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FTC Takes 4-in-1 Shot at Reverse Payment Settlements

February 2008
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The Federal Trade Commission has taken the next step in its long battle against "reverse payment settlements" that some argue delay entry by generic pharmaceutical manufacturers. On February 13, 2008, the FTC filed a complaint against Cephalon, Inc., alleging that the company illegally extended its monopoly over its sleep disorder drug, Provigil, by paying four generic drug manufacturers to delay entry as part of patent litigation settlements with each generic. According to the Commission, each of these four agreements is an unlawful act of monopolization.

The case, brought in the U.S. District Court in the District of Columbia, is extremely significant for brand and generic manufacturers faced with these business and legal decisions. This litigation represents the latest move in an effort by the FTC to develop the law in this area, and the outcome of this litigation could significantly impact the terms under which brand and generic manufacturers may settle patent infringement litigation. Although circuit courts have addressed these issues, the law remains turbid regarding the circumstances under which a patent settlement that includes a payment to a generic and delays entry is unlawful. The law has become more favorable to reverse payment settlements, but FTC remains resolute in its position that the current direction of the law is wrong. The *Cephalon* complaint represents the FTC's first effort to clarify the law in this area and challenge a reverse payment settlement after the Eleventh Circuit ruled against the Commission in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). The outcome of the case also may clarify the effect on the antitrust analysis of additional terms – such as licenses to additional intellectual property, supply agreements, and co-development deals – that brand and generic manufacturers have included in settlement agreements since the *Schering* decision.

The Commission's Complaint

According to the Commission's complaint, Cephalon's compound patent covering its Provigil product expired in 2001. Although Cephalon obtained a formulation patent for its product, four companies filed applications to market generic versions of Provigil the very first day the Federal Drug Administration began accepting such applications. All four therefore became "first filers," entitling each to certain benefits under FDA regulations. As is common, generic entry would have a dramatic impact on Provigil sales. Cephalon predicted that generic entry would reduce its Provigil revenues by at least $400 million within one year, and one of the generic companies predicted that generics would garner 90% of total sales of modanifil (the active pharmaceutical ingredient of Provigil) within one month and that generic prices would be only 10% of the branded price within one year.

Cephalon sued each generic manufacturer under its formulation patent. After discovery, each generic filed for summary judgment on non-infringement as well as invalidity in some cases. Cephalon then entered into settlement agreements with each of the four generics that precluded each from entering before April 2012 (three years before the formulation patent expired). Cephalon and the generic manufacturers also entered into "purportedly independent business transactions" that included payment from Cephalon to each generic manufacturer (totaling over $200 million) for licenses to intellectual property, supply agreements, or co-development deals. According to the complaint, Cephalon did not need any of the benefits from any of these agreements. In addition, each settlement agreement included a "most favored nations" clause that allowed for accelerated

entry in the event that another generic company entered the market. The complaint alleges that these clauses made it less attractive for each successive generic to enter at risk because the other generics could then enter without facing litigation. Further, the agreements prevent each of these four generics from entering "whether or not they infringe Cephalon's" formulation patent, while even a favorable outcome of the lawsuit would have only restricted sales of the companies' current generic versions.

The complaint alleges that the settlement and related agreements harm competition because, absent the reverse payments, (1) one or more of the generics would have entered before litigation ended, (2) Cephalon would not have won all four suits, or (3) the parties would have entered into settlements that provided for generic entry earlier than April 2012.

Legal Landscape

So-called "reverse payment settlements" – settlements that include a payment from the patent holder to the alleged infringer – between brand and generic manufacturers bring to a head policy concerns from antitrust, patent, and regulatory law in addition to the policy that the law favors the settlement of disputes. The proper balance of these policies has been the subject of heated commentary and substantial litigation. Notwithstanding significant challenge from the FTC and private plaintiffs, antitrust law has become more favorable to this type of settlement agreement, with the Second and Eleventh Circuits adopting legal rules that make it difficult to challenge reverse payment settlements.

The entry of generic drugs into the market is regulated by the Hatch-Waxman Act, which created a system to accelerate generic entry while protecting brand manufacturers' legitimate patent rights. The Act allows generics to obtain accelerated FDA approval through an Abbreviated New Drug Application ("ANDA"), which shows that the generic is "bioequivalent" to an already approved brand drug. 21 U.S.C. § 355(j). A firm submitting an ANDA for a product that is covered by current patents must make a "Paragraph IV certification" that any patents listed as covering the brand product are either not infringed by the generic or invalid. *Id.* at § 355(j)(2)(A)(vii)(IV). The certification creates an artificial act of infringement, which allows the patent holder to bring an infringement suit against the generic and triggers an automatic 30-month stay of generic entry. *Id.* at § 355(j)(5)(B)(iv). Importantly, the first generic manufacturer to file a Paragraph IV certification obtains a 180-day period of market exclusivity – no other generic may enter until 180 days after the first filer actually enters. *Id.* Under this regulatory system, therefore, a delay of entry by the first filer effectively forestalls all generic entry.

Due to the commercial dynamics of branded and generic pharmaceuticals, potential entry of generic drugs creates a situation in which both the brand and the first filer may profit from a payment to delay entry; the brand manufacturer's losses caused by generic entry are often greater than the first filer's profits from entry. Perhaps not surprisingly, a number of brand-generic patent infringement suits have produced settlements that included a "reverse payment" and an agreement that the generic will either not enter the market at all or enter only after a date agreed upon by the parties. The amount paid to the generic has sometimes exceeded the generic's expected profits from entry.

Beginning in 2001, the FTC investigated and negotiated consent agreements in several cases challenging this type of reverse payment settlement. *See, e.g.*, *Bristol-Myers Squibb Co.*, 135 F.T.C. 444 (2003); *American Home Products*, 133 F.T.C. 611 (2002); *Hoechst Marion Roussel, Inc.*, 131 F.T.C. 927 (2001). In addition, after a full administrative trial in *Schering-Plough Corp.*, the FTC explained the core of its reasoning in these cases: absent "proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." 2003 FTC LEXIS 187, at *63 (Dec. 3, 2003). According to the Commission, antitrust liability in these cases need not be premised on any assessment of the scope of the underlying patent or the merits of the infringement case. Finding no offsetting consideration, the Commission therefore held that the agreements in *Schering-Plough* violated Section 1 of the Sherman Act as unreasonable restraints of trade. *Id.* at *184.

On appeal, the Eleventh Circuit disagreed with the Commission's analytical model and factual findings. Vacating the Commission's decision, the circuit court followed its previous analysis of reverse payments and held that "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." *Schering-Plough*, 402 F.3d at 1066 (citing *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1312 (11th Cir. 2003)); *see also In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (agreement to delay entry that extended

to non-infringing products *per se* illegal). The court also took particular aim at the Commission's central premise that absent other offsetting consideration, a reverse payment represents an illegal payment to defer entry: "We are not sure where this 'logic' derives from . . . . 'It is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit . . . litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.'" *Id.* (quoting *Valley Drug*, 344 F.3d at 1309). The FTC took the unusual step of filing a petition for certiorari (over the ultimate opposition of the Solicitor General), arguing that the circuit court's approach improperly ignored the uncertainty surrounding whether the patent is valid and infringed. Br. of the Petitioner, *FTC v. Schering-Plough Corp.*, No. 05-273, at 15 (filed Oct. 13, 2005). The Court denied the petition.

Ruling in a case brought by private plaintiffs, the Second Circuit agreed with the Eleventh Circuit that the antitrust analysis must focus on whether the settlement exceeds the exclusionary scope of the patent. *See Joblove v. Barr Labs, Inc.* (*In re Tamoxifen Citrate Antitrust Litigation*), 429 F.3d 370 (2d Cir. 2005), *reprinted as amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007). The court recognized that "[t]here is something on the face of it that does seem 'suspicious' about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn" through entry. *Id.* at 392. But the court reasoned that "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product." *Id.* Noting the public policy favoring settlements, the court held that unless the settlement agreement reaches "beyond the patent's scope," the question is whether the underlying infringement suit is a sham. *Id.* at 397. The FTC filed an amicus brief urging rehearing – arguing that the holding undermined congressional policy manifested in the Hatch-Waxman Act – and also filed an amicus urging the Supreme Court to grant certiorari, but the Second Circuit stood firm, and the Supreme Court (as urged by the Solicitor General) denied certiorari.

The Federal Circuit is next in line to address the issue. The proper legal standard for reverse payment settlements is currently before that circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 2008-1097. In that case, the district court held that the "ultimate question" in reverse payment cases is "whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone" of the patent. *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, 523 (E.D.N.Y. 2005). Rejecting the FTC's arguments as raised by the plaintiffs, the court concluded that it is not "appropriate to discount that exclusionary power of the patent by any probability that the patent would have been found invalid." *Id.* at 539. According to the district court, unless "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." *Id.* at 535. On appeal, the FTC once again filed an amicus brief, arguing that the district court incorrectly equated the exclusionary power of the patent with the "nominal scope of the asserted patent" and that the exclusion from entry stems from the reverse payment, not the strength of the patent. Br. of Amicus Curiae Federal Trade Commission, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 2008-1097, at 15-19 (filed Jan. 25, 2008).

Significance of the FTC's Cephalon Action

The FTC's complaint against Cephalon effectively gives the Commission four shots at shaping the law regarding the antitrust analysis of reverse payment settlements. The complaint alleges that absent the Cephalon settlement agreements, "one or more" of the generic manufacturers would have entered before the conclusion of the respective patent litigation or prevailed in the patent litigation. Alternatively, the complaint alleges that the parties would have settled on terms that did not include a reverse payment but allowed earlier generic entry. Thus, the Commission may be able to prove anticompetitive effects so long as it can show that but for the payments, one of the four generics would have entered earlier.

By taking the unusual step of bringing the case in district court rather than through its own administrative trial process, the Commission eliminated the choice of appellate venue that Cephalon would have enjoyed on an appeal from an FTC administrative litigation. Any appeal in this matter will necessarily go to the D.C. Circuit, which has not yet expressed a view on reverse payment settlements. A favorable decision for the FTC would create a circuit split and increase the odds of certiorari review by the Supreme Court. *See Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck! (the Role of the Commission, Congress, and the Courts)*, Remarks by Commissioner Jon Leibowitz, Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust at 8-9 (Apr. 24, 2006) (explaining that the FTC could bring suit in district court to ensure

appellate forum and create circuit split). Of course, the legal landscape could tilt decisively in favor of permissive review of reverse payment settlement agreements if the D.C. Circuit opts to follow the analysis of the Second and Eleventh Circuits.

The *Cephalon* complaint may therefore mark a significant turning point in this seven-year epic. Public information shows that reverse payment settlement agreements have increased sharply since the Eleventh Circuit's *Schering-Plough* decision. According to the Commission's reports to Congress, none of the 14 patent litigation settlements filed with the Commission in fiscal year 2004 contained reverse payments. *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. In fiscal year 2005, 3 of 11 settlements contained reverse payments. *Id.* In fiscal year 2006, 14 of 28 settlements included such a payment to the generic and an agreement not to enter. *Id.*

As in the *Cephalon* case, several of these agreements included "side deals." These included payments from the brand for licensing intellectual property from the generic, co-promotion agreements, agreements that the generic would supply the brand with raw material or finished products, and the development of unrelated products using the generic's technology. *Id.* at 4-5. The Commission's *Cephalon* complaint reflects the FTC's view that side deals often are a form of reverse payment, and this case may test that theory and help to determine whether and in what circumstances such "side deals" change the antitrust analysis.

The *Cephalon* case demonstrates that the Commission continues to hunt for the appropriate case and appropriate venue to challenge reverse payment settlements, despite unfavorable law from two circuit courts. Brand and generic manufacturers in Paragraph IV infringement actions should therefore take the Commission's action into account when structuring any settlement and should watch closely for further developments in the litigation.