

Per Se Antitrust Risks in Hatch-Waxman Agreements

Federal Trade Commission and Department of Justice Hearings on the Implications of
Competition and Patent Law and Policy

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PRELIMINARY STATEMENT

Agreements between brand name pharmaceutical companies and potential generic entrants that purport to settle patent litigation have been the subject of much antitrust scrutiny over the last several years. These agreements, referred to as “Hatch-Waxman Agreements,” share several commonalities: (1) Each occurred in the context of patent litigation between branded and generic pharmaceutical companies that arose under the complex regulatory provisions of the Hatch-Waxman Act.¹ (2) Each involved substantial payments from the brand name incumbent to the potential generic entrant. (3) Each involved the potential generic entrant agreeing to stay off the market for a defined period of time.

Since March 2000, the Federal Trade Commission has announced three prosecutorial actions involving Hatch-Waxman Agreements, two of which were resolved by consent decrees,² and the third is pending currently in administrative litigation.³ Similarly, two federal district courts have invalidated – under a per se theory – three Hatch-Waxman Agreements (both cases

¹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 301-397 (2001)). The details of the Hatch-Waxman Act are beyond the scope of this presentation. For a useful summary of the pertinent provisions of the Hatch-Waxman regulatory regime, see, e.g., Balto, “Pharmaceutical Patent Settlements: The Antitrust Risks,” 55 Food & Drug LJ 321 (2000).

² FTC v. Hoechst Marion Roussel, Inc., Carderm Capital L.P. and Andrx Corp., Docket No. 9293 (consent order issued May 8, 2001) (FTC Commission Actions: May 11, 2001 (www.ftc.gov)) (referred to as “Hoechst-Andrx”); and Abbott Laboratories and Geneva Pharmaceuticals, Inc., C-3945, C-3946 (consent orders issued May 22, 2000) (FTC Commission Actions: May, 26, 2000 (www.ftc.gov)) (referred to as “Abbott-Geneva”).

³ Schering-Plough Corp. Upsher-Smith Laboratories, and American Home Products Corp., Docket No. 9297 (complaint issued April 2, 2001) (FTC Commission Actions: April 2, 2001 (www.ftc.gov)) (referred to as “Schering”). Note that, as part of this matter, American Home Products and its subsidiary ESI Lederle signed a consent agreement with the FTC.

have been appealed);⁴ and at least two other federal district court cases are pending that also involve challenges to Hatch-Waxman Agreements.⁵

Taken together, these actions have identified two principal fact patterns related to Hatch-Waxman Agreements that are particularly problematic under the antitrust laws: (1) a brand manufacturer paying a potential generic to stay off the market and (2) agreements with collateral restraints that go well beyond any countervailing justification. Some have argued that these identified problems do not render the Hatch-Waxman agreements per se unlawful because the agreements have two offsetting procompetitive justifications: (1) each purports to either partially or fully settled patent litigation, and (2) with exception of the agreement between Abbott and Geneva, each has allowed for entry by the generic at a date earlier than patent expiration.

Both the FTC and the courts have thus far limited their analysis of any one agreement to the facts pertaining only to that agreement. So two fundamental questions remain unanswered regarding the proper antitrust analysis (per se or rule of reason)⁶ to apply to variants of the agreements already considered: (1) Does a per se analysis properly apply to all, some, or none of these agreements? (2) If some are treated as per se unlawful and others are analyzed under the rule of reason, what are the factors that distinguish their analytical treatment?

These questions are the focus of this presentation. In the following outline, given the current Hatch-Waxman antitrust landscape, I propose five principles that I see as governing the

⁴ In re Cardizem CD Antitrust Litigation, 105 F. Supp. 2d 682 (E.D. Mich. 2000) (on appeal to the Sixth Circuit); In re Terazosin Hydrochloride Antitrust Litigation, 164 F. Supp. 2d 1340 (S.D. Fla. 2000) (on appeal to the Eleventh Circuit).

⁵ Private plaintiffs have challenged the same agreements involving Schering, Upsher-Smith, and ESI Lederle that are at issue in the FTC case. Suits have also been filed challenging an agreement between Bayer A.G. and Barr Laboratories, Inc. A federal district court has issued a decision in this case, which provides a factual background of the Hatch-Waxman Agreement at issue. See, In re Ciprofloxacin Hydrochloride Antitrust Litigation, 166 F. Supp. 2d. 740 (E.D.N.Y. 2001).

⁶ In this presentation, I use the term “per se illegal” to mean conclusively unlawful. The term “rule of reason” is used to indicate that a situation merits a more searching inquiry than that of a per se analysis.

analytical treatment of varying Hatch-Waxman Agreements. These principles either stem from the explicit analytical approaches proffered by the FTC and federal courts in their treatment of these agreements or are, in my view, logical extensions of such analyses. Depending on the outcome of the Schering case as well as the Hoechst-Andrx and Abbott-Geneva appeals pending in the 6th and 11th Circuits, these principles may ultimately be corroborated, modified, or rejected.

I also set forth in the following outline a brief summary of antitrust principles applicable to intellectual property and summaries of existing Hatch-Waxman cases. I conclude with some observations on how to minimize antitrust risks in any future Hatch-Waxman Agreement.

OUTLINE OF POINTS

I. First Principles of Antitrust Analysis and Intellectual Property

- A. Intellectual property should be treated no differently than other forms of property under the antitrust laws.
- B. Licensing is generally procompetitive and will in most cases be analyzed under the rule of reason.
- C. Notwithstanding the public policy considerations that favor settlement of litigation, e.g., conservation of scarce judicial resources, settlements, including those involving patent litigation, are not immune from antitrust scrutiny.
- D. This is not news. See, e.g., United States v. Singer Manufacturing Co., 374 U.S. 174 (1963).

II. Summary of Recent Actions Regarding Hatch-Waxman Agreements⁷

A. Hoechst⁸-Andrx

a. Key Facts:

- Andrx was the first to file an Abbreviated New Drug Application (“ANDA”) with the FDA to market a generic version of Hoechst’s Cardizem CD. As such, Andrx secured the 180-day exclusivity right, as provided by the Hatch Waxman Act. Hoechst sued Andrx for patent infringement.
- Hoechst and Andrx entered into an agreement that purported to settle a preliminary injunction (which Hoechst had allegedly threatened, but not filed) and had the following relevant provisions:
 - Andrx agreed to stay off the market from July 1998 until at least January 2000, when Andrx could exercise an option to

⁷ Note that these summaries are based on the facts set forth in public FTC documents (primarily complaints and consent decrees), as well as those in the federal court decisions. Also note that the summaries are confined to only those facts relevant to the principles addressed in the next section of this outline.

⁸ Hoechst, which stands for Hoechst Marion Rousell, Inc., was the predecessor to Aventis Pharmaceuticals.

license Hoechst's IP. Andrx had the discretion to stay off the market longer, until the patent suit was finally resolved.

- Until it marketed a product, Andrx was paid \$40 million a year, starting in July 1998. If it won the patent suit, it was paid retroactively another \$60 million a year during the time in which it stayed off the market.
- Andrx agreed not to relinquish its exclusivity right, preventing other generic competitors from entering the market (if their products were approvable) ("relinquishing restraint"). Andrx also agreed not to market any generic version of Cardizem CD, even if non-infringing ("non-infringing restraint").

b. FTC Allegation and Consent:

- Allegation – The agreement as a whole, and in particular the relinquishing and non-infringing restraints, "constitute unreasonable restraints of trade in violation of Section 5" of the FTC Act. This allegation is broad enough to encompass per se theories.
- Consent – Neither Hoechst nor Andrx can enter into an agreement with a relinquishing restraint or with a non-infringing restraint (except in certain licensing situations). Nor can either party enter a partial settlement where a generic competitor is paid to stay off the market (except if approved by a Court and with notice to the FTC).

c. Federal Court Decision:

- Holding – The Agreement "allocates the entire U.S. market for Cardizem CD and its bioequivalents to [Hoechst] for the life of the Agreement. Accordingly, this Court concludes that it is a naked horizontal market allocation . . . and thus per se illegal." In re Cardizem CD Antitrust Litigation, 105 F. Supp. 2d at 705-06.
- Rejection of Justifications – Hoechst and Andrx advanced three procompetitive justifications for their agreement: (1) it settled a preliminary injunction action, (2) protected Hoechst's patent rights, and (3) allowed Andrx to come on the market earlier than patent expiration. The Court rejected these because the agreement was broader than each purported justification and that

the main thrust of the Agreement was to block generic competition. Id. at 705.

B. Abbott-Geneva

a. Key Facts:

- Geneva was the first to file an ANDA to market a generic version of Abbott's Hytrin. As such, Geneva was awarded the 180-day exclusivity right. Abbott sued Geneva for patent infringement.
- Abbott and Geneva entered into an agreement that purported to settle a preliminary injunction (which Abbott had allegedly threatened, but not filed.) Under the agreement, Geneva was precluded from marketing its generic version of Hytrin until final resolution of the patent litigation and, in return, was paid \$54 million a year (for the time it stayed off the market). Like the Hoechst-Andrx agreement, this agreement also included a relinquishing restraint and a non-infringing restraint.
- Zenith also filed an ANDA to market a generic version of Hytrin. Zenith sued Abbott for wrongful patent listing in the FDA's Orange Book, and Abbott counterclaimed alleging patent infringement. The two parties fully settled their litigation. Under their settlement, Abbott agreed to pay Zenith \$6 million a quarter in return for Zenith's agreeing not to market a generic version of Hytrin until another generic version of Hytrin went to market or until the expiration of Abbott's patents.

b. FTC Allegations and Consent:

- Allegation – The agreement as a whole, and in particular the relinquishing and non-infringing restraints, “constitute unreasonable restraints of trade in violation of Section 5” of the FTC Act. This allegation is broad enough to encompass per se theories.
- Consent – Neither Abbott nor Geneva can enter into an agreement with a relinquishing restraint or with a non-infringing restraint. Nor can either party enter a partial settlement where a generic competitor is paid to stay off the market (except if approved by a Court and with notice to the FTC).

c. Federal Court Decision: The Court held that Abbott's agreements with Geneva and Zenith were illegal per se because each was “an agreement

between competitors at the same level of the market structure to allocate territories in order to minimize competition.” In re Terazosin Hydrochloride Antitrust Litigation, 164 F. Supp. 2d at 1349 (citing Topco Assocs., Inc., 405 U.S. 596, 608 (1972)).

C. Schering

a. Key Facts:

- Upsher-Smith filed an ANDA to market a generic version of Schering’s K-Dur 20. As such, Upsher-Smith was awarded the 180-day exclusivity right. Schering sued Upsher-Smith for patent infringement.
- On the eve of trial, in June 1997, Schering and Upsher-Smith entered into an agreement that fully settled the parties’ patent litigation. Under the agreement, Upsher-Smith was precluded from marketing any generic version of Schering’s K-Dur 20 until September 2001. Also under the agreement, Upsher-Smith was paid \$60 million.
- ESI also filed an ANDA to market a generic version of Schering’s K-Dur 20 and was sued by Schering for patent infringement. By January 1998 Schering and ESI had agreed to settle their suit under the following terms: ESI would not market its generic version of K-Dur 20 until January 2004 and would receive up to \$15 million for staying off the market (and another \$15 million in return for several licenses).

b. FTC Allegations and Consent:

- Allegations – The FTC alleged that Schering’s agreements with both Upsher-Smith and ESI unreasonably restrained commerce and therefore constituted an unfair method of competition, in violation of Section 5 of the FTC Act. These allegations are broad enough to encompass per se theories.
- Consent – The FTC has settled only with ESI. Under the terms of this settlement, ESI cannot enter into a Hatch-Waxman Agreement with a non-infringing restraint. Nor can it enter a full settlement where the generic is paid to stay off the market (except if approved by a court and with notice to the FTC).

D. Bayer-Barr

a. Key Facts:

- Barr filed an ANDA to market a generic version of Bayer's Cipro. Bayer sued Barr for patent infringement.
- Bayer and Barr entered into an agreement settling their patent litigation. Under the agreement, Barr agreed not to market a generic version of Cipro until the patent at issue expired. Also under the agreement, Bayer paid Barr an initial lump-sum payment of \$24.55 million. Bayer was also obligated either to pay Barr \$25 million a year from March 1998 to December 2003 or to permit Barr to market its generic version of Cipro under a license. At least through October 2001, Bayer elected to pay Barr the \$25 million per year.

- b. Court Decision: A federal district court considering the issue of removal found that challenges to the agreement did not depend on whether Bayer's patent was valid or infringed. Specifically, in the suit, "the plaintiffs claim defendants violated state antitrust laws by depriving them of their right to a market in which manufacturers and distributors of generic drugs made their decisions about challenging patents and entering markets free from the influence of cash payments amounting to unreasonable restraints of trade." *Id.* at 749. The resolution of this issue does not depend on whether a valid patent was infringed.

III. *Five Principles Regarding the Antitrust Analysis of Hatch-Waxman Agreements*

- A. Any Hatch-Waxman Agreement in which a generic first-filer (with the 180-day exclusivity right) agrees not to relinquish its exclusivity right should be deemed per se illegal.
- a. Reason for per se illegality: Such an agreement (or a provision) has no countervailing justification and therefore is a naked restraint. Moreover, it has the potential to cause significant anticompetitive effects, as the generic first-filer will be the "cork in the bottle" precluding all generic entry into a market.
- b. This provision was included in both the Hoechst-Andrx and Abbott-Geneva agreements.

- B. Any Hatch-Waxman Agreement in which a generic competitor agrees not to market any generic version of a brand-name company's product, even a non-infringing version, should be deemed per se illegal.
- a. Reason for per se illegality: Such an agreement (or a provision) has no countervailing justification and therefore is a naked restraint. If the parties are settling patent litigation, there is no justification for precluding a generic manufacturer from marketing other products that do not face a patent claim. Such a naked market allocation between actual or potential competitors outside the scope of patent protection is per se unlawful under Palmer v. BRG of Georgia, Inc., 498 U.S. 46 (1990) and Topco.
 - b. Such a provision was included in the Hoechst-Andrx, Abbott-Geneva, and Schering-Upsher agreements.
- C. Any Hatch-Waxman Agreement where the incumbent pays the generic more than nominal consideration for staying off the market should be deemed per se illegal.
- a. Reason for per se illegality: There is only one plausible justification for a patent settlement agreement whereby a generic competitor agrees to stay off the market – the agreed upon time of generic entry reflects the actual merits of the brand manufacturer's and generic entrant's positions in the attendant patent litigation. For example, if a brand manufacturer sues a generic for patent infringement with regard to a patent that will expire in 10 years, and each party to the suit believes it has a 50 percent chance of winning, any agreement settling the suit should allow the generic entrant on the market in no more than 5 years. In such an agreement, it would be irrational for the brand to pay the generic more than nominal consideration unless it was in compensation for the generic to stay off the market longer than the merits of its suit would otherwise dictate. But for the payments, the generic would likely be on the market sooner. The payments, then, bear no relationship to any plausible justification, rendering the agreement per se illegal.
 - b. Allowing for nominal consideration is reasonable because it relates to the procompetitive justification of settling suits and saving resources.
 - c. This is the theory Complaint Counsel is pursuing administratively in the Schering case. It also appears to be the theory the plaintiffs are pursuing in the Ciprofloxican litigation.
 - d. Factual issues to consider:

- Nominal consideration in this context means consideration that approximates what the parties would spend in prosecuting/defending their suit. A payment is not nominal if: (1) it greatly exceeds the cost of litigation or (2) it provides the generic with enough of an incentive to stay off the market longer (e.g., if it approximates a substantial percentage of what the generic would make if it were to market its product). In the Schering case, Complaint Counsel has suggested in its Proposed Order that \$2 million would suffice as nominal consideration, at least in the context of that case.
- Consideration need not take the form of direct payments to the generic to be problematic. Payments may be masked (as is the theory in Schering). Consideration may also take the form of something other than money provided to the generic. It can include anything of value given to the generic that provides an incentive to stay off the market (e.g., a license to market another product).
- Future investigations in this area could explore, in the context of a Hatch-Waxman Agreement, whether a generic manufacturer was given consideration to stay off the market. This could involve examining business relationships between the two settling firms, including when the relationships were formed relative to the patent settlement, how they were formed, and the consideration extended both parties in each of the relationships.

D. Even without a relinquishing restraint, a non-infringing restraint or payment of more than nominal consideration to the generic, any Hatch-Waxman Agreement where a generic first-filer (with the 180-day exclusivity right) agrees to stay off the market may be illegal if it has the actual or reasonably likely effect of delaying other generics from entering. The analysis here would be rule of reason.

- a. Rationale for the rule of reason inquiry: In this circumstance, the generic firm is not paid consideration and therefore the time in which it agrees to enter the market may approximate the merits of its position in the patent litigation. Without exploring the possible anticompetitive effects of such an agreement, one cannot presume (as with a per se theory) that the agreement provided the generic an incentive to stay off the market longer than the merits of the patent litigation would otherwise dictate. On a cautionary note, if the generic agrees to stay off the market for a significant amount of time and retains its exclusivity right, a presumption may arise that the possibility of the generic losing its right of exclusivity (which would happen if it lost the patent infringement suit) may have

given it an incentive it to stay off the market longer than the merits of the patent litigation would otherwise dictate. This could be anticompetitive.

- b. Such an agreement would likely be closely scrutinized and possibly challenged if other potential generic entrants would be blocked from entering the market as a result of the first-filer's exclusivity right.
- E. A Hatch-Waxman Agreement (without a non-infringing restraint) where the potential generic entrant that does not have the 180-day exclusivity right is allowed to enter at a date in the future (and is not paid more than nominal consideration) will likely not merit a challenge and, in any event, should be analyzed under a rule of reason.
- a. Rationale for the rule of reason inquiry: Under this agreement, the potential generic entrant will not have an effect on third-party entrants (as might a generic first-filer with the exclusivity right) and will not have an incentive to stay off the market any longer than its position in the patent litigation would otherwise dictate. This is competitively neutral.

IV. Suggestions for Minimizing Legal Risks Arising from Hatch-Waxman Agreements

- A. Avoid substantial "reverse payments" from an incumbent to a potential generic entrant.
- B. Avoid collateral restraints in any agreement that do not reasonably relate to a legitimate justification for entering the agreement. Two examples would be the relinquishing and non-infringing restraints discussed above.
- C. If a settlement agreement involves a generic first-filer with the 180-day exclusivity right agreeing to stay off the market for any period of time, consider having the generic firm relinquish its right to exclusivity.
- D. Seek judicial approval of a settlement agreement. While this may be difficult in the context of a final settlement (as it is not clear that a court will view itself as having jurisdiction to approve a private agreement to dismiss a lawsuit), it is more feasible in the context of interim agreements. Moreover, submission of the agreement for a court's approval may, under certain circumstances, strengthen Noerr-Pennington defenses, provided that such approval is obtained. If such approval is unavailable, consider seeking an advisory opinion from the Federal Trade Commission or its staff.