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Cephalon: FTC's Challenge To Patent Settlements

Tuesday, Feb 19, 2008 --- Last week, the Federal Trade Commission ("FTC" or "commission") brought the latest in a series of challenges to patent settlements between brand and generic firms in the pharmaceutical industry.

The current suit challenges brand firm Cephalon's settlements with four generic firms regarding the company's $800 million drug Provigil. The FTC alleges that these settlements – and, in particular, the payments from Cephalon to the generic firms accompanying each of these settlements – caused the generic firms to delay their entry into the market until 2012.

The FTC has challenged similar agreements in the past, including two suits in 2000, resulting in consent orders with the brand and generic firms involved.[1]

The FTC challenged another settlement in 2001 between Schering-Plough and two generic firms. The commission issued an opinion in Schering-Plough in 2003 finding those agreements unlawful. The Eleventh Circuit, however, subsequently overturned that decision.

A similar case, Tamoxifen, brought by private parties in the Second Circuit also implicitly rejected the FTC's Schering-Plough theory: that such payments in the context of a patent settlement by a brand to a generic – referred to as "reverse payments" or "exclusion payments" – violate the antitrust laws where the payments cause delayed entry by the generic firm.[2]

Following the appellate rulings in Schering-Plough and Tamoxifen, and the Supreme Court's denial of certiorari in both cases, the FTC has been threatening to bring another reverse-payment settlement challenge. The commission has clearly stated its goal to create a split in the circuit courts, and thereby foster Supreme Court review on this issue.[3]

The Cephalon suit fulfills the FTC's promise to bring another case, and thus may serve as the vehicle for the FTC to ultimately obtain – following trial and appeal – Supreme Court review of the antitrust issues presented in pharmaceutical patent settlements.

The facts surrounding the Cephalon case and the manner in which it was brought present several interesting issues, namely:

The case was brought against the brand firm on monopolization grounds under Sherman Act Section 2 – whereas the FTC's prior pharmaceutical settlement challenges also named the generic firms involved and focused on

allegations that the agreements were illegal under Sherman Act Section 1.

The FTC filed suit in federal district court, rather than bringing the case through its own administrative trial process as it typically does for such anti-competitive conduct.

The complaint provides significant detail on the manner in which the alleged payments were made by Cephalon to the generic firms – generally, through what the FTC terms "side-term inducements." The allegations regarding these "inducements" may provide guidance on the types of and circumstances under which the FTC might investigate or challenge such deals in the future.

Factual Background Regarding FTC Suit Against Cephalon

The FTC filed its 27-page complaint against Cephalon in the U.S. District Court for the District of Columbia on Feb. 13, 2008. The case is brought under the rubric of Section 5 of the FTC Act, but specifically alleges the requisite components of a Sherman Act Section 2 monopolization claim.

In particular, the complaint alleges that "Cephalon has monopoly power in the United States with respect to Provigil,"[4] and that it "willfully maintained" such power "through its course of anti-competitive conduct" by agreeing with Teva, Ranbaxy, Mylan and Barr "not [to] compete by marketing generic versions of Provigil until April 2012 in exchange for compensation."[5]

The commission underscored its monopolization claim by contending that "Cephalon obtained this result not through the strength of its patent, but by paying its potential competitors to accept the April 2012 entry date."[6]

Provigil And Cephalon's Patent Litigation

Cephalon's Provigil product was approved by the FDA in 1998. The original patent covering the active ingredient, modafinil, expired in 2001.

A second patent, which was the subject of the patent litigation between Cephalon and the four generics, issued in 1997 and does not expire until October 2014. That patent covers a formulation of modafinil consisting of a specified distribution of small particles, which the FTC describes as a "narrow formulation patent."[7]

In December 2002, Teva, Ranbaxy, Mylan, and Barr each filed Abbreviated New Drug Applications (ANDAs) with the FDA seeking approval for generic versions of Provigil.

Each of these firms filed on the first day the FDA could accept an ANDA for Provigil, and thus, per FDA rules and interpretations, shared the 180-day exclusivity period granted under the Hatch-Waxman regime.These companies, referred in the complaint as the "first filers," therefore would enjoy such market exclusivity if they entered the market following FDA

approval of their product.[8]

Cephalon sued each of the first filers in March 2003 for patent infringement on the formulation patent. Under Hatch-Waxman, this triggered a 30-month stay that prohibited generic entry in most circumstances until June 2006.

By the time of the settlements, summary judgment motions were fully briefed by the parties on both noninfringement and invalidity. The FTC alleges that "had the patent litigation proceeded, Cephalon was [] unlikely to prevent generic entry by the first filers. To do so, Cephalon had to show that each of the generic modafinil products infringed the particle size patent and defeat each of the generics' invalidity arguments."[9]

The complaint further alleges that by late 2005 generic entry "appeared imminent" to Cephalon, the generic firms, and industry analysts, as each of the first filers was likely soon to obtain FDA approval to market its products, and could have launched "at risk" (i.e., launch prior to a decision by the district court on the patent merits).[10]

Settlement Agreements

According to the FTC, to "protect its Provigil monopoly, Cephalon set out to settle its patent litigation with the four first filers under terms that would eliminate potential generic competition for a substantial period."

The complaint further alleges that Cephalon was willing to pay the generic firms "handsomely to secure their agreements not to compete," and details the particular terms of the settlements with each generic.[11]

As discussed in greater detail below, these settlements involved "side-term inducements" including intellectual property license payments from the brand, as well as supply agreements and product development agreements under which the brand compensated the generics.[12]

The complaint also alleges that the generic firms were unwilling to settle for the April 2012 entry date – three years prior to the relevant patent expiry – without compensation.[13]

The commission contends that these settlements harmed competition by eliminating the first filers as potential competitors and, thereby denying consumers access to lower-priced generic versions of Provigil prior to April 2012.[14] The FTC further alleges that,absent the compensation to the generic firms, one or more of the first filers would have entered prior to the conclusion of the patent litigation.[15]

Relief Sought By FTC

The FTC is seeking a permanent injunction from the district court against Cephalon that would allow generic Provigil entry prior to 2012, a finding that Cephalon's conduct violates the FTC Act, and an order barring Cephalon

from engaging in similar conduct in the future.[16]

The commission voted 5-0 to approve this complaint. Commissioner Leibowitz issued a separate "concurring in part and dissenting in part" statement, which is discussed below.[17]

Observations On the FTC Suit Against Cephalon

Why Did The FTC Only Sue Cephalon On Monopolization Grounds, And Not Name The Generic Filers As Defendants?

In the FTC's prior actions challenging pharmaceutical patent settlements, it brought suit not solely against the brand firm, but also against the generics involved. The commission thus challenged these agreements as violations of Section 1 of the Sherman Act, which prohibits agreements among competitors that "unreasonably" restrain trade (as opposed to unilateral conduct targeted by Sherman Act Section 2).[18]

For example, the Schering-Plough case was brought primarily on Section 1 grounds (although there was a monopolization theory pursued as well), and the analysis in the commission opinion and the Eleventh Circuit's reversal detailed how Section 1 analysis should be applied in the pharmaceutical patent settlement context.

Thus, it is somewhat surprising that in bringing Cephalon – a case that is presumably being pursued to take on the Eleventh Circuit's analysis in Schering-Plough – the FTC would proceed solely on a Section 2 monopolization theory.

By pursuing a different angle to challenge the patent settlements in Cephalon, it could potentially make it more difficult following appeal for the FTC to argue that Cephalon is squarely at odds with Schering-Plough and Tamoxifen and thereby create the necessary split in the circuits needed to obtain Supreme Court review.

The FTC's Cephalon complaint, nonetheless, provides some insight into how the commission's approach in this case will likely differ from prior cases.

In particular, the monopolization theory will allow the commission to challenge Cephalon's conduct as a whole, rather than trying to win discrete claims, as the commission would need to do if it challenged individual agreements (as it did in Schering-Plough) under a Section 1 analysis.

This broader attack on Cephalon's conduct is apparent from the following allegation:

[A]bsent the compensation Cephalon agreed to provide, generic competition to Provigil would have occurred prior to April 2012 because (1) one or more of the First Filers would have entered with its version of generic Provigil before conclusion of the patent litigation; (2) Cephalon would not have

prevailed against each of the four First Filers in its patent litigation; or (3) Cephalon would have agreed to settle its patent litigation on terms that did not compensate the First Filers, but instead provided for generic entry earlier than April 2012.[19]

Thus, the commission asserts that it need only demonstrate that one of four generics would have entered earlier than 2012 to prevail, as opposed to proving that each individual agreement resulted in delayed generic entry. At a more practical level, suing only one company as opposed to five makes the federal court litigation more manageable, as the FTC will only need to respond to one set of procedural and substantive motions, and not have to litigate against five companies concurrently.

Commissioner Leibowitz's separate statement also addressed whether suit should have been brought against the first filers. While noting that he "entirely agree[s] that monopolization is an appropriate theory of liability," he dissented in part because he "also would have named any generic company that took these payoffs and now refuses to relinquish their 180-day exclusivity, thus blocking generic entry into the Provigil market that otherwise could occur in 2008."

He further explains that if each of the first filers relinquished its rights to the 180-day exclusivity period, generic entry into the Provigil market would become unblocked. This would have resulted in other generic companies – specifically noting that Apotex and Caraco already have FDA approval – entering the market, and also allowing the four first filers to enter per the terms of their settlements.

According to Commissioner Leibowitz, "[u]ltimately, there could have been as many as six or seven competitors in the market" with prices falling by as much as 80% to 90%.[20]

Why Did The FTC File A Federal Court Complaint As Opposed To Initiating Administrative Litigation?

In challenging allegedly anti-competitive conduct, the FTC typically uses its own administrative trial procedure, whereby the case is tried before an administrative law judge and then subsequently reviewed by the full commission. Indeed, such an approach is consistent with Congress' rationale for setting up the FTC in 1914 as an expert antitrust body.

There are exceptions to this administrative trial practice, for example, where the FTC is seeking a preliminary injunction against a merger or to obtain disgorgement of profits, both of which can only be accomplished through the federal courts.

Those exceptions do not apply here, however, which raises the question why the FTC brought this case in federal court.

The answer likely lies in the rules that govern appeals following a

commission decision. These rules provide that the losing party can appeal to any federal court of appeals. Thus, the losing parties can engage in permissible appellate forum shopping – selecting the forum most advantageous to their case.

Following the Eleventh Circuit's reversal of the commission decision in Schering-Plough, it is highly likely that, if the commission prevailed during these administrative proceedings, the defendants would appeal to that circuit (or perhaps, the Second Circuit in light of Tamoxifen).

By bringing the case in federal court, the FTC can steer clear of the Eleventh and Second circuits. Any suit brought in the U.S. District Court for the District of Columbia, where the FTC filed, must be reviewed by the U.S. Court of Appeals for the District of Columbia.

The D.C. Circuit is considered by many to be a sophisticated antitrust court (e.g., Judge Ginsburg formerly was the head of the Department of Justice's Antitrust Division), and it has issued several significant Section 2 decisions, such as its 2001 liability finding against Microsoft for monopolization.

By pursuing litigation in federal court in D.C., the FTC likely believes that it has increased its likelihood of success in this matter, thus teeing up its theories regarding reverse-payment settlements for Supreme Court review.

Analysis Of "Side-Deals" Alleging Compensation Flowing From Cephalon To The Generic Firms

In recent years, the FTC has consistently presented its view that "side-deals" in the context of a patent settlement may serve as a vehicle to compensate generics for delayed entry. The Schering-Plough case involved allegations that Schering-Plough paid generic firm Upsher-Smith to delay its entry into the relevant market through a $60 million payment purportedly for a license to a cholesterol lowering product in development by Upsher-Smith.

Recent FTC reports on pharmaceutical settlements also have detailed the types of side-deals that the Commission views as suspect.[21]

The Cephalon complaint provides significant detail on the settlement terms with each of the first filers – including what the FTC characterizes as "side-term inducements." Specifically, the FTC states that "Cephalon provided these inducements in the form of purportedly independent business transactions – 13 in all totaling in excess of $200 million – such as licenses to intellectual property, supply agreements, or co-development deals."[22]

The allegations in the complaint regarding the nature and context of these agreements provide some insight not only into the FTC's rationale for challenging the conduct in Cephalon, but also provide some guidance for parties entering into future patent settlements that might be subject to FTC review.

For example, the commission alleges that certain intellectual property licenses granted by the generic firms to Cephalon in exchange for royalties were not necessary for Cephalon to manufacture and sell Provigil.[23]

Likewise, the commission notes that certain supply agreements for active pharmaceutical ingredients involved prices "substantially higher" than the amount Cephalon paid its existing suppliers.[24]

The complaint also elaborates on the context and timing of the side deals, which again provides some insight on the circumstances under which the FTC might scrutinize future settlements.

The FTC broadly characterizes Cephalon's settlements with the first filers as "not independent business transactions, but [] instead inextricably linked with the agreed-upon generic entry date of April 2012." In making this allegation, the FTC recites several factors, including: that the side deals were entered into "simultaneously" with the patent settlements; that prior to settlement negotiations, Cephalon had no significant discussions with the generic firms regarding matters relating to the side deals; and that Cephalon was willing to agree to the side deals only if the generic companies agreed not to compete with Provigil.[25]

Conclusion

The FTC's suit against Cephalon confirms the commission's continued adherence to its antitrust theories regarding reverse-payment patent settlements in the pharmaceutical industry, despite adverse appellate decisions in Schering-Plough and Tamoxifen. The FTC presumably believes that the monopolization theory advanced in Cephalon improves its chances of success on the merits.

Such an approach, however, also could make establishing a circuit split more difficult.

Regardless, we will not know for many years whether the FTC will succeed in its quest to change the law regarding patent settlements, as this case will first have to proceed through trial and then up to the D.C. Circuit. Only then will the issue (perhaps) be ripe for Supreme Court review.[26]

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[1] See In the Matter of Abbott Labs., FTC No. C-3945 (May 22, 2000); In the

Matter of Hoechst Marion Rousel, Inc., FTC No. 9293 (April 2, 2001).

[2] Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006); In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2d Cir. 2006), cert. denied, 75 U.S.L.W. 3333 (2007).

[3] See Oral Statement of Commissioner Jon Leibowitz before the Subcommittee on Commerce, Trade, and Consumer Protection, May 2, 2007, available at www.ftc.gov/speeches/leibowitz/070502reversepayments.pdf ("It's public knowledge that we're looking to bring a case that will create a clearer split in the circuits ... ").

[4] Complaint, at ¶¶ 94-96, available at http://www.ftc.gov/os/caselist/0610182/080213complaint.pdf.

[5] Complaint, at ¶ 99.

[6] Complaint, at ¶ 3.

[7] Complaint, at ¶¶ 2, 32-35.

[8] Complaint, at ¶¶36-39 (regarding facts relating to the first filers); see generally Complaint at ¶¶ 12-18 (regarding Hatch-Waxman generally, and details regarding 180-day exclusivity period and 30-month stay).

[9] Complaint, at ¶¶ 42-45.

[10] Complaint, at ¶¶ 46-47.

[11] Complaint, at ¶¶ 54-55

[12] Complaint, at ¶¶ 57-80.

[13] Complaint, at ¶ 51.

[14] Complaint, at ¶ 82.

[15] Complaint, at ¶ 83.

[16] Complaint, at pp. 26-27.

[17] Leibowitz Statement, available at www.ftc.gov/os/caselist/0610182/080213comment.pdf.

[18] Standard Oil v. United States, 221 U.S. 1, 58 (1911).

[19] Complaint, at ¶ 83.

[20] Leibowitz Statement, at pp. 1-2.

[21] Certain patent settlement agreements between pharmaceutical firms are required to be filed with the FTC pursuant to the 2003 Medicare Modernization Amendments ("MMA"). The FTC has issued reports for each of the last three years summarizing certain data relating to agreements filed pursuant to the MMA provisions. Those reports and information regarding the MMA filing requirement can be found at www.ftc.gov/bc/healthcare/drug/index.htm.

[22] Complaint, at ¶ 56.

[23] See, e.g., Complaint, at ¶ 61.

[24] See, e.g., Complaint, at ¶ 66.

[25] Complaint, at ¶ 57.

[26]Commissioner Leibowitz's Statement notes that "[a]lthough I am confident the Commission will win this case against Cephalon, it will likely take years, as most antitrust cases do. In the meantime, Congress should pass the bipartisan legislation – now moving through both Houses – that would ban these pay-for-delay deals completely (while still allowing legitimate settlements)." Leibowitz Statement, at p. 3.