Antitrust Implications of Patent Settlements: Balancing Patent Policy, Antitrust Law, and the Practical Limits of Litigation

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In a perfect world, all patents would be valid and none infringed. In a near-perfect world, a mechanism would exist to rapidly and efficiently determine whether a patent is valid and infringed. We live in neither world. Our method—litigation—is not rapid or efficient. When disputes arise, parties litigate, and then, most often, negotiate and settle.

Resolution by settlement is not unique to patent disputes. However, it has a unique feature. The right to exclude competition is a central right of patent owners. Very often, the competitor will concede in the terms of the settlement to discontinue selling its product. In entering such an agreement, the parties raise issues of patent and antitrust law. They have served the interest of the patent law; they have promoted "the progress of science and the useful arts" by securing for the patent owner "the exclusive right" to its invention.[1] However, they have also implicated an issue of antitrust law: two competitors have reached an agreement that might be characterized as a restraint of trade.

When confronted with such agreements, courts have attempted to fashion an appropriate test to distinguish between legitimate settlements and those antitrust violations masquerading as settlements. In doing so, the courts have recognized that traditional antitrust rules are not well-suited to the task. In their stead, courts have created new tests that seek a balance between patent and antitrust interests. At the same time, they have been mindful of a critical and practical consideration: the judiciary cannot afford to discourage settlements.

I. Patent Settlement Agreement: Pretext for Collusion?

Patent law and antitrust law have the same goal ultimately: to promote economic growth. The former seeks to achieve that goal by rewarding innovators with monopoly-type rights. Under patent law, an inventor has "the right to exclude others from making, using, offering for sale, or selling [his] invention throughout the United States or importing the invention into the United States" for a limited term of years.[2]

Antitrust law, on the other hand, seeks to achieve the same goal by prohibiting behavior that would interfere with competition. The Sherman Act prohibits "[e]very contract, ... or conspiracy, in restraint of trade or commerce among the several States"[3] and "monopoliz[ation] or attempt[s] to monopolize, or combin[ations], or conspir[acies]... to monopolize any part of the trade or commerce among the several States."[4]

As the Eleventh Circuit put it, when evaluating patent settlements, "a delicate balance must be drawn between the two regulatory schemes."[5] If the interests of antitrust law were ignored, patent law could be used as a pretext for collusion. A company could use an invalid patent for, among other things, cover for a price-fixing scheme.

> Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patent produce for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices—masks—for fixing prices....[6]

Ignoring the interests of patent law would lead to an equally undesirable result. Under patent law, and the Constitution, patent owners are granted the exclusive right to exploit their inventions. A patent owner wanting to exercise that right would not have the option of obtaining a settlement that includes an agreement by its competitor to withdraw from the market. Because such a settlement would be too vulnerable to antitrust challenge, the patent owner would be forced to litigate his patent suit to final judgment or give up on his exclusive right.

> Requiring parties to a lawsuit to either litigate or negotiate a settlement in the public interest... is, as a practical matter, tantamount to establishing a rule requiring litigants to continue to litigate when they would prefer to settle and to act as unwilling private attorneys general and to bear the various costs and risks of litigation."[7]

II. Balancing Patent and Antitrust Law

Traditional antitrust law tests, such as the per se rule and the rule of reason, are difficult to adapt to evaluation of patent settlements because they do not take into account a patent owner's legitimate right to exclude. As stated by the Eleventh Circuit in *Schering-Plough Corporation v. FTC*,[8] both the per se rule and the rule of reason are

> 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.[9]

Early last century, in *Standard Oil Co. v. United States*,[10] the Supreme Court stated that the starting point in establishing a balance between the two interests is to determine whether the dispute between the patent owner and the competitor is legitimate.[11] Courts since have generally followed this principle. In *In re Tamoxifen Citrate Antitrust Litigation,*[12] the Second Circuit stated, "[u]nless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent."[13]

Sitting by designation, Judge Posner set forth a test for determining whether a suit is objectively baseless.[14] The test focuses on whether "a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed."[15]

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In reviewing settlement agreements, courts have generally been willing to give the settlement agreements the benefit of the doubt. In *Tamoxifen,* a settlement agreement was reached after a district court had invalidated a patent, and while the judgment was on appeal to the Federal Circuit. The Second Circuit held that the settlement was legitimate. The court found that the risk of reversal on appeal was sufficient to justify the agreement. "There is a risk of loss in all appeals that may give rise to a desire on the part of both the appellant and the appellee to settle before the appeal is decided."[16]

III. Reverse Payments

An additional issue is raised by a settlement agreement known as a "reverse payment" settlement or "exit payment" settlement. In a reverse payment settlement, the competitor agrees to discontinue making and selling the accused product. As part of the bargain, the patent owner agrees to make a payment to the competitor. Such payments can be very large, and they are most common in the pharmaceutical context.[17]

Courts have acknowledged that such settlements may appear to be "suspicious" on their face.[18] At the same time, they have not been willing to create legal tests that would make it easier to subject these settlements to antitrust liability.[19] In *In re Tamoxifen Antitrust Litigation*, the Second Circuit held that a reverse payment settlement does not violate antitrust law "so long as the patent litigation is neither a sham or otherwise baseless."[20]

The Second Circuit in *In re Tamoxifen* also dismissed the suggestion that an antitrust violation should be found where the amount of the reverse payment exceeds the profit the competitor could have earned had it continued to manufacture the accused product. The Second Circuit stated that a large reverse payment might betray the patent owner's doubts regarding its ability to prevail on the merits in its case. According to the court, however, those doubts do not mean that the litigation is a sham or baseless.

> Of course, the law could provide that the willingness of the patent holder to settle at a price above the generic manufacturer's projected profit betrays a fatal disbelief in the validity of the patent or the likelihood infringement, and that the patent holder therefore ought not to be allowed to maintain its monopoly position. Perhaps it is unwise to protect patent monopolies that rest on such dubious patents. But even if large reverse payments indicate a patent holder's lack of confidence in its patent's strength or breadth, we doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder's fear of losing it.[21]

The court also reasoned that placing a cap on the amount of a reverse payment would only benefit the patent owner.

> We are unsure, too, what would be accomplished by a rule that would effectively outlaw payments by patent holders to generic manufacturers greater than what the latter would be able to earn in the market were they to defend successfully against an infringement claim. A patent holder might well prefer such a settlement limitation—it would make such a settlement cheaper—while a generic manufacturer might nonetheless agree to settle because it is less risky to accept in settlement all the profits it expects to make in a competitive market rather than first to defend and win a lawsuit, and then to enter the marketplace and earn the profits. If such a limitation had been in place here, [the patent owner] might have saved money by paying [the competitor] the maximum such a rule might allow.... But the resulting level of competition, and its benefit to consumers, would have been the same. The monopoly would have nonetheless endured—but to no apparent purpose, at less expense to [the patent owner] and less reward for [the competitor].[22]

The court rejected the argument that permitting the reverse payment settlement would disserve the public interest in having the validity of patents litigated. As the court observed, "[t]he Settlement Agreement was a virtual invitation to other generic manufacturers" to challenge the validity of the patent.[23]

In *Schering-Plough,* the Eleventh Circuit rejected the Federal Trade Commission's assertion that reverse payments settlement agreements violate section 1 of the Sherman Act and section 5 of the Federal Trade Commission Act.[24] In reaching this conclusion, the court acknowledged that some settlements could result in economic inefficiency, but recognized that the alternative to settlement is not a rapid and efficient method of determining whether a patent is valid or infringed. Rather, it is the ordeal of patent litigation.

> Patent litigation breeds a litany of direct and indirect costs, ranging from attorney and expert fees to the expenses associated with discovery compliance. Other costs accrue for a variety of reasons, be it the result of uncompromising legal positions, differing strategic objectives, heightened emotions, lawyer incompetence, or sheer moxie.[25]

A rule that encouraged patent litigation, the court reasoned, could end up hindering innovation. "[T]he caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around [an inventor's] ability to research, develop, and market the patented product or allegedly infringing product."[26]

Thus, the court reasoned that, although, a rule too liberal in allowing settlements might not be perfect, such a rule would be preferable to the next-best alternative, litigation. "The intensified guesswork involved with lengthy litigation cuts against the benefits proposed by a rule that forecloses a patentee's ability to settle its infringement claim."[27]

CONCLUSION

Patent settlements raise unique issues for federal courts. Courts are called upon to question whether a settlement is legitimate or a sham. A rule that is too permissive risks allowing competitors to collude, using patent litigation as cover. A rule that is too restrictive risks forces competitors to litigate against their will, potentially discouraging innovation and burdening an already taxed judicial system with a new species of litigation. Although some circuits have weighed in, these issues seemed destined to reach the Supreme Court. Until that time, the risk of government and private antitrust enforcement will cause parties to be cautious in crafting terms of settlement agreements.

Endnotes

1 *See* U.S. Const,, art. I, § 8.

2 35 U.S.C. § 154(a)(1)-(2).

3 15 U.S.C. § 1.

4 15 U.S.C. § 2.

5 Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1067 (11th Cir. 2005)).

6 *Id.*

7 *In re* Ciprofloxacin Hydrochloride Antitrust Litigation, 363 F. Supp. 513, 532 (E.D.N.Y. 2005) (citations and internal quotations omitted).

8 402 F.3d 1056 (11th Cir. 2005).

9 *Id.* at 1065-66 (citing Valley Drug Co. v. Geneva Pharms., 344 F.3d 1294, 1312 (11th Cir. 2003). *Cf. In re* Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003) (an interim agreement in which the brand name patent holder agreed to pay a potential generic entrant to delay entry pending resolution of a lawsuit was per se illegal).

10 283 U.S. 163 (1931).

11 *Id.* at 171 ("Where there are legitimate conflicting [patent] claims, ... a settlement by agreement, rather than litigation, is not precluded by the Sherman Act.")

12 Joblove v. Barr Labs, Inc. *(In re* Tamoxifen Citrate Antitrust Litigation*)*, 429 F.3d 370 (2nd Cir. 2005), *reprinted as amended*, 466 F.3d 187 (2nd Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007).

13 *Id.* at 213 (quoting *In re* Ciprofoxacin Hydrochloride Antitrust Litigation¸ 363 F. Supp.2d 514, 535 E.D.N.Y. 2005).

14 Ashai Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc., 289 F. Supp.2d 986, 991 (N.D. Ill. 2003) (Posner, J. sitting by designation)

15 *Id.* at 993.

16 *In re* Tamoxifen Citrate Antitrust Litigation, 466 F.3d at 205.

17 *See In re* Tamoxifen Citrate Antitrust Litigation, 466 F.3d at 206 ("[R]everse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them").

18 *Id.* at 208.

19 *Cf. In re Cardizem*.

20 *In re* Tamoxifen Citrate Antitrust Litigation, 466 F.3d at 208.

21 *Id.* at 210.

22 *Id.* at 211.

23 *Id.* at 212, n.25. Reverse payment settlement agreements in the pharmaceutical industry have significantly increased since the Eleventh Circuit's *Schering-Plough* decision. In 2004, none of the 14 patent settlement agreements filed with the Federal Trade Commission included reverse payment provisions. *See Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2006*, A Report by the Bureau of Competition at 4. By 2005, three of 11 settlements contained such payments. *Id.* By 2006, that number had increased to 14 of 28 settlements. *Id.*

24 *Schering-Plough Corp.*, 402 F.3d at 1076.

25 *Id.* at 1075.

26 *Id.*

27 *Id.*