**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.*

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 the market." [9] In addition to pTj-27.779 -1.15 TD0 Tc0 Tw( begn )n a

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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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 comw