

Recent Court Rulings Indicate That Patent Rights May Trump the Antitrust Laws

BY CHAD A. LANDMON

Chad A. Landmon is an associate at Axinn, Veltrop & Harkrider, LLP, where his practice involves patent and other intellectual property litigation and counseling, including antitrust and FDA aspects thereof. He can be reached at (860) 275-8100 or cal@avhlaw.com.

Over the past decade, practitioners, policymakers and commentators have increasingly debated the issues involved when the antitrust laws intersect with patent rights. Both the antitrust and patent laws are designed to promote competition and, as a result, societal wellbeing. However, the two legal regimes attempt to accomplish this goal through alternative means – the antitrust laws seek to reduce market power and eliminate most monopolies, while the patent laws seek to bestow certain exclusive rights in order to encourage research and innovation. As such, there can be friction between the antitrust and patent laws in certain unique circumstances.

Perhaps nowhere is this more prevalent than in the pharmaceutical industry. Over the last century, brand name drug companies have developed a plethora of new drugs and dosage forms, improving the overall health of society. Such innovation has been possible, in part, because of the patent laws, which give brand companies a period of time in which they are the exclusive supplier of the new drugs they create. This exclusive market right has provided an incentive to brand companies to invest the substantial resources necessary to discover and develop new drugs, often requiring tens of millions of dollars over a long period of time.

Although these patent rights have certainly fueled expansive development in the pharmaceutical industry, such patents have also been the basis for agreements that potentially threaten competition. For example, brand companies have entered into agreements with potential generic entrants, typically structured as settlements of patent infringement litigation, in which the brand companies have paid significant sums of money to generic companies in exchange for a delay in market entry. Such payments have been called “reverse payments” because the flow of funds is opposite of that

usually seen in patent infringement settlements, where the infringer typically pays money to the patent holder. These agreements have been challenged under the antitrust laws by both the Federal Trade Commission (“FTC”) and private plaintiffs, resulting in financial settlements and other restrictions upon the companies who entered into these agreements.¹

Recently, two different Circuit Courts of Appeals – the Eleventh and Second Circuits – considered antitrust challenges to patent infringement settlements involving reverse payments. In both of these cases, *Schering-Plough Corp. v. FTC* (hereinafter, “*Schering*”)² and *Joblove v. Barr Labs. Inc. (In re: Tamoxifen Citrate Antitrust Litig.)* (hereinafter, “*Tamoxifen*”),³ the courts determined that the agreements at issue did not violate the antitrust laws because the provisions of the agreements, including the reverse payments and delay in generic entry, did not exceed the “exclusionary potential” of the brand company’s patent.

As discussed more fully below, the Eleventh and Second Circuits recognized that the patent laws and antitrust laws are in conflict in these circumstances. In resolving this conflict, both courts came out strongly in favor of patent rights, allowing patent holders to engage in virtually any activity within the exclusionary power of a patent. Furthermore, neither court evaluated the merits of the underlying patent infringement claim in reaching its holding. Unless the Supreme Court intervenes or Congress acts, the legal community and policymakers at the FTC may need to adjust their approaches in recognition of the fact that at least the Eleventh and Second Circuits will give patent rights priority over the antitrust laws.

SCHERING – CONFIRMING THE “EXCLUSIONARY POTENTIAL” TEST

In 1995, Upsher-Smith and ESI Lederle sought FDA approval to market generic versions of Schering’s K-Dur 20 potassium supplement. Schering brought suit for infringement of its patent on the extended-release coating for the product, which will expire in September 2006.

In 1997, Schering settled with Upsher, agreeing to permit Upsher to launch as early as September 1, 2001. In the settle-

ment, Schering agreed to pay \$60 million to Upsher (and future royalties) in exchange for a license to market Upsher’s Niacor product outside North America. In 1998, Schering settled with ESI, agreeing on a January 1, 2004 entry date for ESI. In addition, Schering agreed to pay ESI \$5 million, with another \$10 million payment contingent upon ESI receiving FDA approval by a certain date. Schering and ESI also entered into a license agreement pursuant to which ESI granted Schering licenses to enalapril and buspirone in exchange for \$15 million. In both settlements, the agreed generic entry dates were earlier than the expiration of Schering’s K-Dur 20 patent.

The FTC filed an administrative complaint against Schering, Upsher and ESI parent American Home Products (“AHP”), alleging that the settlements were illegal agreements in restraint of trade. Specifically, the FTC alleged that the settlement agreements unreasonably restrained trade in violation of Section 1 of the Sherman Act⁴ and Section 5 of the Federal Trade Commission Act.⁵ AHP entered into a consent decree, but the legality of the ESI settlement with respect to Schering was still at issue. An Administrative Law Judge ruled that the settlements did not violate the antitrust laws, finding that the presence of payments was not anticompetitive *per se*. The ALJ indicated that the strength of the patent and its exclusionary power needed to be assessed in a rule of reason analysis.

On December 8, 2003, the Commission reversed the decision, first determining that the payments were not legitimate consideration for the Schering licenses. The Commission then stated that earlier entry dates might have been agreed upon in the absence of the payments. Although not finding the reverse payments *per se* illegal, the Commission found them to be “red flags” and declined to consider the strength of the patent. Ultimately, the FTC order prohibited the parties from entering into settlements in which a generic company: (i) receives anything of value (in excess of the expected legal fees of the patentee, not to exceed \$2 million); and (ii) agrees to defer its own research, development, production or sales activities.

The parties petitioned for review before the Eleventh Circuit. In vacating the order involving Upsher, the court applied the substantial evidence standard set forth in *California Dental Ass’n v. FTC*,⁶ and determined that the Commission’s “conclusion that Niacor was not worth \$60 million, and that settlement payment was to keep Upsher off the market ‘is not supported by law or logic.’”⁷

In vacating the order involving ESI, the court affirmed its holding in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*⁸ Although the *Valley Drug* court conceded that an agreement to allocate markets is “clearly anticompetitive,” the court reasoned that a patent conveys an exclusionary power that requires primary consideration. The *Schering* court explained:

We think that neither the rule of reason nor the *per se* analysis is appropriate in this context. We are bound by our decision in *Valley Drug* where we held both approaches to be ill-suited for an antitrust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market. . . . By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present. What is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects. . . . Therefore, in line with *Valley Drug*, we think the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.⁹

At the same time, the Eleventh Circuit reaffirmed that patentees may not extend their monopoly beyond the scope of the patent. For example, a patent owner who knows a patent is invalid may not use the patent to mask otherwise anticompetitive conduct, such as market division.

Following *Valley Drug* and Judge Posner’s decision in *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.* (hereinafter, “*Asahi Glass*”),¹⁰ the Eleventh Circuit also reasoned that reverse payments should not be inherently suspect because they are a “natural by-product” of the Hatch-Waxman regulatory regime,¹¹ which allows for the patent issues to be litigated prior to generic entry. Thus, “ESI and Upsher gained considerable leverage in patent litigation: the exposure to liability amounted to litigation costs, but paled in comparison to the immense volume of generic sales and profits.”¹² Under the FTC’s approach, which largely ignored the exclusionary power of the patent, the Eleventh Circuit expressed concern that patent settlements would be highly risky and discouraged. The court explained that strong public policy inter-

ests favor the settlement of patent litigation and that the FTC’s approach could undermine these interests.

TAMOXIFEN

In 1985, Barr Laboratories, Inc. (“Barr”) sought FDA approval to market a generic tamoxifen citrate product, which was being sold under the brand name Nolvadex by AstraZeneca Pharmaceuticals LP (“Zeneca”). At the time, tamoxifen was the most widely prescribed drug for the treatment of breast cancer. In 1987, Barr amended its ANDA to include a Paragraph IV certification¹³ to the listed patent, which prompted a patent infringement lawsuit by the then patent holder, Imperial Chemical Industries, PLC (Zeneca was a former subsidiary of Imperial Chemical and succeeded to the ownership rights to the patent during the course of the lawsuit).

On April 20, 1992, the district court ruled that the tamoxifen patent was “invalid based on the court’s conclusion that ICI had deliberately withheld ‘crucial information’ from the Patent and Trademark Office regarding tests that it had conducted on laboratory animals with respect to the safety and effectiveness of the drug.”¹⁴ During the course of the appeal to the Federal Circuit in 1993, the parties entered into a settlement agreement whereby Zeneca paid Barr \$21 million, Barr received a license to sell tamoxifen manufactured by Zeneca and Barr agreed to change its Paragraph IV certification in its ANDA to a Paragraph III certification, effectively agreeing not to market its own generic tamoxifen product until the expiration of Zeneca’s patent. Barr was allowed to convert its Paragraph III certification back to a Paragraph IV certification in the event that the patent was subsequently declared invalid or unenforceable in a final, unappealable decision. In addition, Zeneca agreed to pay Barr’s raw material supplier \$9.5 million upfront, followed by an additional \$35.9 million over a ten year period. The settlement was contingent upon the vacatur of the district court judgment, which was subsequently granted by the Federal Circuit.¹⁵

Following the settlement, three other generic companies filed ANDAs for tamoxifen, which precipitated patent infringement suits by Zeneca. In contrast to the suit against Barr, Zeneca’s patent was upheld in all three of these actions, and injunctions were issued to prohibit the generic companies from marketing their products until Zeneca’s patent expired.

Approximately 30 different lawsuits were filed by consumers and consumer groups challenging the 1993 Zeneca/Barr

settlement agreement under the antitrust laws. These suits were consolidated in 2001 in the Eastern District of New York. As summarized by the Second Circuit:

At the heart of the lawsuit was the contention that the Settlement Agreement enabled Zeneca and Barr effectively to circumvent the district court’s invalidation of Zeneca’s tamoxifen patent . . . , which, the plaintiffs asserted, would have been affirmed by the Federal Circuit. The result of such an affirmance, according to the plaintiffs, would have been that Barr would have received approval to market a generic version of tamoxifen; Barr would have begun marketing tamoxifen, thereby triggering the 180-day exclusivity period; other generic manufacturers would have introduced their own versions of tamoxifen upon the expiration of the exclusivity period, with Zeneca collaterally estopped from invoking its invalidated patent as a defense; and, as a result, the price for tamoxifen would have declined substantially below the levels at which the Zeneca-manufactured drug in fact sold in the market shared by Zeneca and Barr through the Settlement Agreement.¹⁶

On May 15, 2003, the district court granted the defendants’ motion to dismiss.¹⁷

A Second Circuit panel, with one dissent, affirmed the dismissal. In so doing, the Second Circuit began by acknowledging that both the antitrust laws and the patent laws have the “ultimate goal of stimulating competition and innovation.”¹⁸ The court also recognized that “[i]t is the tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the patent laws, as complicated by the Hatch-Waxman Act, that underlies this appeal.”¹⁹

In its opinion, the court stressed that the settlement of litigation is to be encouraged, not discouraged, and that parties’ decisions to settle a lawsuit should not be second-guessed based on *post hoc* considerations.²⁰ Following the Eleventh Circuit’s discussion in *Valley Drug*, the Second Circuit stated that “[r]ules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.”²¹ Similar to the Eleventh Circuit in *Schering*, the Second Circuit also gratuitously determined²² that reverse payments are not a *per se* violation of the antitrust laws and are “particularly to be expected in

the drug-patent context because the Hatch-Waxman Act created an environment that encourages them.”²³

Relying heavily on the Eleventh Circuit’s *Schering* decision, Judge Posner’s *Asahi Glass* decision and the recent Eastern District of New York decision relating to ciprofloxacin,²⁴ the Second Circuit determined that the Zeneca/Barr settlement agreement did not violate the antitrust laws because the exclusionary effect of the agreement did not exceed the scope of the patent.²⁵ Notably, the court reasoned that patent settlement agreements including even “excessive” reverse payments²⁶ were not unlawful as long as the patent litigation was not a sham or otherwise baseless.²⁷ “Whatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder by patent law unless the terms of the settlement enlarge the scope of that monopoly.”²⁸

WHAT DOES THIS MEAN FOR PRACTITIONERS?

The *Schering* and *Tamoxifen* courts undertook a detailed analysis of the antitrust principles at stake. At the same time, however, both courts recognized the critical innovation incentives created by the patent laws. In balancing these two legal regimes, both courts came out squarely in favor of the patent laws.

Although many commentators have been hesitant to admit this, the patent and antitrust laws are at odds in these cases. As recognized by the Second and Eleventh Circuits, the antitrust laws try to reduce market power while the patent laws seek to bestow market power in order to encourage innovation. Faced with these contradictory laws, the courts are left with little guidance from Congress on how the scales should tip. The *Schering* and *Tamoxifen* courts have left little doubt that they believe the scales should tip in favor of patent rights, despite the resulting reduction in competition.

Of course, the balancing of the patent and antitrust laws is far from over. The Supreme Court could review either the *Schering* or *Tamoxifen* decisions. The Sixth Circuit appears to have taken the opposite approach in *Cardizem*, although the case is factually distinct from *Schering* and *Tamoxifen*. Although Judge Posner from the Seventh Circuit has been on record in *Asahi Glass* as supporting the patent laws over the antitrust laws,²⁹ these issues have not been addressed by the other Circuits. Thus, it is entirely possible that some Circuits will come down on the side of the antitrust laws. Ultimately, Congress may be called upon to put its finger on one side of the scale.

For now, however, these cases make it clear that patent settlement terms should not be second-guessed unless the litigation (or the settlement) is shown to be a sham. In fact, if the words “exclusionary potential” are read to mean the life of the patent, these cases support the argument that virtually any settlement of non-sham patent litigation that is not a facade for other anti-competitive activity is permissible, even if significant monetary or other compensation flows from the patentee to the defendant.

As practitioners, then, where does this leave us? Under the courts’ decisions in *Schering* and *Tamoxifen* are non-sham patent settlement agreements completely immune from antitrust scrutiny? Perhaps not. Even if these decisions are upheld and followed by other Circuits, antitrust plaintiffs seem to be left to argue that the likelihood of the patentee prevailing on both validity and infringement issues should be taken into account in assessing the “exclusionary potential” of the patent. For example, it might be argued that the settlement of weak (though not necessarily sham) patent claims involving extraordinary payments to the defendant and significant entry delays remains open to scrutiny to determine whether the settlement merely masks an anticompetitive agreement to stay off the market. This appears to be similar to the approach taken by the district court following the remand of the Eleventh Circuit’s *Valley Drug* decision.³⁰

Such an argument, however, runs contrary to many aspects of *Schering* and *Tamoxifen* and would nonetheless encounter substantial problems of proof. Moreover, the FTC would have to reverse its longstanding position that the merits of the underlying patent suit are irrelevant to the antitrust analysis.

Until this issue is resolved by the Supreme Court or Congress, there will certainly continue to be much uncertainty in evaluating whether a patent settlement agreement containing a reverse payment can withstand antitrust scrutiny. These recent decisions indicate, however, that at least certain appellate courts are willing to give patent holders a great deal of leeway by determining that patent rights should sometimes trump the antitrust laws. **IPT**

ENDNOTES

1. See, e.g., *In re: Hoechst Marion Roussel, Inc.*, FTC Dkt. No. 9293 (May 8, 2001) (Cardizem CD/diltiazem hydrochloride); *In re: Abbott Labs.*, FTC Dkt. No. C-3945 (May 22, 2000) (Hytrin/terazosin); *Abbott, Geneva Pharms. to Pay in \$30.7M Settlement*, DOW JONES NEWS SERVICE, March 31, 2005 (Hytrin/terazosin).
2. 402 F.3d 1056 (11th Cir. 2005), *reh’g denied*, 2005 U.S. App. LEXIS 23487 (2005).

3. Dkt. No. 03-7641, 2005 U.S. App. LEXIS 23653 (2d Cir. Nov. 2, 2005).
4. 15 U.S.C. § 1.
5. 15 U.S.C. § 45(c).
6. 128 F.3d 720, 725 (9th Cir. 1997), *rev’d on other grounds*, 526 U.S. 756 (1999).
7. *Schering*, 402 F.3d at 1070.
8. 344 F.3d 1294 (11th Cir. 2003).
9. *Schering*, 402 F.3d at 1065-66 (citations and internal quotation marks omitted).
10. 289 F. Supp. 2d 986 (N.D. Ill. 2003) (Posner, J., sitting by designation).
11. In 1984, Congress passed the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetics Act (“FDCA”), aiming to increase the number of generic drugs on the market by providing a streamlined process for manufacturers to obtain approval for generic drugs. 21 U.S.C. § 355. In particular, manufacturers of generic drugs are allowed to file an Abbreviated New Drug Application (“ANDA”), relying on the safety and efficacy data of the brand name drug and simply demonstrating that the proposed generic product is bioequivalent to the approved drug. 21 U.S.C. § 355(j). In addition, the Hatch-Waxman Amendments encourage generic companies to challenge brand company patents and allow for the litigation of patent infringement disputes to begin prior to the generic company receiving FDA approval and entering the market. *Id.*
12. *Schering*, 402 F.3d at 1074.
13. A generic drug company seeking FDA approval for a generic version of a brand name drug must file, in addition to technical data, a certification with respect to any patent claiming the generic product or a method of using such product. These certifications include: (I) that the brand company has not filed patent information; (II) that the patent has expired; (III) that the patent will expire on a particular date (and until such time the generic company is not seeking to market its generic product); or (IV) that the patent is invalid or would not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12)(i)(A). This final certification is commonly referred to as a “Paragraph IV certification.”
14. *Tamoxifen*, 2005 U.S. App. LEXIS 23653, at *14. See also *Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F. Supp. 619, 626-27 (S.D.N.Y. 1992).
15. *Imperial Chem. Indus. PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811 (Fed. Cir. 1993) (unpublished opinion).
16. *Tamoxifen*, 2005 U.S. App. LEXIS 23653, at *25-26.
17. *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003).
18. *Tamoxifen*, 2005 U.S. App. LEXIS 23653, at *39.
19. *Id.*
20. *Id.* at *42-50.
21. *Id.* at *44 (citing *Valley Drug*, 344 F.3d at 1308).
22. The plaintiffs had not asked the court to find that reverse payments are a *per se* violation.
23. *Id.* at *52-57.
24. *In re: Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005).
25. *Tamoxifen*, 2005 U.S. App. LEXIS 23653, at *58-82. In this respect, the Second Circuit distinguished the Zeneca/Barr agreement from the agreement found *per se* illegal by the Sixth Circuit in *Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.* (*In re: Cardizem CD Antitrust Litig.*) (hereinafter, “*Cardizem*”), 332 F.3d 896 (6th Cir. 2003), which also prohibited the generic company from marketing certain non-infringing products. *Tamoxifen*, 2005 U.S. App. LEXIS 23653, at *74-75.
26. The plaintiffs had alleged that the size of the reverse payment at issue was “excessive” and a violation of the antitrust laws because it was greater than the profits Barr expected if it had launched its generic product.
27. *Id.*
28. *Id.* at *72.
29. See *Asahi Glass*.
30. *In re: Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005).