because Geneva was the first filer with the FDA and other companies could not market their generic products until 180 days after Geneva's entry.

In January 1993, Geneva filed an ANDA with the FDA for a generic version of terazosin HCL in tablet form; Geneva filed a similar ANDA for a generic version of terazosin in capsule form in December 1995. In April 1996, Geneva filed a Paragraph IV certification with the FDA for both ANDAs.

On June 4, 1996, Abbott sued Geneva, claiming patent infringement by Geneva's generic terazosin HCL tablet product. Abbott mistakenly made no such claim against Geneva's capsule version of the product, even though both tablets and capsules involved the same potential infringement issues. Pursuant to the Hatch-Waxman Act, Abbott's lawsuit triggered a 30-month stay of final FDA approval of Geneva's generic tablet ANDA, until December 1998. Because no similar lawsuit was filed regarding the generic capsule, the FDA's review and approval process regarding this product continued.

The complaint alleges that Geneva, confident that it would win its patent infringement dispute with Abbott, planned to bring its generic terazosin HCL capsule to market as soon as possible after FDA approval. As the first filer for approval of generic Hytrin capsules, Geneva would enjoy the 180-day exclusivity period provided under the Hatch-Waxman Act.

When Geneva actually received FDA approval to market its generic capsules, Geneva contacted Abbott and announced that it would launch its product unless Abbott paid it not to enter the market. Abbott, which estimated that the entry of a generic would eliminate $185 million in Hytrin sales in the first six months, reached an agreement with Geneva on April 1, 1998, pursuant to which Geneva would not bring a generic terazosin HCL product to market until the earlier of: 1) final resolution of the patent infringement lawsuit involving the generic tablet product (including possible review by the Supreme Court); or 2) entry into the market of another generic terazosin HCL product. Geneva also agreed not to transfer, assign or relinquish its 180-day exclusivity right to market its generic product.

In exchange, the complaint alleges, Abbott would pay Geneva $4.5 million per month until the district court ruled on the ongoing patent infringement dispute. If the court found that Geneva's tablet product did not infringe any "valid and enforceable claim" of Abbott's patent, Abbott agreed to pay $4.5 million monthly after that decision into an escrow account until the final resolution of the litigation. Under the agreement, the party ultimately prevailing in the patent litigation would receive the escrow funds. The court hearing the patent infringement case was not made aware of the agreement between the companies.

In accordance with the agreement, Geneva did not introduce its generic capsules in April 1998, and instead began collecting the $4.5 million monthly payments from Abbott, which exceeded the amount Abbott expected Geneva to receive from actually marketing the drug. On September 1, 1998, the district court granted Geneva's motion for summary judgment in its patent litigation with Abbott, invalidating Abbott's patent. Despite this victory, Geneva still did not enter the market with its generic product, content to have Abbott make monthly $4.5 million payments into the escrow account. On July 1, 1999, the Court of Appeals for the Federal Circuit affirmed the decision invalidating Abbott's patent. Under the agreement,

Geneva was to await Supreme Court consideration of the matter before entering. According to the complaint, Geneva did not enter until August 13, 1999, when, aware of the Commission's investigation, it canceled its agreement with Abbott.

The complaint alleges that Abbott's agreement with Geneva had the "purpose or effect, or the tendency or capacity" to restrain competition unreasonably and to injure competition by preventing or discouraging the entry of competition into the relevant market. As a result of the anticompetitive behavior, the complaint alleges, the lower-priced generic version of Hytrin was not made available to consumers, pharmacies, hospitals, insurers, wholesalers, government agencies, managed care organizations and others during the time the agreement was in place.

Entry by a generic competitor would have had a significant procompetitive effect. The complaint alleges that the agreement between Abbott and Geneva constituted an unreasonable restraint of trade; that Abbott monopolized the relevant market; that Abbott and Geneva conspired to monopolize the relevant market; and that the acts and practices are anticompetitive in nature and tendency and constitute unfair methods of competition, all in violation of Section 5.

The Proposed Consent Orders

Under the terms of the proposed settlement, Abbott and Geneva would be barred from entering into agreements pursuant to which a first-filing generic company agrees with a manufacturer of a branded drug that the generic company will not 1) give up or transfer its exclusivity or 2) bring a non-infringing drug to market. In addition, agreements involving payments to a generic company to stay off the market would have to be approved by the court when undertaken during the pendency of patent litigation (with notice to the Commission), and the companies would be required to give the Commission 30 days' notice before entering into such agreements in other contexts. In addition, Geneva would be required to waive its right to a 180-day exclusivity period for its generic terazosin HCL tablet product, so other generic tablets could immediately enter the market.

The proposed orders, which would expire in 10 years, also contain certain reporting and other provisions designed to help the Commission monitor compliance by the companies.

The Commission vote to issue the administrative complaint against Hoechst/Andrx was 5-0. The vote to accept the proposed consent orders with Abbott and Geneva was 5-0.

In a unanimous statement, the Commissioners said: "These consent orders represent the first resolution of an antitrust challenge by the government to a private agreement whereby a brand name drug company paid the first generic company that sought FDA approval not to enter the market, and to retain its 180-day period of market exclusivity. Because the behavior occurred in the context of the complicated provisions of the Hatch-Waxman Act, and because this is the first government antitrust enforcement action in this area, we believe the public interest is satisfied with orders that regulate future conduct by the parties. We recognize that there may be market settings in which similar but less restrictive arrangements could be justified, and each case must be examined with respect to its particular facts.

"We have today issued an administrative complaint against two other pharmaceutical companies with respect to conduct that is in some ways similar to the conduct addressed by

these consent orders. We anticipate that the development of a full factual record in the administrative proceeding, as well as the public comments on these consent orders, will help to shape further the appropriate parameters of permissible conduct in this area, and guide other companies and their legal advisors.

"Pharmaceutical firms should now be on notice, however, that arrangements comparable to those addressed in the present consent orders can raise serious antitrust issues, with a potential for serious consumer harm. Accordingly, in the future, the Commission will consider its entire range of remedies in connection with enforcement actions against such arrangements, including possibly seeking disgorgement of illegally obtained profits."

The Commission is accepting public comment on the consent in the Abbott/Geneva matter until April 17, 2000, after which it will decide whether to make it final. Comments should be sent to the FTC, Office of the Secretary, 600 Pennsylvania Ave., N.W., Washington, D.C. 20580.

NOTE: The Commission issues or files a complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. Neither complaint is a finding or ruling that the named party has violated the law. The administrative complaint marks the beginning of a proceeding in which the allegations will be ruled upon after a formal hearing by an administrative law judge.

NOTE: The consent agreement reached in the Abbott/Geneva matter is for settlement purposes only and does not constitute an admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of $11,000.

Copies of the Commission's complaints in both matter, consent in the matter of Abbott/Geneva, and analysis to aid public comment in the matter of Abbott/Geneva are available from the FTC's web site at *http://www.ftc.gov* and also from the FTC's Consumer Response Center, Room 130, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580; 877-FTC-HELP (877-382-4357); TDD for the hearing impaired 202-326-2502. To find out the latest news as it is announced, call the FTC NewsPhone recording at 202-326-2710.

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(FTC File No. 981-0368, Hoechst-Andrx)
(FTC File No. 981-0395, Abbott-Geneva)

(Drug Cases Combined.wpd)

EXHIBIT 3

Antitrust Issues in Settlement of Pharmaceutical Patent Disputes

Prepared Remarks of Thomas B. Leary
Commissioner, Federal Trade Commission

Sixth Annual Health Care Antitrust Forum
Northwestern University School of Law

Chicago, Illinois

November 3, 2000

1. Introduction

I want to thank the Healthcare Antitrust Forum for the invitation to talk about some recent developments in healthcare antitrust at the FTC.(1) An agency representative's usual response to such an invitation is a survey of cases across a spectrum, but I will not do that today. Instead, I would like to focus in some depth on the antitrust issues involved in the settlement of pharmaceutical patent disputes.

Five months ago, the Commission announced a settlement agreement with two drug makers, Abbott Laboratories and Geneva Pharmaceuticals, Inc. resolving charges that the companies had entered into an anticompetitive agreement, which had the potential effect of delaying the entry of generic alternatives to Abbott's brand-name hypertension and prostate drug, Hytrin.(2) At the same time the Abbott/Geneva matter was settled, the Commission filed an administrative complaint challenging an agreement that raised similar issues between Hoechst Marion Roussel (now Aventis), the maker of Cardizem CD, a widely prescribed drug for treatment of hypertension and angina, and Andrx Corporation, the maker of a generic version of the product.(3) This case is still pending. Moreover, just last month the Commission announced a proposal to conduct a focused study of generic drug competition, and has requested public comment on the process it would use to collect relevant information from manufacturers nationwide.(4) The proposed study will examine whether brand-name and generic drug manufacturers have entered into agreements, or have used other strategies that could have an impact on competition from generic versions of patent-protected drugs.

As the following remarks will make clear, I think the issues in these patent settlements are difficult and individual facts are important. These settlements, like any patent settlement, require a resolution of two conflicting policies. On the one hand, there is a policy in favor of resolving disputes in order to conserve public and private resources and, in some cases, to facilitate entry. On the other hand, there is always a risk of a collusive agreement to share monopoly profits from an invalid patent. In the pharmaceutical area, these issues are played off against a special regulatory framework.

These comments on the Abbott/Geneva settlement do not suggest that I have made up my mind about the issues in Hoechst/Andrx, or in other settlement agreements that may be

uncovered if the study goes forward.[5] I also speak only for myself, and no other Commissioner.

2. Regulatory Setting

The Hatch-Waxman Act

In order to understand the context of the conduct at issue in the Abbott/Geneva matter, it is necessary to delve into the unique regulatory framework that governs the approval process of pharmaceuticals. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"),[6] any applicant seeking to market a new drug must first obtain FDA approval by filing a new drug application ("NDA").[7] NDA applicants must provide, among other things, "full reports of the investigations" that demonstrate a drug product to be safe and effective for its intended use. In 1984, Congress adopted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. The Hatch-Waxman Act contains several important features intended to streamline the development and approval of generic drugs in order to "make available more low cost generic drugs," while at the same time protecting the interests of the patent-holding pioneer branded drug manufacturer.[8]

The Hatch-Waxman Act created the abbreviated new drug application, or "ANDA." Before passage of the Hatch-Waxman Act, manufacturers of generic drugs were required to duplicate the time-consuming and expensive safety and effectiveness studies already performed on the pioneer drugs. Under the ANDA process, an applicant can sidestep this lengthy process and rely on the safety and efficacy tests conducted by the pioneer drug manufacturer, so long as it can demonstrate that its generic drug is the same as and is bioequivalent to the approved drug product (also known as the reference listed drug).[9]

In addition to demonstrating bioequivalence, the ANDA applicant must provide a certification with respect to each patent listed in the so-called Orange Book,[10] which claims the reference drug or a method of using it. The certification must make one of four statements: (I) no patent information on the drug product that is the subject of the ANDA has been submitted to the FDA; (II) there was a patent which has expired; (III) such patent will expire on a particular date; or (IV) such patent is invalid or will not be infringed by the manufacture, use or sale of the drug product for which the ANDA is submitted. The last certification is known as a "Paragraph IV" certification.[11]

ANDA filers certifying under Paragraph IV must provide notice to each owner of the patent and the NDA holder for the listed drug, along with a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed by marketing of the generic product. A pioneer drug owner who receives notice of a Paragraph IV certification has 45 days to initiate a patent infringement suit against the applicant. If no action is initiated within 45 days, the FDA review and approval process may proceed according to the FDA's expedited schedule. If a patent infringement suit is filed within the 45 days, FDA approval of the ANDA is automatically stayed until the earliest of the date the patents expire, a final determination of non-infringement is entered in the patent infringement litigation, or the expiration of the 30-months from the patentee's receipt of notice of the Paragraph IV certification.[12]

(A pioneer drug owner may still sue for infringement after the 45 day period, but will not receive the 30-month stay.) The 30-month period is intended to allow time for judicial resolution of the merits of the patent. The statute contemplates that the 30-month stay may be extended or shortened by the court depending on the circumstances of the case.

The Hatch-Waxman procedure provides an additional incentive for generic manufacturers to file a Paragraph IV certification and to challenge patents that may be invalid or not infringed by the ANDA product. Under the provision, the first applicant submitting an ANDA which contains a Paragraph IV certification ("first applicant") is protected from competition from subsequent generic versions of the same drug for a period of 180 days from the earlier of (i) the date of a court decision holding the patent invalid or not infringed or (ii) the date the generic manufacturer begins marketing the drug.(13) This provision is commonly known as the "180-day exclusivity" provision.

The statute thus gives something to both sides. The owner of the pioneer patent gets what is in effect an automatic preliminary injunction, which may last as long as 30 months, and the would-be generic competitor gets an expedited FDA approval process and a six-month head start on additional generic marketers.

In many ways, the statute seems to have worked. A 1998 Congressional Budget Office (CBO) study found that savings to consumers from purchasing generic drugs in place of their more expensive branded counterparts amounted to between $8 and $10 billion from retail pharmacy sales alone in 1994.(14) Since the passage of the Hatch-Waxman Act, the generic drug share of U.S. prescription sales has grown from 19 percent in 1983 to over 40 percent in 1995.(15) There has also been an increase in the percentage of branded drugs that have a generic competitor on the market - nearly 100 percent of the top-selling drugs with expired patents have generic versions, compared to only 36 percent in 1983, (16) and generic share of prescription drug volume has increased by almost 150 percent since 1984.(17)

At the same time, the automatic stay provisions in Hatch-Waxman seem to have stimulated, or at least preserved, the incentives for pharmaceutical innovation. In recent years there has been a dramatic increase in innovation and the U.S. industry unquestionably leads the world.(18)

Balancing Conflicting Goals

The Hatch-Waxman Act, like most other laws, may also create perverse incentives and encourage behavior that can undercut its primary objectives. I will address these potential difficulties in a moment. But first, I would like to note that it is refreshing -- at least, to me -- to see a statute that so openly attempts to reconcile these two seemingly conflicting objectives: i.e., promotion of generic competition and preservation of incentives to innovate. Let me digress from the principal theme of this talk for a moment to put the patent settlement issue in a larger context.

The real world is a complicated place, and people have to balance conflicting goals all the time. Individuals and families have to resolve tradeoffs in budgeting matters -- for example, the balance between present consumption and future security. Business

enterprises face similar conflicts -- for example, when evaluating the costs and benefits of capital investments. And the need to strike a balance between potentially inconsistent objectives lies at the heart of our legal system -- particularly, the patent and antitrust laws, with which we are here most concerned.

Much has been said about the supposed conflicts between the patent and antitrust regimes but, if you think about it, they rest on similar intellectual foundations.(19) Both regimes recognize that present effects and future effects sometimes have to be weighed in the balance. The patent system grants investors a twenty-year monopoly and tolerates immediate consumer harm, based on the expectation that this incentive will stimulate innovation both in the industries involved and throughout the entire economy, for ultimate long-term benefit of consumers. Conversely, some antitrust cases (involving claims of predation) are premised on the theory that present consumer benefits, or at least the absence of present harm, may be outweighed by the potential for future exploitation by an entrenched monopoly.

If you add to these balancing elements the potential advantages and disadvantages of settling patent disputes, the issues become even more complex. Settlements can conserve public and private resources and eliminate uncertainty; they can also, depending on how they are structured, facilitate new entry. On the other hand, as discussed below, settlements can allow the holder of a possibly invalid patent to avoid the full rigors of competition by sharing monopoly profits with potential challengers.(20)

It is against this complex background of conflicting objectives, that we now move to a discussion of the Abbott/Geneva case.

3. The Abbott/Geneva Consent

Factual Background

The following "facts" are extracted from the complaint or the Analysis to Aid Public Comment.(21) Some of them might well have been challenged in court had the case been litigated but, since it was settled, they are the predicate for the Commission's order. Abbott Laboratories markets and sells the prescription drug Hytrin, the brand name for terazosin HCL. Hytrin is used to treat hypertension and benign prostatic hyperplasia ("BPH" or enlarged prostate). Both hypertension and BPH are chronic ailments affecting millions of Americans each year, many of them senior citizens.

In January 1993, Geneva Pharmaceuticals, Inc., an indirect wholly-owned subsidiary of Novartis Corp. and one of the leading generic drug manufacturers in the United States, filed an ANDA with the FDA for a generic version of terazosin HCL in tablet form. In December 1995, Geneva filed a similar ANDA for a generic version of terazosin in capsules. Geneva filed a Paragraph IV certification with the FDA for both ANDAs, which meant that Abbott had 45 days to initiate a patent infringement suit against Geneva and thereby invoke the Hatch-Waxman Act's 30-month stay of final FDA approval for the ANDAs.

On June 4, 1996, Abbott sued Geneva, claiming patent infringement by Geneva's generic terazosin HCL tablet product. Abbott mistakenly did not file suit against Geneva's

capsule terazosin HCL product, even though it raised the same potential infringement issues as the tablet product.

Abbott's lawsuit triggered the Hatch-Waxman Act 30-month stay of final FDA approval of Geneva's generic tablet ANDA, i.e., until December 1998. However, the FDA's review and approval process regarding Geneva's generic capsule product continued, because Abbott had failed to file a lawsuit within the 45 day window allowed in the Hatch-Waxman Act.

Geneva was confident that it would win its patent infringement dispute with Abbott, and planned to bring its generic capsule product to market as soon as possible after FDA approval. Geneva would then enjoy the Hatch-Waxman Act 180-day exclusivity period as the first ANDA filer for generic Hytrin capsules.

On the day that Geneva was granted FDA approval to market generic terazosin HCL capsules, Geneva contacted Abbott and announced that it would launch its generic capsules unless it was paid by Abbott not to enter.[22] Two days later, on April 1, 1998, Abbott and Geneva entered into an agreement pursuant to which Geneva agreed not to enter the market with any generic terazosin HCL capsule or tablet product until the earlier of: (1) the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, including review through the Supreme Court; or (2) entry of another generic terazosin HCL product.

Abbott agreed to pay Geneva $4.5 million per month until there was a district court judgment in the parties' patent infringement suit, and thereafter (assuming Geneva won before the district court), Abbott agreed to pay the $4.5 million monthly payments into an escrow fund until the final resolution of the litigation. Abbott would get the escrow funds back if the district court judgment was reversed, but the payments prior to judgment were irrevocable.

The $4.5 million in monthly payments were well over the estimated $1 to $1.5 million profits that Abbott believed that Geneva would forego by staying off the market. Abbott was willing to pay Geneva a "premium" to refrain from competing because of the substantial impact that launch of a generic version of Hytrin would have on Abbott's overall financial outlook. Abbott had forecasted that entry of a generic terazosin HCL on April 1, 1998 would eliminate over $185 million in Hytrin sales in just six months.

At Abbott's insistence, Geneva also agreed not to transfer, assign, or relinquish its 180-day exclusivity right. Since Geneva's agreement not to launch its product meant that the 180-day exclusivity period would not expire, the effect of this provision in the agreement was to ensure that no other company's generic terazosin HCL product could obtain FDA approval and enter the market during the term of the agreement.

The district court upheld Geneva's position that Abbott's patent was invalid, and the court of appeals affirmed in July of 1999. Geneva's agreement not to enter would not have terminated on its own terms, however, until disposition of the litigation by the Supreme Court. After Abbott and Geneva became aware of the Commission's investigation they did terminate their agreement in August of 1999. Geneva finally brought its generic terazosin HCL capsule product to market on August 13, 1999.

Theory of the Commission's Action

The Commission's complaint charges that the agreement prevented competition that Abbott's Hytrin product would otherwise have faced from generic products of Geneva and other potential generic competitors. As explained in the Analysis To Aid Public Comment, generic drugs can have a swift marketplace impact because pharmacists are permitted, and in some instances required, to substitute lower-priced generic drugs for their branded counterparts, unless the prescribing physician directs otherwise. Certain third-party payors of prescription drugs (*e.g.*, state Medicaid programs and many private health plans) encourage or insist on the use of generic drugs wherever possible. Abbott had forecast that generic terazosin HCL would capture roughly 70 percent of Hytrin sales within the first six months following its launch.

The Commission viewed the challenged conduct as an agreement not to compete between potential horizontal competitors. Geneva was viewed as a potential competitor because it had certified to the FDA that its entry with generic HCL would not infringe a valid patent, and was confident that it ultimately would prevail in its patent infringement dispute with Abbott. In fact, in early 1998, Geneva was making preparations to launch its generic terazosin HCL capsules as soon as possible. (Remember that Abbott had mistakenly not filed suit against the capsule product, so there was no automatic stay.)

The agreement also created a potential bottleneck that could delay entry by other potential generic competitors. Under the then-prevailing interpretation of the statute, this meant that no other ANDA filer could obtain FDA approval until Geneva's 180-day exclusivity period expired.[(23)] There were other companies developing generic terazosin HCL products, and at least one other generic manufacturer had satisfied the FDA's requirements for approval by February 1999, but was barred from entering the market because of Geneva's failure to launch its product.

Analysis of the Commission's Theory

The Commission's case, as outlined in the complaint and Analysis seems straightforward. But, had the case gone to trial, it would have been necessary to contrast the world that the parties created by the challenged agreement and the "but for" world that would have existed in the absence of the agreement. Here, matters become more complex. (For the purpose of this analysis, we may assume hypothetically that the proven facts are not necessarily the same as those stated above.)

An initial question is whether the legality of the contract should be judged by the facts as they appeared at the time the contract was made or in the light of hindsight, considering subsequent events. In this case, for example, generic entry was not delayed as long as it might have been because the agreement in question was terminated[(24)] when the Commission began its investigation. The law is clear - at least for injunctive actions, as opposed to actions for damages - that legality should be tested by the facts as they appeared when the contract was made.[(25)] But this issue can obviously affect an equity court's choice of remedies and, if a troublesome contract were terminated before a Commission investigation, it could have an impact on prosecutorial discretion.

The most difficult issue, for me, arises from the fact that a potentially anticompetitive incentive will be present in the vast majority of these patent settlement cases, and it is not at all easy to distinguish between the situations that are pernicious and those that are not-particularly, when the uncertain outcome of patent litigation is factored in. As stated in the factual background of the Abbott/Geneva case, Geneva's generic entry would have a negative impact on Abbott's expected profits considerably in excess of any positive impact that entry would have on Geneva's expected profits. This imbalance is likely to exist for many other drugs, as well. Generic entry will cause prices to drop sharply, and the resulting reduction in the monopoly profits of the pioneer manufacturer will far exceed the anticipated profits of the generic manufacturer in a more competitive market (with at least two suppliers). The profit imbalance also creates a significant incentive for a generic manufacturer to delay entry until a patent infringement suit is resolved because potential damages for infringement (measured by the pioneer's lost profits) will exceed profits for the entrant.(26) The fact that the entrant may not be able to pay these damages is a further complicating factor which can induce a pioneer manufacturer to settle, even if it is confident about its litigation prospects. This combination of factors creates an incentive for both parties to cooperate and share monopoly profits, but hostility to this incentive, carried to its logical extreme, would cast a cloud over all patent settlements.

To complicate matters further, the sharing of monopoly profits will be harmful to consumers in some situations and benign, or even helpful, in others. If the patent is valid, the pioneer manufacturer is entitled to its monopoly profit, and a settlement that merely transfers a portion of that profit to a potential generic manufacturer causes no harm. In fact, the sharing may be helpful if the revenue stream enables the generic manufacturer to become a more potent competitor when the patent expires. If the patent is invalid, however, the settlement can obviously cause consumer harm because it buys off a likely challenger and perpetuates a stream of improper monopoly profits.

The trouble with this distinction is that the Commission is extremely ill equipped to determine on its own whether patents are valid or not. Theoretically, it could decide the issue on the basis of the parties' own evaluations, as disclosed in internal documents or testimony.(27) In extreme cases, this might work - i.e., internal evidence might disclose that the pioneer manufacturer was just fighting a delaying action or that the potential generic competitor was just looking for a nuisance payoff. But, internal evidence is much more likely to be equivocal, and it is subject to manipulation anyway. Companies with sophisticated counsel can generate documents that are helpful either in patent litigation or in defense of a settlement.

Although it is not articulated in the Analysis, I believe that the Abbott/Geneva settlement ultimately is based on a standard that resembles the "less restrictive alternative" test, but with a very significant difference. The Commission focused on settlement terms -- like the so-called "reverse payments" from Abbott to Geneva and the ban on Geneva's waiver of 180-day exclusivity -- that went well beyond the provisions that would normally be contained in a stipulated temporary injunction.(28) In traditional antitrust analysis, however, the argument that an agreement went too far only comes into play if a particular transaction has already been demonstrated to have the potential both for anti-competitive harm and for pro-competitive efficiencies. The issue then is whether the parties could have achieved all, or most of the efficiencies by less restrictive means.(29)

In the drug settlement context, however, an assessment of potential competitive harms and benefits would really require a judgment on patent validity and, as indicated, that is an issue that the Commission cannot really decide. So, the Commission considered the less restrictive alternative issue up front, rather than at the end.

Assume hypothetically that there is a genuine issue of patent validity in a case like Abbott/Geneva and that the parties want to avoid the expense and risks of litigation. A less restrictive way to resolve the controversy might be to grant a license that would permit the generic manufacturer to market its product sometime before the expiration of the Hatch-Waxman stay.(30) This is not really an entirely adequate test by itself, however, because the pro-competitive benefits may be illusory. If the royalty rate is high, generic entry will not cause prices to fall dramatically and the holder of a perhaps invalid patent will continue to earn both supra-competitive profits and a royalty. As mentioned above, a risk averse generic manufacturer may decide that a bird in hand is better than two on the wing, even if the case for invalidity is sound. A settlement that accelerates generic entry will surely be viewed with less suspicion than a settlement that defers it, but I doubt that the Commission should declare a safe harbor.

There are comparable objections to declarations of per se illegality. Consider the reverse payments that flow from the patent holder to the potential generic challenger rather than the other way around. A settlement that includes these reverse payments may on its face look a lot more like a cynical bargain to share the spoils from a patent that both sides agree is invalid. However, there may be extenuating circumstances. Suppose both parties agree on a licensing solution, but the generic manufacturer is not yet ready to come to market and needs interim funds to get ready. Later entry coupled with some interim reverse payments and a lower royalty rate, may actually lead ultimately to stronger generic competition for the benefit of consumers. Presumptive strong suspicion of reverse payments may be justified, but at this stage I would hesitate to make the presumption conclusive.

An additional issue in the Abbott/Geneva case was the settlement provision that prohibited Geneva from waiving the 180-day exclusivity rights that it is granted under the Hatch-Waxman Act. The settlement agreement, coupled with the statutory scheme that recognizes Geneva's priority, thus had the effect of not only delaying Geneva's entry but also delaying entry by any other generic manufacturer. The anti-competitive potential is obvious. Again, however, it is possible to imagine situations where a waiver provision is justified on balance. The pioneer manufacturer may be more willing to negotiate a reasonable license with one generic manufacturer if it does not immediately have to deal with a number of others, and the waiver prohibition may actually accelerate entry by the first generic, although it delays entry by the others. So, again, I am not willing to make a presumption absolute.

Finally, an additional restraint prohibited by the order in Abbott/Geneva could be the most problematic of all. The order bars, without qualification, any agreement by the generic manufacturer that would prevent entry with a non-infringing version of the patented product.(31) Any attempt to extend the reach of a lawful patent monopoly beyond the boundary of the patent is subject to attack under traditional antitrust principles(32) and, in my view, presents issues that are less interesting. Any such broadly

drafted provision would be ill-advised standing alone,(33) and could well have an impact on the way the Commission views other provisions that are less obviously troublesome.

4. Practical Implications for Counselors

As the previous discussion indicates, the issues raised by pharmaceutical patent settlements are complex, fact intensive and not susceptible to hard-and-fast rules, at least at this stage. The most critical issue - namely, the question of patent validity - will vary from case to case and is not something that the Commission can comfortably evaluate in any event. Facts developed in the pending administrative case, involving Hoechst and Andrx, and in the proposed industry-wide study of the settlements may provide the opportunity for further elaboration of agency views. In the meantime, however, what practical advice can counselors give to their clients?

One place to start would be an examination of the consent order that was entered in Abbott/Geneva. Significant features of the order are the following:

> (1) Outright prohibition of agreements that (a) restrict the generic company's ability to waive its Hatch-Waxman 180-day exclusivity rights, and (b) restrict its ability to enter the market with a non-infringing product.(34) This unconditional ban obviously signals that the Commission views these two provisions as the most problematical. A ban in the context of an order, however, does not mean that the Commission regards the practice as per se illegal in a different factual context. I personally believe a restriction on non-infringing products would be extraordinarily hard to justify in any context. As said already, I am less certain that a restriction applicable to 180-day exclusivity waivers is always pernicious, but it does require careful thought. (35)
>
> (2) Interim settlement of patent litigation that involves payments to a generic company to delay entry are not banned outright, but must be approved by the court with an opportunity for the Commission to express its views.(36) The parties also must give the Commission notice of similar agreements in a non-litigation context.(37) For counseling purposes, a provision with reverse payments should raise a flag but does not signal that barriers are down. I personally think this is the right message at this time. The line between reverse payments and other benefits flowing to the generic manufacturer, like an earlier license or a reduced license fee, is too fuzzy for ironclad distinctions.

The requirement for court approval in this order raises the question of how much comfort other parties can derive from possible judicial approval of pharmaceutical patent settlements. Obviously, these parties would derive maximum comfort from a court-approved settlement that made specific findings in matters of potential competitive concern.(38) On the other hand, some courts might be reluctant to give what would in effect be an advisory opinion on matters about which the parties appear to be in agreement, and the parties may understandably be reluctant to suggest procedures that would invite comments from the Commission(39) or other interested generic

manufacturers. This is yet another issue on which I believe we are still feeling our way.

I have said very little up to now about the issue of intent, which is always important for counselors to explore. Mixed motives must be assumed in most cases. A genuine desire to reduce litigation risks (a benign objective) is likely to be mixed with the desire to perpetuate, or perhaps share in, monopoly returns (a less benign objective). Counselors also encounter mixed motives in other contexts; aggressive pricing, for example, may be prompted by an intent to respond to competitors who are themselves aggressive as well as by an intent to foreclose competition altogether. The resulting ambiguities on the evidence of intent have led courts to rely on more objective cost-based presumptions. Similar ambiguities here may justify reliance on the more objective indicia specifically mentioned in the Abbott/Geneva order - even though, like cost-based tests, they are imperfect.

It is, however, always desirable for counselors to inquire about basic business objectives up front, not only to identify potential problems but also to aid in consideration of possibly less troublesome routes to the same objective. Counselors would be well advised to note the provisions that were regarded as problems in Abbott/Geneva, to recognize that they are likely to raise questions in other settlements and to explore alternatives. Good lawyers have been doing the same thing for a long time in analogous situations - for example, by counseling that a long term supply agreement may be less risky than a joint venture, while providing all or most of the benefits. Legal risks are like costs that can offset the perceived benefits of a transaction, and clients should be encouraged to think about them in this way.

The legal risks associated with anticompetitive patent settlements can be very high. In Abbott/Geneva, the Commission issued a unanimous statement warning that in future cases it might seek additional remedies, including disgorgement of profits.[(40)] I am both unwilling and unable to predict the circumstances that would trigger any such draconian remedy. However, you should know that the Commission views the antitrust issues as very serious.

In pharmaceutical patent settlement cases, the harm can be immense and immediate. For this reason, potential violations are likely to be pursued far more widely and aggressively than they have been up to now. At the Commission, we are barely embarked on the process, but it will go forward. We welcome your views, as we go along.

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1. I wish to acknowledge the assistance of attorney advisor Holly Vedova in the preparation of this speech. I take sole responsibility, however, for the opinions expressed.

2. Abbott Labs. and Geneva Pharms., Inc., Docket No. C-3945 (2000).

3. Hoechst Marion Roussel, Inc., Docket No. 9293 (administrative complaint filed Mar. 16, 2000).

4. *See* 65 Fed. Reg. 61334 (Oct. 17, 2000).

5. The Commission also recently confirmed that it is investigating an agreement between Bristol-Myers-Squibb, Co. and American Bioscience, Inc., regarding the cancer drug Taxol. *See* FTC Press Release entitled, *FTC to Study Generic Drug Competition,* dated October 11, 2000, *available at:*

<http://www.ftc.gov/opa/2000/10/genericdrug.htm> As this matter is currently under investigation, I will also not discuss it any further.

6. 21 U.S.C. §§ 301 *et seq.* (1999).

7. 21 U.S.C. §355(a) (1999).

8. H.R. Rep. No. 98-857 (I), 98th Cong., 2d Sess. at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647-48.

9. 21 U.S.C. §355(j) (1999).

10. The FDA's Orange Book (officially entitled "Approved Drug Products with Therapeutic Equivalence Evaluations") lists all approved drugs and related patents for each drug. 21 U.S.C. §355(j)(7)(A)(iii) (1999). The FDA obtains this information from NDA applicants, which must include information on any patent covering the drug, any method of using the drug for treatment of disease, or any method of delivery of the drug, for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. §355(b)(1) (1999).

11. 21 U.S.C. §355(j)(2)(A)(vii)(IV) (1999).

12. 21 U.S.C. §355(j)(5)(B)(iii) (1999).

13. 21 U.S.C. §355(j)(5)(B)(iv) (1999).

14. Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, ch. III, at 1, 20 (July 1998). *See also* David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks,* 55 Food and Drug L.J. 325 (Fall 2000).

15. Congressional Budget Office, *supra* note 14 at Ch. III,1.

16. *Id.* at 5.

17. *Id.* at 27.

18. Almost half of all new medicines in the world are discovered by U.S. companies. *See* Pharmaceutical Research and Manufacturers of America, *Fact Sheet*, December 1999, *available at:* <http://www.phrma.org/publications/backgrounders/world/12_global.phtml>.

19. For a more detailed discussion of this topic, *see* Thomas B. Leary, Commissioner, Federal Trade Commission, *Antitrust Law as a Balancing Act*, Prepared Remarks Before Tenth Annual Seattle Computer Law Conference (Dec. 17, 1999), *available at:* <http://www.ftc.gov/speeches/leary/leary991217.htm>.

20. The FDA has expressed concern about private agreements arising in the context of the Hatch-Waxman Act, and has observed that the incentives for companies to enter into such arrangements are becoming greater, as the returns to the brand name company from extending its monopoly increasingly exceed the potential economic gains to the generic applicant from its 180-day market exclusivity. *See* FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42882-83 (to be codified at 21 C.F.R. pt 314.107)(proposed Aug. 6, 1999).

21. The Analysis to Aid Public Comment, issued simultaneously with the complaint and the agreed-on settlement terms, is designed to elaborate on the Commission's underlying theories.

22. Abbott could, of course, still pursue a patent infringement claim against the generic capsules, but it would not get an automatic stay.

23. 21 U.S.C. §355(j)(5)(B)(iv)(II) (1999). The FDA has proposed a new rule that would allow subsequent ANDA filers to trigger the 180-day exclusivity period in certain circumstances. *See* FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873 (to be codified at 21 C.F.R. pt. 314.107)(proposed Aug. 6, 1999).

24. Note that termination occurred only one month after the court of appeals had affirmed a finding of patent invalidity. In litigation, the parties might have claimed that the parties would likely have terminated the agreement after this appellate decision anyhow, and thus the delay would have been minimal in the "but for" world.

25. *See e.g.,* John D. Calamari and Joseph M. Perillo, *Contracts*, Third Edition, §9-31 (1987)(general rule of contract interpretation is that courts will consider the intentions of the parties at the time they made their agreement).

26. Note also that entry by the generic manufacturer will start the running of its 180-day period of exclusivity, 21 U.S.C.§355(j)(5)(B)(iv) (1999). This can supply an additional motive for the generic manufacturer to delay entry until the infringement suit is resolved.

27. Note that initiation of an infringement suit with knowledge that the patent is invalid, may be attacked as an antitrust violation by itself, regardless of the settlement terms. *See, e.g.,* Handgards, Inc. v. Ethicon, Inc., 743 F.2d 1282 (9th Cir. 1984), *cert. denied*, 469 U.S. 1190 (1985).

28. *See* Sheila F. Anthony, Commissioner, Federal Trade Commission, *Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property*, Remarks Before the ABA "Antitrust and Intellectual Property: The Crossroads" Program, San Franscisco, CA (June 1, 2000), *available at:* <http://www.ftc.gov/speeches/anthony/sfip000601.htm>. Payments in settlement would normally be expected to flow from the alleged infringer to the patent holder; in Abbott/Geneva, the patent holder paid the alleged infringer. Moreover, the ban on Geneva's waiver expands on the temporary restraints provided by the statute.

29. *Cf.* United States Department of Justice and Federal Trade Commission, Guidelines for Collaborations Among Competitors, §3.36 (April 7, 2000), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶13,160.

30. In the actual Abbott/Geneva case, there was no stay applicable to the generic capsule product, which Abbott had inadvertently failed to challenge in a timely manner. However, this highly idiosyncratic fact should not be outcome-determinative by itself. Abbott might still get a preliminary injunction from a court and even if it did not Geneva might decide to avoid risk by settling for a license rather than entering before patent validity had been decided.

31. Abbott Labs. and Geneva Pharms., Docket No. C-3945, Consent Order at ¶ 2 (2000).

32. *Cf.* Brulotte v. Thys Co., 379 U.S. 29, 33 (1964) (it is patent misuse to "enlarge the monopoly of the patent" by collecting post expiration royalties).

33. I do not believe a provision of this kind can be justified as an ancillary restraint, merely because it is part of a larger agreement. *Cf.* NCAA v. Board of Regents, 468 U.S. 85 (1984).

34. Abbott Labs. and Geneva Pharms., Inc., Docket No. C-3945, Consent Order at ¶ 2 (2000).

35. There have been suggestions for modification of the Hatch-Waxman 180-day exclusivity rights in order to reduce the first generic's ability to forestall entry by others. The FDA has proposed to amend its rules by placing a time limit (180 days) on when the first-filed ANDA applicant must trigger its rights to obtain the 180-day marketing exclusivity period and by clarifying which applicants are eligible for the 180-day marketing exclusivity. *See, e.g.*, FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873 (to be codified at 21 C.F.R. pt. 314.107)(proposed Aug. 6, 1999). I express no opinion on these proposals but, if adopted, they obviously

could have an impact on the antitrust analysis of a settlement agreement because they would change the "but for" world. They also could change the incentives of parties to enter into settlement agreements.

36. Abbott Labs. and Geneva Pharms., Inc., Docket No. C-3945, Consent Order at ¶ 3 (2000).

37. *Id.* at ¶ 4.

38. *Cf.* the doctrine of collateral estoppel, or issue preclusion, which bars the relitigation of issues actually adjudicated and essential to the judgment in a prior suit between the same parties. *See* Edward I. Niles, *Federal Civil Procedure*, §2.152 (1984).

39. *See* Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, *In the Matter of 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications,* FDA Docket No. 85N-0214 (Nov. 4, 1999), *available at*: <http://www.ftc.gov/be/v990016.htm>. An alternative risk in some circumstances would be government involvement as *amicus curiae. See* brief of Federal Trade Commission as amicus curiae in American Bioscience, Inc. v. Bristol-Myers Squibb Co., et al., Case No. CV-00-08577 U.S. Dist. Ct., Central Dist., Ca., W. Div., Sept. 1, 2000.

40. Abbott Labs. and Geneva Pharms., Docket No. C-3945 (2000)(Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle and Thomas B. Leary).

UNITED STATES OF AMERICA
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

ORDER GRANTING HOECHST MARION ROUSSEL, INC.'S MOTION IN LIMINE TO EXCLUDE EVIDENCE OR ARGUMENT THAT THE STIPULATION AND AGREEMENT IS ILLEGAL *PER SE*

IT IS HEREBY ORDERED that Respondent Hoechst Marion Roussel, Inc.'S Motion in Limine to Exclude Evidence or Argument That the Stipulation and Agreement Is Illegal *per Se* is hereby GRANTED.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: November __, 2000

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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

CERTIFICATE OF MAILING

I, Peter D. Bernstein, hereby certify that on November 16, 2000, a copy of Hoechst Marion Roussel, Inc.'S Motion *in Limine* to Exclude Evidence or Argument That The Stipulation and Agreement Is Illegal *per Se* was served upon the following persons by hand delivery and/or Federal Express as follows:

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

Richard Feinstein
Federal Trade Commission
601 Pennsylvania Avenue, N.W., Room 3114
Washington, D.C. 20580

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

Markus Meier
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