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FTC's $1.2 Billion Disgorgement Settlement With Cephalon: Heightened Scrutiny of Hatch-Waxman Settlements

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On May 28, 2015, the ***Federal Trade Commission (FTC)*** announced the settlement of its 2008 lawsuit against **Cephalon, Inc**. (now owned by *Teva Pharmaceutical Industries*, Ltd.), which alleged that Cephalon had made "reverse payments" to four generic drug manufacturers in order to delay sales of generic versions of its branded sleep disorder drug Provigil. According to the FTC, Cephalon had 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.

Settlement Followed Denial of Cephalon Motion to Preclude FTC From Seeking Disgorgement

According to the settlement terms, the FTC obtained significant equitable monetary (disgorgement) relief of $1.2 billion, although certain payments made by Cephalon in separate settlements with purchasers will be credited against this amount, making the FTC's net recovery for its "Settlement Fund" uncertain. Cephalon also agreed to certain conduct relief, including a prohibition on "payments" to generic manufacturers in connection with settling Abbreviated New Drug Application (ANDA) litigations without prior approval of the FTC.

- This settlement followed soon after an April 15, 2015, District Court opinion denied Cephalon's motion to preclude the FTC from seeking disgorgement as a remedy. (Cephalon opposed disgorgement as an available remedy, claiming various legal and equitable impediments, including the concern that July 2013 was the first time the FTC indicated that it intended to seek equitable monetary remedies in the litigation.) A separate opinion of FTC Commissioners Ohlhausen and Wright, accepting the proposed consent order, expressed "continuing concerns about the lack of guidance the Commission has provided on the pursuit of this extraordinary [disgorgement] remedy in competition cases."

What are Deemed "Payments"?

The definition of “payments” included in the (proposed) stipulated order is broadly defined as “transfer of value by the NDA Holder to the ANDA Filer (including, but not limited to, money, goods or services), regardless of whether the ANDA Filer purportedly transfers value in return, where such transfer is either (i) expressly contingent on entering a Brand/Generic Settlement Agreement, or (ii) agreed to during the 60 day period starting 30 days before executing a Brand/Generic Settlement Agreement and ending 30 days after executing a Brand/Generic Settlement Agreement.”

- A variety of potential transfers of value, however, are excluded from the definition of “payment,” including (a) saved future litigation expenses; (b) provisions providing the generic an entry date; (c) provisions providing the generic an exclusive license; (d) provisions allowing generic entry triggered by other entry; (e) agreements settling other litigations (subject to timing caveats); and (f) the continuation of certain existing agreements.

Broader Than “Payment” Concerns Under *Actavis*

This stipulated definition of “payments” arguably goes far beyond that contemplated in *FTC v. Actavis*, 133 S. Ct. 2223 (2013), wherein the Supreme Court established that the antitrust “rule of reason” should apply when evaluating reverse-payment settlement agreements, rejecting both the settlement-friendly “scope of the patent” test and the presumption of illegality test proffered by the FTC.

- In *Actavis*, the Supreme Court expressed concern primarily with “large and unjustified” payments flowing to the generic, without providing much guidance to lower courts to evaluate the form, size, or timing of payments that might satisfy this test and justify further inquiry.

- But *Actavis* did expressly recognize, among other things, that a reverse payment reflecting “traditional settlement considerations, such as avoided litigation costs or fair value for services,” does not raise the same concern that a patentee is using monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement. And yet, the stipulated definition of “payments” in the Cephalon settlement applies “regardless of whether the ANDA Filer purportedly transfers value in return,” thus ignoring (presumably for ease of enforcement) the traditional settlement consideration of “fair value for services.”

Parties to a litigation with the FTC may settle upon whatever terms they choose (subject to court approval), but the definition of “payments” in the FTC’s settlement with Cephalon may reveal little about how a court would or should apply the teachings of *Actavis* to other alleged “pay-for-delay” situations. The case also suggests that the FTC will continue to pursue a broad view of what constitutes a payment under the *Actavis* decision.

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