

## E-ALERT | Antitrust

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### DISTRICT COURT PERMITS REVERSE PAYMENT CASE TO PROCEED TO DISCOVERY

In the latest development in the Federal Trade Commission's efforts to challenge Hatch-Waxman patent litigation settlements, earlier this week a federal district court in Pennsylvania denied in part defendants' motions to dismiss antitrust complaints challenging a series of such settlements. The court rejected the argument of the FTC and other plaintiffs that a settlement that includes a "reverse payment" from the patent holder to the generic entrant is a *per se* antitrust violation and adopted instead the "scope of the patent" standard followed by most other courts. Under that standard, the court concluded that plaintiffs had alleged sufficient facts that, if true, could establish that the settlements granted greater rights than those conferred under the patent at issue. Accordingly, the court permitted the matter to continue to discovery on this basis.

#### The "Cephalon" Case

The case, *In re Modafinil*, consolidates sixteen cases filed by the FTC and other plaintiffs against Cephalon, Inc., and four generic pharmaceutical firms—Teva Pharmaceutical Industries, Ltd./Teva Pharmaceuticals USA, Inc.; Ranbaxy Laboratories, Ltd./Ranbaxy Pharmaceuticals, Inc.; Mylan Laboratories, Inc.; and Barr Laboratories, Inc. Cephalon holds the patent for modafinil, the active ingredient in Provigil®, a treatment for sleep disorders. The company filed suit against the four generic firms in 2003, alleging that the Abbreviated New Drug Applications they had filed pursuant to the Hatch-Waxman Act infringed its modafinil patent. In late 2005 and early 2006 Cephalon entered into agreements with the generic firms to settle those lawsuits. Each agreement included a "reverse payment" from Cephalon to the generic firm and provided, *inter alia*, that the generic firm would not manufacture or sell generic modafinil prior to April 6, 2012, three years prior to the expiration of the patent. The *In re Modafinil* plaintiffs allege that the agreements violate the Sherman Antitrust Act.

#### Per Se Rule Inappropriate for Reverse Payment Cases

After reviewing the precedent of the 2<sup>nd</sup> (*Tamoxifen*), 6<sup>th</sup> (*Cardizem*), 11<sup>th</sup> (*Valley Drug* and *Schering-Plough*) and Federal (*Cipro*) Circuits, the district court rejected the *per se* standard put forward by the FTC and determined that plaintiffs cannot proceed with their antitrust claims unless they can establish that the settlement agreements exceed the exclusionary rights granted to Cephalon by its modafinil patent. The court noted that "a patent grants its owner the lawful right to exclude others" and determined that "a reflexive conclusion that the agreements in question are *per se* violations, as urged by Plaintiffs, and in particular the FTC, ignores the 'exclusionary' patent rights afforded to Cephalon." The court also concluded that condemning the agreements as *per se* antitrust violations "would tend to ignore the long standing preference under the law favoring settlements," that "reverse payment settlements seem to be a natural consequence of the Hatch-Waxman Act," and that "imposing a *per se* prohibition on reverse payment settlements would reduce a generic manufacturer's incentive to challenge patents."

#### Case to Proceed to Discovery Under Alternative "Scope of the Patent" Standard

Reviewing defendants' motions to dismiss under the standard established by the Supreme Court in the *Iqbal* and *Twombly* decisions, the court held that plaintiffs' cases should proceed to discovery

under the “scope of the patent” standard. According to the court, plaintiffs had alleged that the settlements exceeded the scope of Cephalon’s patent in four different ways:

1. the underlying litigation was a “sham” because Cephalon knew that its patent was invalid, unenforceable, and/or not infringed;
2. through operation of the Hatch-Waxman Act the settlements created a bottleneck preventing entry into the market by other generic companies;
3. the agreements were part of a larger antitrust conspiracy that allocated all sales of modafinil in the U.S. to Cephalon; and
4. the settlement agreements prohibit the sale of generic versions of modafinil beyond those at issue in the underlying patent litigation.

In permitting the case to proceed to discovery, the court concluded that if “a factual basis exists on any of these theories, Plaintiffs may be able to prevail under a scope of the patent test and move forward with their antitrust claims . . . . Consequently, plausible antitrust allegations have been pled.”

The court’s memorandum opinion can be found at  
<http://www.paed.uscourts.gov/documents/opinions/10d0302p.pdf>

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