# CLIENT ALERT

## FTC Continues Hard Line Against Reverse Payment Patent Settlements in the Pharmaceutical Sector

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The FTC announced on May 28, 2014 that, just days before trial, it had settled its long-running antitrust lawsuit against Cephalon, Inc. and its parent company Teva Pharmaceutical Industries, Ltd. In the suit, the agency alleged that Cephalon unlawfully protected its monopoly for the sleep-disorder drug Provigil through a set of so-called "reverse payment patent settlements" with potential generic entrants. According to the FTC, the payments were in the form of commercial contracts that were favorable to the generic companies and executed as part of the settlement agreements.

The settlement requires Teva to make $1.2 billion available to compensate buyers that paid higher prices due to the reverse payment settlements. The monetary relief, the largest in the FTC's history, underscores the agency's continued attention to reverse payment patent settlement agreements in the pharmaceutical industry and sends a cautionary signal to pharmaceutical companies that negotiate patent settlement agreements as part of larger commercial arrangements.

In 1997, Cephalon secured a U.S. patent covering the formulation of modafinil, the active ingredient in the brand-name drug Provigil, which is approved for the treatment of various wakefulness disorders including narcolepsy and sleep apnea. In 2002, Teva, Ranbaxy, Mylan, and Barr (the "Generics") each filed an Abbreviated New Drug Application (ANDA) seeking to market a generic version of Provigil. Each claimed that its product did not infringe Cephalon's patent, or that the patent was invalid. In March 2003, Cephalon filed a patent infringement action against the Generics.

Under the framework for generic entry established by the Hatch-Waxman Act, if the branded pharmaceutical company claims that its approved drug is covered by a patent, a generic company seeking entry before the patent expires must state in its ANDA that its product does not infringe the patent or that the patent is invalid. Once notified that a generic company has made what is known as a "paragraph IV certification," the branded pharmaceutical company can immediately file a patent infringement lawsuit, which triggers a 30-month stay on FDA approval of the generic ANDA. At the same time, the first ANDA application triggers a 180-day exclusivity period for the applicant delaying the approval of other generic versions until 180 days after (1) the first commercial marketing of the generic, or (2) an appellate court's finding that the patent is invalid.

The parties settled in 2005, agreeing that the Generics would not introduce their generic versions of Provigil until April 2012. In addition, the parties contemporaneously entered into a series of business transactions, including among other things, supply agreements and intellectual property licensing agreements that the FTC argued were not necessary for Cephalon to continue marketing its branded Provigil product. Cephalon and certain Generics also entered into co-development agreements, which the FTC claimed Cephalon had concluded were unprofitable. According to the FTC, these transactions led to payments from Cephalon to the Generics in excess of $300 million.

In 2008, the FTC filed a complaint alleging that the agreement violated Section 5 of the FTC Act because, absent Cephalon's payments, the Generics would have begun marketing and selling their generic versions of Provigil prior to April 2012. According to the FTC, the reverse payments took the form of "at least twelve business transactions negotiated and executed at the same

time that Cephalon settled its patent suits," and provided Cephalon with "six years of protection from generic drug competition that its patent could not provide."

Cephalon's decision to settle with the FTC came a week before the scheduled start date of trial. In addition to the $1.2 billion in disgorgement,[2] Cephalon will also be enjoined from certain types of patent settlements, unless pre-approved by the FTC. *See* Proposed Order. The FTC stated that it takes no issue with "truly independent business transactions . . . or other types of settlement agreements in which the value transferred is unlikely to present antitrust concerns." But this historic settlement confirms that the agency will aggressively pursue reverse payment settlements regardless of whether that payment comes in the form of cash or a favorable business transaction.

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[1] The FTC alleged that Cephalon faced imminent competition because the Generics had identified a way to circumvent Cephalon's Particle Size Patent, which would have permitted the Generics to manufacture their generic versions of Provigil without infringing on the patent. The Generics had also received FDA approval.

[2] In a related Provigil patent case, a district court held that "Cephalon made a deliberate choice to deceive the PTO about the origin of its claimed invention." Though the FTC's lawsuit was not based on this fraudulent conduct, the FTC did note that the fact that Cephalon used the fraudulent patent to secure the reverse payment settlements was an "equitable consideration in fashioning a remedy" for Cephalon's conduct.

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