PATENT FILE

FTC settles $1.2bn 'pay for delay'


Maria Raptis


Molly Delaney

The regulator claims victory, but there's still no clear legal precedent pathway, argue **Maria Raptis** and **Molly Delaney**

The Federal Trade Commission (FTC) announced on 28 May, 2015 that it reached a settlement with Teva, resolving the FTC's long-standing lawsuit against Cephalon (acquired by Teva in 2012), which claimed that the company had made reverse payments to generic drug manufacturers to delay competition for its sleep-disorder drug Provigil. Under the settlement, Teva will pay $1.2bn to settle the case, but may offset this amount with other payments made in separate Provigil settlements, including a $512m settlement entered in April with private plaintiffs. Despite the FTC's portrayal of the agreement as a major victory and potential benchmark for other pharmaceutical settlements, beneath the surface the settlement may be of limited precedential value in other reverse payment cases.

Background

The FTC initially filed a lawsuit seeking injunctive relief against Cephalon in 2008, alleging that the drug maker violated Section 5 of the FTC Act by paying four generic manufacturers upwards of $300m to refrain from entering the market with generic versions of Provigil. According to the complaint, each of the four companies – Teva, Ranbaxy, Mylan, and Barr – certified that their products did not infringe the Provigil patents. Cephalon filed a patent infringement lawsuit against all four companies in 2003. By 2006, with summary judgment still pending, Cephalon reached settlements with each of the generics. According to the FTC's complaint, the four companies agreed to delay marketing generic versions of Provigil until 2012 in exchange for a variety of lucrative intellectual property licenses, supply agreements and/or co-development deals with Cephalon. The FTC maintained that absent these valuable agreements, generic competition would have commenced in 2006.

The FTC's case was stayed pending the Supreme Court's decision in *FTC v Actavis,* where it was established that settlements alleged to contain "reverse payments" should be evaluated under the rule of reason rather than the "scope of the patent" test followed by many circuit courts. Trial was scheduled to begin 1 June, 2015. On the eve of trial, the FTC and Cephalon reached a settlement agreement providing for a $1.2bn disgorgement payment, and conduct remedies preventing certain types of side agreements. The settlement contains certain carve-outs which permit Teva to enter into transactions where the value is unlikely to raise antitrust concerns, such as a payment for future saved litigation expenses of up to $7m.

Implications

In recent years, the FTC has pursued disgorgement with increased vigour, and the Cephalon settlement may further embolden the agency to seek disgorgement, particularly within the reverse payment context. In 2012, the FTC withdrew the 2003 Policy Statement on Monetary Equitable Remedies in Competition Cases, which limited disgorgement to exceptional cases. Since that time, the FTC obtained a $26.8m disgorgement settlement with Cardinal Health in April, 2015, and filed a complaint in 2014 against AbbVie, Inc, seeking disgorgement of AbbVie's profits from allegedly delaying generic competition for Androgel. Although the FTC likely will cite the Cephalon settlement as precedent for its ability to seek disgorgement in other reverse payment cases, it is important to recognise that the Provigil outcome results from a voluntary settlement as opposed to a litigation judgment and therefore does not establish definitive legal precedent on the use of the remedy.

It is also important to note that the Cephalon settlement does not directly implicate the post-*Actavis* reverse payment standard, as the underlying case involved a patent previously found to have been obtained by fraud on the Patent and Trademark Office. In 2011, Judge Goldberg (in a related matter) determined that the Provigil patent in the underlying case was invalid due to inequitable conduct during the procurement process. In denying defendants' motion for summary judgment, Judge Goldberg also highlighted direct statements from Cephalon's internal personnel "suggesting that [Cephalon] had knowledge of the . . . patent's weaknesses," noting one consultant's admission that "Provigil 'faces the certain prospect of generic competition by June 2006.'" This scenario – which arguably would have run afoul of the pre-*Actavis* "scope of the patent standard" – is decidedly different from other pharmaceutical settlements currently facing antitrust scrutiny, many of which involve brand and generic manufacturers settling patent infringement lawsuits well within the parameters of the then-prevailing law. Notwithstanding the FTC's enthusiasm, obtaining disgorgement in a case that arguably would have run afoul of the pre-*Actavis* "scope of the patent standard" is markedly different from seeking disgorgement from brand and generic pharmaceutical companies who legally settled patent infringement suits under prevailing circuit law at the time.

Finally, since Teva may offset the disgorgement payment by other Provigil settlements, the amount the FTC will actually recover – while still significant – is substantially less than the $1.2bn advertised.

In short, the FTC's victory is not so clear cut and the extent to which the FTC will be able to utilise the Cephalon settlement as a benchmark for future reverse payment settlements given the exceptional nature of the case is uncertain. What is certain, however, is that resolution of the Cephalon case now allows the FTC to direct more of its resources towards other reverse payment cases, with this area likely to remain extremely active.

Maria Raptis is a partner and Molly Delaney is an associate in Skadden's New York office, both practicing in the global antitrust and competition group.