Statement of the Federal Trade Commission[1]
FTC v. Cephalon, Inc.
May 28, 2015

The Federal Trade Commission has entered into a landmark settlement with Cephalon, Inc. and its parent company, Teva Pharmaceutical Industries Ltd., to resolve its action against Cephalon for illegally monopolizing the market for the sale of its blockbuster sleep-disorder drug Provigil.[2] At a federal court trial scheduled to begin next week in Philadelphia, the Commission was prepared to prove that Cephalon paid four generic competitors to abandon their challenges to Cephalon's Provigil patent and stay off the market for six years in violation of the antitrust laws, resulting in significantly higher prices for the drug and substantial consumer harm.[3]

The settlement, the first in an FTC pay-for-delay case since the Supreme Court's decision in *FTC v. Actavis* confirmed that reverse payment patent settlements are subject to antitrust scrutiny,[4] is an important victory for the public. The proposed Stipulated Order for Permanent Injunction and Equitable Monetary Relief, filed today in federal district court, prohibits Cephalon and Teva,[5] the nation's largest generic drug manufacturer, from engaging in one of the most common forms of pay-for-delay patent settlements in the future. The proposed order also requires a payment of $1.2 billion into a fund to compensate Provigil purchasers. This equitable monetary relief is the largest in the FTC's history.

This settlement is an important step in the Commission's longstanding bipartisan effort to end pay-for-delay settlements in the pharmaceutical industry. These collusive deals have cost consumers and taxpayers billions of dollars, driving up health care costs and depriving patients of needed medications.[6] As the settlement demonstrates, the FTC will use all available remedies at its disposal to obtain meaningful relief for consumers.

I. The FTC's Lawsuit Against Cephalon

Filed in 2008, the Commission's long-running enforcement action challenges Cephalon's anticompetitive course of conduct to prevent the entry of lower-cost generic competition to Provigil, its branded prescription drug used to treat certain sleep disorders. The Commission alleged that Cephalon unlawfully protected its Provigil monopoly through a series of unlawful pay-for-delay patent settlements with generic drug makers Teva, Ranbaxy Pharmaceuticals, Mylan Pharmaceuticals, and Barr Laboratories, all of whom were first to challenge the Provigil patent. In late 2005 and early 2006, facing the imminent threat of generic competition, Cephalon

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[1] This statement reflects the views of Chairwoman Ramirez, Commissioner Brill, and Commissioner McSweeny.
[2] *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141 (E.D. Pa.).
[3] The settlements not only prevented competition from the four settling generics, who were the first to file applications seeking Food and Drug Administration approval to market generic Provigil, but also later-filing generics.
[4] 133 S. Ct. 2223 (2013).
[5] Teva acquired Cephalon in 2012.
[6] *See, e.g.*, Fed. Trade Comm'n, Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions (Jan. 2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

paid these four generic rivals to settle their pending patent litigation and forgo entry for six years, until April 2012. These reverse payments took the form of at least twelve business transactions, negotiated and executed at the same time that Cephalon settled its patent suits. In these transactions, Cephalon agreed to pay the four generic companies a total of more than $300 million, purportedly for the purchase of active pharmaceutical ingredient, the licensing of intellectual property, and the co-development rights in a new drug.[7]

With these large payments, Cephalon secured six years of protection from generic drug competition that its patent could not provide. During this six-year period, consumers paid substantially higher prices for Provigil than if generic entry had occurred. These supra-competitive prices resulted in significant ill-gotten profits for Cephalon. In the year before generic entry, for instance, Provigil sales in the United States exceeded $1 billion.

In January 2015, after nearly seven years of litigation, the district court denied Cephalon's motion for summary judgment. In its opinion, the court applied the legal framework set forth in *Actavis*, the "familiar antitrust rule of reason," where "[p]laintiffs must present evidence of a large reverse payment," which then shifts the burden to defendants "to justify the reverse payment as procompetitive."[8] After a detailed assessment of the evidence, the court concluded that the FTC presented sufficient evidence to establish that "the side agreements between Cephalon and the [g]eneric [d]efendants were a means of disguising payments for delay and/or inducing the [g]eneric [d]efendants to stay off of the market."[9] Trial was scheduled to begin on June 1, 2015.

II. The Proposed Order

The proposed order bars Teva from entering into the type of reverse payments that Cephalon used to protect Provigil and that commonly raise antitrust concerns—business transactions contemporaneous with the patent settlement that are designed to compensate the generic firm for its agreement to delay, or refrain from, competing.[10] Importantly, this

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[7] The FTC alleged, and was prepared to prove, that these contemporaneous side deals were merely a mechanism for Cephalon to pay the generic challengers to forgo entry. For example, Cephalon entered into supply agreements with three of the generics or their partners to purchase the active pharmaceutical ingredient in Provigil despite evidence that Cephalon already had adequate supply available at significantly lower prices. *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 2015 WL 356913, at *15 (E.D. Pa. Jan. 28, 2015) (discussing evidence). Cephalon also agreed to pay up to $131 million to license intellectual property even though it had previously rejected any concerns about possible infringement risk. *Id.* at *16. Finally, Cephalon entered into product development deals with Mylan, despite internal projections showing a negative net present value to Cephalon. *Id*.

[8] *King Drug Co.*, 2015 WL 356913, at *1.

[9] *Id.* at *16.

[10] The proposed order applies only to agreements involving generic applicants that have filed an Abbreviated New Drug Application (ANDA). While the proposed order does not apply to agreements involving so-called "505(b)(2) applications," which are also used to seek FDA approval but are not at issue in this case, these agreements can raise antitrust concerns. In 2014, the Commission filed a lawsuit alleging an unlawful reverse payment settlement involving a 505(b)(2) application filed by Teva. *See* Compl., *FTC v. AbbVie Inc.*, No. 14-cv-5151 (E.D. Pa. filed Sept. 8, 2014), *available at* https://www.ftc.gov/enforcement/cases-proceedings/121-0028/abbvie-inc-et-al.

prohibition applies to all branded and generic U.S. pharmaceutical operations of Teva, the largest generic drug maker in the United States.

Specifically, it prohibits agreements in which the branded drug manufacturer makes a monetary payment or otherwise compensates the settling generic and (1) makes that transfer of value expressly contingent on settlement of existing patent litigation, or (2) the transfer occurs 30 days before or after the patent settlement.[11] Certain arrangements are excluded from the ban, such as settlements without payments from the brand to the generic resulting in an entry date before patent expiration or settlements with payments reflecting reasonable avoided litigation costs.

The proposed order also includes substantial equitable monetary relief. Although our decisions and orders generally focus on remedies intended to prohibit conduct that could lead to future competitive harm, we have previously emphasized that equitable monetary remedies can also be an important tool to promote the deterrence goals of antitrust enforcement by requiring a defendant to relinquish illegally-obtained profits. In fact, the Commission observed back in 2003 that equitable monetary relief might very well be appropriate in reverse payment cases.[12] The economic and regulatory context of brand-generic competition creates incentives for companies to collude rather than compete, and the brand's profits from preserving a monopoly through an anticompetitive settlement can be enormous.[13] In these circumstances, a monetary remedy to deprive a wrongdoer of ill-gotten gains may be necessary if antitrust enforcement is to deter unlawful conduct.[14]

Two additional considerations make this case an especially appropriate one for an equitable monetary remedy.

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[11] The proposed order does not prohibit all of the types of agreements that have the potential to raise antitrust concerns and is instead tailored to the specific conduct at issue in this case. For example, the proposed order does not reach certain exclusive licensing agreements that could amount to so-called "no authorized generic" agreements, where the branded drug firm compensates the generic through an agreement not to market an "authorized generic." The Commission believes that these agreements can serve as anticompetitive reverse payments by limiting the competition faced by generics. *See, e.g.*, Br. of Fed. Trade Comm'n as Amicus Curiae in Supp. of Pl.-Appellants, *King Drug Co. of Florence, Inc. v. SmithKlineBeecham Corp.*, No. 14-1243 (3d Cir. filed Apr. 28, 2014), *available at* http://www.ftc.gov/system/files/documents/amicus_briefs/re-lamictal-direct-purchaser-antitrust-litigation/140428lamictalbrief.pdf.

[12] *See* Fed. Trade Comm'n, Policy Statement on Monetary Equitable Remedies in Competition Cases, 68 Fed. Reg. 45820, 45822 (Aug. 4, 2003) (withdrawn July 31, 2012) (stating that the FTC had warned pharmaceutical companies that it would consider the entire range of remedies "including possibly seeking disgorgement of illegally obtained profits" in connection with reverse payment agreements).

[13] *See* Michael Carrier, *Solving the Drug Settlement Problem*, 41 Rutgers L. J. 83, 91 (2009) ("Because the brand makes more by keeping the generic out of the market than the two parties would receive by competing in the market, the parties have an incentive to split the monopoly profits, making each better off than if the generic had entered."): C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1580-81 (2006).

[14] As the Supreme Court has stated, "[a] Government plaintiff . . . must seek to obtain the relief necessary to protect the public from further anticompetitive conduct and to redress anticompetitive harm." *Hoffman-La Roche Ltd. v. Empagram S.A.*, 542 U.S. 155, 170 (2004). Depriving violators of the gains from their unlawful conduct is a well-accepted goal when crafting an antitrust remedy. *See, e.g., United States v. Grinnell Corp.*, 384 U.S. 563, 577 (1966); *Schine Chain Theatres, Inc. v. United States*, 334 U.S. 110, 128 (1948).

First, although the FTC initially sought a remedy enabling immediate entry of generic Provigil and did its best to expedite the case, Cephalon succeeded in exploiting the full six-years of protection for Provigil secured by its reverse payments. In 2006, shortly after announcing the reverse payment settlements, Cephalon's general counsel assured investors that, if it sued, the FTC would have no "practical remedy" because an enforcement action would take too long to "limit or undo or negate" Cephalon's financial gain from the settlements.[15] Although that prediction ultimately proved true, Cephalon should not stand to benefit from it.

Additionally, requiring Cephalon to surrender ill-gotten profits is especially warranted here because the challenged patent settlements arose out of litigation derived from a patent procured by fraud. Following a 2011 trial in a related Provigil case, the district court concluded that "Cephalon made a deliberate choice to deceive the PTO about the origin of its claimed invention."[16] Cephalon used this fraudulent patent to secure the four pay-for-delay settlements at issue in the FTC's case. Although the FTC's action against Cephalon was not based on this conduct, the element of fraud is a relevant equitable consideration when fashioning a remedy for unlawful conduct. Even prior to *Actavis*, courts considering reverse payment antitrust claims acknowledged that the use of such payments to protect a fraudulently-procured patent raised antitrust concerns.[17]

The proposed order requires Cephalon to pay $1.2 billion into a settlement fund that will provide redress to purchasers who overpaid for Provigil as a result of Cephalon's illegal conduct. To avoid the possibility of duplicative recovery by private parties who have sued Cephalon for the same conduct, the settlement fund will be offset by the amount of the damage awards or settlements in those private cases. The settlement fund may also be used to satisfy any settlements or damage awards other parties, such as states or federal purchasers, may secure. The FTC will administer an escrow account to disburse funds for this purpose. Any remaining funds will go to the U.S. Treasury.

The Commission believes the proposed order is a just resolution of this longstanding case. The proposed order precludes the largest generic company in the United States from entering into one of the most common forms of anticompetitive reverse payments in the future. Moreover, by depriving Cephalon of its ill-gotten gains, it ensures that injured consumers are compensated and is likely to deter pharmaceutical companies from engaging in similar unlawful conduct.

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[15] Transcript of Q2 2006 Cephalon, Inc. Earnings Conference Call, Aug. 3, 2006, at 10-11.

[16] *Apotex, Inc. v. Cephalon, Inc*., 2011 WL 6090696, at *28 (E.D. Pa. Nov. 7, 2011), *aff'd*, 500 F. App'x 959 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 825 (Dec. 16, 2013); *see also id.* at *26 (finding that "[h]ad the PTO been aware of this information, it would not have allowed the patent to issue.").

[17] *See, e.g., Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 106 (2d Cir. 2010); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005).