

The FTC on Pharmaceutical Patent Litigation Settlements: Not Walking Softly, but Still Carrying a Big Stick?

By: Clifford M. Davidson, Esq.

BIOGRAPHY



Clifford M. Davidson, Esq. is a founding partner at Davidson, Davidson & Kappel, LLC, an Intellectual Property law firm with offices in New York City and Frankfurt, Germany. He counsels phar-

maceutical clients in pharmaceutical patent-related matters, including patent prosecution, freedom to operate and infringement opinions, due diligence and tech-transfer, and litigation (including ex parte and inter partes proceedings worldwide). He has assisted specialty pharma and drug development companies to create significant patent portfolios, and the patents he has written and the patent portfolios he has created have been recognized as creating significant value for his clients. He has written patents covering virtually all areas of drug development, and has pioneered strategic patent focus on the pharmacokinetic profiles and the pharmacologic activity of drug/drug formulations. Mr. Davidson earned his BS in Pharmacy and his JD from Rutgers University and is a member of the New York and New Jersey Intellectual Property Law Associations, the American Pharmaceutical Association, and The Controlled Release Society. His area of expertise includes new chemical entities; new pharmaceutical formulations (including controlled-release oral dosage forms, injectables, transdermals, ophthalmics, inhalation, intranasal, sublingual, suppository, and implantation administration); new combinations of previously known drugs; new modes of administration of previously known drugs; method of treatment; pharmaceutical excipients; and methods of preparation.

There is a palpable tension between certain federal courts and the Federal Trade Commission concerning pharmaceutical brand-generic patent litigation settlements. The United States Patent and Trademark Office (PTO) awards lawful monopolies to patent owners. Those patents are then challenged through the courts by generic manufacturers as part of the Hatch-Waxman framework. On one side, federal courts favor settlements of patent infringement litigations; and on the other side, the Federal Trade Commission (FTC) conservatively views any payment from a brand manufacturer to a generic manufacturer in return for the generic manufacturer's delay of market entry to be illegal. The FTC aims to protect the public against unlawful anticompetitive practices. Recently, three federal circuit courts have considered the legality of brand-generic patent litigation settlements.

To review, pursuant to the Medicare Modernization Act (MMA), brand-generic patent settlement agreements must be submitted to the FTC for approval. While patents award limited term monopolies to inventors that disclose their discoveries, the FTC ensures that the public is not injured through illegal anticompetitive activity. The FTC has recently focused on brand-generic patent litigation settlements resulting from numerous practices by brand and generic manufacturers that have been found to be anticompetitive and illegal.

A decision from the Second Circuit Court of Appeals involved the drug tamoxifen citrate used for the treatment of breast cancer. The suit was brought by consumers against Astra Zeneca (who manufactured a branded version of tamoxifen citrate), challenging their patent litigation settlement with generic competitor Barr Laboratories. The settlement involved quarterly payments of \$10 million and a license for Barr to sell an authorized generic manufactured by Astra Zeneca. Following the lower court's finding that the settlement was not illegal, the consumers appealed to the Second Circuit Appellate Court. Though the consumers challenged the large amounts of the payments, the Second Circuit held that these payments are not *per se* illegal. *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 429 F.3d 370 (2d Cir. 2005). The Second Circuit Appellate Court held that "[i]f however, there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process, a third party should not be permitted to haul the parties to the settlement over the hot coals of an antitrust litigation." [citing *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991-92 (N.D. Ill. 2003)]. The Second Circuit also provided guidance as to "suspicious circumstances." When a settlement is used as a device for circumventing antitrust law, it is vulnerable to an antitrust suit. One example would be where a brand manufacturer 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 patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices for fixing prices, in violation of antitrust law. See: *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 429 F.3d at 392. The Second Circuit did not take the opportunity to consider a scenario where the patent is clearly not infringed by the accused generic product.

In the Sixth Circuit, a suit was brought by consumers against Hoechst Marion Roussel, Inc. (HMR) who manufactured a branded version of diltiazem hydrochloride (for treatment of cardiovascular conditions), and generic challenger, Andrx Pharmaceuticals, Inc. The parties entered into a patent infringement settlement agreement where Andrx received quarterly payments of \$10 million to not enter the market even after the generic received FDA

marketing approval. Because the ANDA that Andrx filed was prior to the MMA (closing loopholes leading to gaming of 180-day generic exclusivity), the failure of Andrx to enter the market effectively blocked all generic competition to HMR's product. Because the anti-competitive effect of this agreement, the lower court's holding of the settlement per se illegal was affirmed by the Sixth Circuit Appellate Court. See: *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (D.N.Y. 2005).

In the Eleventh Circuit, a suit was brought by the FTC challenging the settlement agreement between brand manufacturer Schering and generic challengers Upsher Smith and ESI involving K-Dur[®] (extended-release potassium chloride). The Upsher agreement involved a delayed entry of Upsher's generic product (not extending beyond the patent term), and a three-part license agreement where Schering paid Upsher for rights to market five of Upsher's products. Under the agreement, Schering was to pay \$60 million in initial royalties to Upsher; \$10 million in milestone royalty payments; and 10% to 15% royalties on sales. Under the Schering-ESI settlement, ESI would launch its generic 3 years prior to the expiration of the patent term in exchange for a \$10 million payment to ESI. A simultaneous license agreement paid ESI \$15 million for licenses to its enalapril and buspirone products for overseas sale.

The FTC's case against Schering was initially heard by an administrative law judge (ALJ) who determined that the settlements were not per se illegal and that Schering did not maintain an illegal monopoly in the potassium chloride supplement market. Upon appeal to the full Commission, the ALJ's decision was reversed. The Commission found that the settlements, though not *per se* illegal, were exit payments leading to a delay of generic competition and injury to competition and the public. The Commission added that the payments to Upsher and ESI were not legitimate payments for the licenses Schering obtained. Consequently, the Commission prohibited settlements under which the generic received anything of value and agrees to defer its own research, development, production, or sales activities. An exception to this prohibition was settlement payments for litigation costs. Where payments did not exceed \$2 million, the parties would not need to worry about an antitrust attack.

Schering subsequently appealed to the Eleventh Circuit Appellate Court, which reversed the full Commission, holding that the settlements were not illegal as being anticompetitive. The Court relied on the *Valley Drug* decision, holding that "in the context of patent litigation, however, the anticompetitive effect may be no more broad than the patent's own exclusionary power. *Valley Drug*, 344 F.3d at 1309. Where the *Valley Drug* case involved a delay of generic competition beyond the patent by foreclosing other generics because of gaming with the Hatch-Waxman framework, the present case does not foreclose other patent challenges from entering the market.¹ To expose those agreements to antitrust liability would obviously chill such settlements." *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1064 (11th Cir. 2005). The Court further noted that there was no evidence suggesting that the asserted patents were invalid, or that the resulting infringement suits against Upsher and ESI were shams. *Schering-Plough Corp. v. FTC*, 402 F.3d at 1068. Because other generics were not blocked from challenging the Schering patents, and because the agreements to delay entry were for a period shorter than the patent term, the agreements were deemed to not result in an unreasonable restraint on trade. *Id.* Lastly, the Court encouraged settlements and noted that settlements were

endorsed by the Supreme Court in *Standard Oil Co. v. United States*, 283 U.S. 163, 170-71 n.5, 75 L. Ed. 926, 51 S. Ct. 421 (1931). The Court also reasoned that the full Commission's opinion would leave brand-generic settlements, including those endorsed by a federal court, with little confidence. *Id.*, at 1072. The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits." *Id.*

The FTC has shown no indication that it will reconsider its position, although the Eleventh Circuit contradicted its view on patent litigation settlements. Following the Eleventh Circuit's denial of FTC petition for a rehearing, the FTC petitioned the United States Supreme Court to reconsider the Eleventh Circuit decision. In its brief to the Supreme Court, the FTC raises the evidentiary issue regarding whether the Eleventh Circuit should have deferred to the ALJ or the full Commission for findings of fact. Substantively, the FTC asks the Supreme Court to decide whether an agreement between a brand patent holder and a generic challenger, where the patent holder makes a substantial payment to the challenger for the purpose of delaying the challenger's entry into the market, is an unreasonable restraint of trade. The FTC argues that agreements between competitors should not escape anti-trust scrutiny simply because the agreement is within the potential scope of the patent. The FTC maintains its hard line rule that settlements involving payments from the patentee to the generic competitors to induce them to abandon their patent challenges and to delay generic entry raise serious antitrust concerns. The FTC has taken the position that every day that the [Hatch-Waxman] statutes are thwarted because a generic is paid to stay off the market is a day that prescription drug prices remain higher than a competitive market would have provided.

The FTC makes several arguments challenging the Eleventh Circuit decision citing "fundamental errors." First, the FTC asserted that the Eleventh Circuit erred in assuming that the Upsher and ESI products infringed the asserted patent (it is black-letter patent law that the patentee bears the burden of proof on this issue). The FTC asserts that patent infringement was vigorously contested, and that if any assumption is appropriate, it is that the competing products did not infringe the patent. Is the FTC taking the position that the patentee must prove infringement and/or validity in order for a settlement agreement to be upheld?

WHAT IS NEXT?

At this point, it is not clear whether the Supreme Court will hear this controversy. If it decides to grant certiorari, and upholds the Eleventh Circuit, the FTC will likely change its recent perspectives on patent litigation settlements. On the other hand, a reversal of the Eleventh Circuit decision would lead to a change in several present settlement agreements currently before the FTC for approval. Many of these agreements involve simultaneous license agreements and other payments that the FTC may challenge. It will be interesting to see how big or small the FTC's stick could become!

REFERENCES

1. For purposes of antitrust analysis, the relevant market must be determined. The patents for Schering's product only protected against a specific type of delayed-release potassium chloride. Schering's patent protection did not block other manufacturers from selling the drug in immediate-release form or in a controlled-release form that was not bioequivalent to K-Dur.