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Getting To A Rule For Reverse Payments

Law360, New York (June 28, 2012, 1:24 PM ET) -- For a decade now, courts have been grappling with whether so-called "reverse payments" by pioneer pharmaceutical manufacturers to generic competitors in settlement of patent infringement litigation violate the antitrust laws, and with how the competitive effects of reverse-payment settlements should be analyzed. The year 2003 saw a spate of opinions on reverse-payment settlements by circuit courts, the Federal Trade Commission, and noted antitrust scholar Judge Richard Posner (sitting by designation in federal district court).[1]

These opinions ranged from the Sixth Circuit's per se invalidation of such settlements as payments to competitors in consideration for unlawful agreements not to compete, notwithstanding the possibility that the competing product infringed intellectual property rights, to the Second Circuit's requirement that all such settlements were per se lawful absent a showing that the patent infringement litigation was itself objectively baseless or that the underlying patent(s) was procured by fraud on the U.S. Patent and Trademark Office, or a showing of some other anti-competitive conduct.[2]

To date, the U.S. Supreme Court has denied certiorari on multiple occasions, leaving the circuit courts to develop guidance.[3] In FTC v. Watson Pharmaceuticals et al.,[4] decided in late April, the Eleventh Circuit shifted the balance of authority toward the Second Circuit, holding that, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."[5] The court's wrestling with the issues illustrates the fundamental difficulties inherent in assessing the competitive effects of reverse-payment settlements.

The case involved settlements of litigation brought by Solvay Pharmaceuticals, the manufacturer of Androgel (a topical gel for treatment of low testosterone in men), against three generic competitors: Watson Pharmaceuticals, Par Pharmaceutical Companies, and Paddock Laboratories. Per the settlements, the generics would receive: (1) payments[6] and (2) "delayed licenses" permitting generic entry in 2015, five years before Solvay's patent expired. Solvay would receive certain marketing and drug supply services. The settlements resolved all litigation between the parties, and prior to any adjudication on the merits.

The FTC challenged the settlements as anti-competitive, alleging that Solvay was "not likely to prevail" in the patent infringement litigation — but not alleging that the litigation was objectively baseless — and therefore the settlements, by delaying generic entry until 2015, harmed competition. The district court dismissed the FTC's complaint pursuant to Federal Rule of Civil Procedure 12(b)(6), accepting the defendants' argument that the FTC was required to allege, but had failed to allege, that the settlements excluded competition beyond the scope of the patent-in-suit.

The Eleventh Circuit began its analysis by pointing to its 2003 opinion in Valley Drug Co. v. Geneva Pharmaceuticals,[7] which also involved reverse-payment settlements:

> Our Valley Drug decision began by acknowledging that antitrust laws typically prohibit agreements where one company pays a potential competitor not to enter the market, but we reasoned that reverse payment settlements of patent litigation presented atypical cases because "one of the parties own[s] a patent." The patent made all the difference because it meant that the patent holder had a "lawful right to exclude others" from the market.[8]

But a patent is only a limited grant of the right to exclude others from practicing the invention that is defined in the patent; indeed, it is the patent's so-called "limitations" that define it. The Eleventh Circuit itself recognized the limited nature of the patent grant, stating:

> A patent holder ... cannot enter into an agreement that excludes more competition than the patent has the potential to exclude. ...
>
> [A] patent gives its holder a "bundle of rights," but any new exclusionary rights the holder buys to add to that bundle do not fall within the scope of the patent grant and for that reason do not fall within the scope of the patent's antitrust immunity.[9]

Notably, the prohibition on buying additional exclusionary rights holds regardless of the form of consideration paid. A patent holder who extends the scope of its exclusion beyond the scope of the patent risks violating the antitrust laws whether it pays cash or gives something else of value. The existence of a reverse payment by itself is not dispositive.

The conundrum faced by the Eleventh Circuit in Watson Pharmaceuticals, and by many other courts before it, was how to account for the limited exclusionary power of the patent absent a judicial determination of the scope of that power. This conundrum is inherent in reverse-payment settlement cases because often it is the settlement itself that precludes a determination of the patent's lawful scope. If antitrust law begins where patent law ends, how to determine where antitrust begins if one does not know where the patent ends? It is the "Catch-22" of reverse-payment cases.

The Watson Pharmaceuticals court attempted to resolve the conundrum by rejecting the premise that it was necessary to determine the patent's actual scope and whether the generic product actually infringed the patent.[10] Instead, the court held that "parties to a reverse payment settlement should be immune from antitrust liability if the anticompetitive effects of their settlement fall 'within the scope of the exclusionary potential of the patent.'"[11]

What precisely the court meant by "potential," however, it did not say. "Potential" could be construed as: (1) the maximum "potential" scope of the patent as its claims and limitations are literally read, itself not an easy task and one that often costs much in patent attorney expertise, or (2) the maximum "potential" scope of the patent as read literally and construed in accordance with patent law and all of its doctrines of novelty, nonobviousness, claim construction, etc., again the subjects of much patent attorney expertise.

The first construction of "potential scope" of the patent, while perhaps relatively simple to use, is divorced from patent law and therefore would exclude competition from a broader range of products than patent law deems justifiable. The second construction would embroil the antitrust court in the very relitigation of the patent dispute that the Eleventh Circuit sought to avoid with its rule. The Watson Pharmaceuticals court expressly rejected the FTC's argument that the exclusionary potential of the patent be determined by " 'viewing the situation objectively as of the time of the settlement.'"[12] According to the court, the FTC's approach

> would require an after-the-fact calculation of how "likely" a patent holder was to succeed in a settled lawsuit if it had not been settled. Predicting the future is precarious at best; retroactively predicting from a past perspective a future that never occurred is even more perilous. And it is too perilous to serve as a basis for antitrust liability and treble damages.[13]

It "would also impose heavy burdens on the parties and courts"; in the case of the Androgel patent litigation, "assaying the infringement claim ... would have required mining through mountains of evidence" in an already settled case.[14] Furthermore, that would "undo much of the benefit of settling patent litigation, and discourage settlements. Our legal system can ill afford that."[15]

Conclusions

The Watson Pharmaceutical court's exclusionary-potential rule thus appears to suffer from some of the same difficulties the court found plagued the FTC's approach to reverse-payment settlement cases. It is hornbook antitrust law that lawful exclusion of competition, including through patents and other intellectual property, must be taken into account in any antitrust analysis. But the patent litigation settlements themselves often foreclose this inquiry in reverse-payment settlement cases, causing the inherent, fundamental problem in assessing their competitive effects. The existence of reverse payments does not necessarily shed any light on the problem.

A rational patent holder may pay the generic manufacturer something even if the patentee objectively is "likely to prevail." As the Eleventh Circuit gruesomely but effectively put it, "With four chambers of a seven-chamber revolver unloaded, a party pulling the trigger is likely (57% to 43%) to survive, but the undertaking is still one that can lead to undertaking. Patent litigation can also be a high stakes, spin-the-chambers, all or nothing undertaking."[16]

There is at least one possible rule, however, that: provides value to generic manufacturers, thereby inducing settlement of costly litigation; avoids reopening settled patent litigation; provides certainty to litigating parties that they will not be subjected to antitrust liability;

and promotes the earlier entry of generic competition as envisioned by the Hatch-Waxman Act.

A delayed license granted by the patentee allows generic entry at some point after the settlement (hence the term, "delayed license") and before patent expiration. The value of such a license is quantifiable, as it is known how much of a patented product's sales are likely to be captured by generic entry on average. Precluding antitrust liability where the settlement contains a delayed license, and thereby provides for earlier generic entry than would have existed but for the patent litigation, fulfills precisely the objectives of the Hatch-Waxman Act.

While the FTC would argue that reverse payments skew that entry later than it would be without the reverse-payment component of the settlement, that is perhaps not the relevant inquiry. Rather, because the settlement is only attendant to the litigation from which it results, the relevant inquiry is: But for the entire litigation, when would generic entry have occurred? If the answer is that, but-for the litigation, generic entry would have occurred only upon patent expiration, then the litigation and settlement have achieved a procompetitive outcome. Although it may not be the most procompetitive outcome from the perspective of drug price competition, antitrust law does not require the most procompetitive result; antitrust only prohibits net anti-competitive results.

This is not to say that such a rule be woodenly applied. For example, a settlement paying the generic competitor several hundred million dollars and containing a delayed license to begin one day before patent expiration might be a naked payment not to compete (although perhaps not if the drug is a blockbuster and even a nine-figure reverse payment accounts for a small portion of the drug's profits and therefore represents a small chance that the generic prevails in the patent litigation). While uncertainty would remain for cases on the margins, many settlements would likely fall within a safe harbor as could be defined by the FTC or the courts.

--By Ankur Kapoor, Constantine Cannon LLP

Ankur Kapoor is a partner in Constantine Cannon's New York office.

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[1] See Copeland et al., "2003 Antitrust Developments in Regulated Industries," Supplement to the Milton Handler Antitrust Review, published in 2004 Colum. Bus. L. Rev. 459, 468-87 (2004).

[2] See id.

[3] Andrx Pharms. Inc. v. Kroger Co., 543 U.S. 939 (2004); Valley Drug Co. v. Geneva Pharms. Inc., 543 U.S. 939 (2004); Walgreen Co. v. Abbott Labs., 543 U.S. 939 (2004); Ark. Carpenters Health and Welfare Fund, Paper, A.F. of L. v. Bayer AG, 129 S. Ct. 2828 (2009); La. Wholesale Drug Co. Inc. v. Bayer AG, 131 S. Ct. 1606 (2011).

[4] No. 10-12729 (11th Cir. Apr. 25, 2012).

[5] Slip op., at 30.

[6] "Solvay agreed to pay Par/Paddock $10 million per year for six years and an additional $2 million per year for [] backup manufacturing assistance," and "agreed to share some of its Androgel® profits with Watson through September 2015, projecting that those payments

would be between $19 million and $30 million per year." Id. at 14.

[7] 344 F.3d 1294 (11th Cir. 2003).

[8] Slip op., at 19 (quoting Valley Drug, 344 F.3d at 1304) (internal citations omitted) (alteration in original).

[9] Slip op., at 22-23.

[10] Id. at 28 n.8.

[11] Id. at 23 (quoting Valley Drug, 344 F.3d at 1311) (emphasis added). Also, if the patent litigation is objectively baseless sham litigation or the patent was procured by knowing fraud on the PTO, then there is no potential for the patent lawfully to exclude the allegedly infringing product, and the settlement runs afoul of the antitrust laws that way. See id. at 30.

[12] Id. at 31

[13] Id. at 34.

[14] Id. at 35.

[15] Id.

[16] Id. at 32-33.

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