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Quo Vadis FTC?: The Meaning Of FTC Case Against Endo


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This article, the title of which is adapted from a March 30, 2016, Federal Trade Commission staff attorney blog post,[1] considers the FTC's first lawsuit challenging a so-called "no-AG" agreement. No-AG agreements are components of Hatch-Waxman patent infringement litigation settlements in which the brand manufacturer agrees, expressly or through exclusive licenses, not to launch an "authorized generic" for a period of time after the generic manufacturer's entry. The FTC's complaint attacks two such settlements that Endo Pharmaceuticals Inc. and the Japan-based patent holder for one of the relevant patents reached with generic manufacturers Watson Laboratories (and Watson's current owner, Allergan PLC) and Impax Laboratories, to settle Hatch-Waxman litigation involving Endo's two most important products — the pain relievers Opana ER and Lidoderm.[2]

The FTC's complaint and its simultaneous settlement with the Japanese patent holder and its U.S. subsidiary (collectively, "Teikoku") are less a window into the FTC's thinking, which at this point is hardly unpredictable, than they are into its litigation strategy and what drug manufacturers need to consider regarding potential FTC and private actions as they continue to wrestle with the many issues that remain unresolved post-Actavis.[3]

Background

Hatch-Waxman Paragraph IV Certifications

The mechanics of Hatch-Waxman paragraph IV certifications and the ensuing patent infringement suits are familiar. A drug manufacturer seeking to market a generic version of a branded drug must file an abbreviated new drug application with the U.S. Food and Drug Administration. The manufacturer must make one of four certifications about patents covering its product, the most important for present purposes being a "paragraph IV" certification that the patents for the branded drug are invalid or will not be infringed by the generic drug. The generic must then notify the patent holder, which has 45 days to initiate patent infringement litigation against the generic. If it does so, the FDA cannot grant final approval of the ANDA until the earlier of (1) the expiration of the patent(s), (2) district court resolution of the litigation in the generic's favor, or (3) the expiration of the automatic 30-month stay.

If the generic prevails in subsequent litigation, and was the first to have filed an ANDA referencing the branded product and containing a paragraph IV certification, it is eligible to obtain a 180-day period of

exclusivity, during which no other generic approved via the ANDA process may be sold. Absent a contrary agreement, the NDA holder is free during this 180-day period to market an "authorized generic" ("AG") — generally, an AB-rated version of the branded product (i.e., one subject to generic substitution) that is manufactured by or under license from the NDA holder. The period of generic exclusivity is understood to be quite profitable for the generic drug that enjoys it. This profitability is reduced — the FTC alleges by 50 percent — where an AG is also in the market.[4]

Endo's Settlement with Impax for Opana ER[5]

Opana ER is an extended-release formulation of oxymorphone, which is used "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time."[6] Endo launched Opana ER in 2006 as the only extended-release version of oxymorphone in dosage strengths of 5, 7.5, 10, 15, 20, 30 and 40 mg.[7] Over time, Endo listed four separate patents for Opana ER in the Orange Book.[8]

Impax was the first generic to submit an ANDA with a paragraph IV certification seeking approval to market a generic version of Opana ER in 5, 10, 20, 30 and 40 mg doses.[9] Endo filed patent infringement litigation against Impax,[10] and the FDA subsequently approved Impax's ANDA.[11] In anticipation of Impax's launch of generic Opana ER, Endo had been developing a reformulated "crush-resistant" version of Opana ER for which Impax's generic would not be an FDA-approved substitute.[12]

In June 2010, after two days of the patent infringement trial — and a week before Impax was expected to receive FDA approval of its ANDA — Endo and Impax reached a settlement that would delay entry of Impax's generic until January 2013.[13] Endo agreed not to launch an AG to compete with Impax's generic, and guaranteed that Impax would receive cash value commensurate with what the FTC described as "supracompetitive profits that come with being the only seller of generic Opana ER for 180 days ('Guaranteed No-AG Payment')." That payment depended in part on whether Endo, prior to generic entry, introduced its crush-resistant dosage form. The introduction would likely reduce (or eliminate, if the prior version were withdrawn) sales of the prior formulation that would have been available to Impax under the generic substitution laws. Endo also agreed to pay Impax between $10 and $40 million "purportedly for an independent development and co-promotion deal ('Side Deal Payment')," although the FTC disputes the value of this deal to Endo.[14] Ultimately, Endo did introduce its Reformulated Opana ER, which triggered an obligation to pay Impax more than $102 million.[15]

Overall, the FTC alleges that the "[settlement] compensation package" was "large" and "not justified," thereby satisfying the threshold test under Actavis for potential antitrust concern.[16] The FTC further contends the side deal made "no business or economic sense for Endo independent of Impax's agreement to defer generic Opana ER entry until January 2013," a characteristic that, as discussed below, the FTC alleges makes the side deal payment unlawful.[17]

Endo's Settlement with Watson for Lidoderm

Teikoku, which owns the '529 patent for certain lidocaine patch formulations,[18] entered into an exclusive license with Endo to sell the Lidoderm patch in the United States.[19] Watson was the first generic company to file an ANDA with a paragraph IV certification covering the '529 patent.[20] In response to the certification, Endo and Teikoku sued Watson for patent infringement.[21] During the 30-month Hatch-Waxman stay of ANDA approvals, Watson invested more than $40 million in a manufacturing plant to produce the generic patches and purchased millions of dollars of raw materials.[22] After Watson prevailed on claim construction for the '529 patent, Endo filed a separate

court action alleging that Watson's generic infringed three additional patents.[23] However, after a February 2012 infringement trial on the '529 patent, Watson was allegedly confident in its litigation position.[24]

In May 2012, before the court ruled on the '529 patent, Endo, Teikoku and Watson settled both of the litigations.[25] Endo agreed (1) not to launch an authorized generic for up to 7.5 months, and (2) to provide Watson's wholly owned wholesale distributor with free branded Lidoderm product worth up to approximately $240 million through 2015.[26] Watson agreed to delay launching its generic version of Lidoderm until September 2013 unless a third party launched a generic, and to pay Endo a 25 percent royalty on the gross profit from sales of its generic Lidoderm sales before entry of a second generic product.[27] Again, to satisfy Actavis the FTC alleges that the payments to Watson were both "large" and "not justified," emphasizing that the payments "far exceed[] any reasonable measure of avoided litigation costs in the parties underlying patent litigation," which had concluded other than post-trial briefing.[28]

The FTC's Settlement with Teikoku

The FTC also filed a stipulated order for permanent injunction with Teikoku, which licensed the Lidoderm patents to Endo and approved the settlement, limiting that company's ability to enter into Hatch-Waxman settlements and certain commercial agreements with generics in the future, but calling for no disgorgement.[29] The Teikoku stipulated order broadly prohibits "payments" to generics, defining that term generally to mean "a transfer of value by the NDA Holder to the generic Filer (including, but not limited to, a No-AG Commitment, money, goods, or services), regardless of whether the Generic Filer purportedly transfers value in return," in excess of future litigation expenses.[30] Permissible litigation expenses, in turn, are limited to an inflation-adjusted $7 million.[31]

The FTC's vote to file the Endo Complaint was 3-to-1. Continuing an internal debate that has been ongoing for several years, Commissioner Maureen Ohlhausen dissented from the decision to sue, believing that a violation of law had occurred but that a claim for disgorgement was inappropriate and that the matter should be handled administratively.[32] The vote to approve the Teikoku settlement was unanimous.

Discussion

The Endo complaint reflects a number of positions that the FTC has taken in litigation or in amicus briefs, but more broadly reflects two characteristics of commission legal actions against Hatch-Waxman settlements. First, the FTC is dogged in presenting its hard-line approach, and indeed actively searches out opportunities to press its antipathy towards "reverse-payment" settlements to make new law. Second, while reflecting a structural adherence to Actavis, commission filings appear to some observers to depart significantly from what the U.S. Supreme Court already decided in Actavis, continuing to advance positions that the court declined to accept. These themes play out in connection with a number of positions taken in the Endo complaint and the stipulated order. A few are of particular interest:

No-AG Agreements Are Unlawful Under Actavis

The FTC's position that no-AG settlements constitute unlawful "reverse payments" is consistent with the conclusion of a majority of courts that impermissible "payments" under Actavis need not be limited to cash.[33] Indeed, last year's Lamictal ruling in the Third Circuit held that no-AG agreements were within Actavis' scope, rejecting an argument that they should be construed as exclusive licenses expressly

authorized under the Patent Act.[34] The Lamictal decision is currently before the Supreme Court on a petition for certiorari, and the court has requested a response from the plaintiffs below, which had waived their right to file an opposition.[35]

Even if the law settles on the conclusion that no-AG provisions are within the scope of prohibited settlements under Actavis, the cases suggest the additional requirement of causation must be shown.[36] In this context, causation means an allegation, and ultimately proof, that the no-AG clause caused the brand not to launch an AG that would have provided additional competition to the generic entrant during the exclusivity period. The Endo complaint seeks to satisfy this burden in a number of ways, including through allegations that Endo had the "legal right and financial incentive" to introduce an AG of Opana ER, and Lidoderm.[37] It recites further that Endo "was planning to launch" an AG for Lidoderm,[38] but based on the publicly available complaint no such allegation is made as to Opana ER. Although material in the extensive redactions to the public version of the compliant may supplement the public record, the facts on display provide rather sparse support for an allegation of causation.

Side Deals Integral to Hatch-Waxman Settlements Are Unlawful

One of the most significant practical holdings of Actavis is that side deals can be part of an unlawful "payment," but only if the amount the brand pays to the generic exceeds the "fair value for services" provided by the generic.[39] The FTC has never liked this formulation, preferring instead to argue that any side deal providing funds to the generic in connection with a Hatch-Waxman settlement is unlawful, whether or not it reflects "fair value."[40]

The Endo complaint reveals how the FTC has deconstructed Actavis in order to support this conclusion. Thus, the FTC explains that the payment made by Endo under the Side Deal "cannot be justified solely as compensation for ... services," because "the purpose and effect" of the payment was ostensibly to provide a further incentive for the settlement.[41] Rephrasing the Actavis test to require that a side deal "solely" reflect the value of services adds just one word to the test the Supreme Court actually articulated, but it changes the meaning of that test significantly. Whereas the Actavis test unambiguously requires an assessment of the value of services rendered, the substitute proposed by the FTC turns on the mere delivery of some revenue to the generic, irrespective of whether that revenue otherwise reflects the product of an arm's-length transaction. And because side deals to settlements are likely to be integral to those settlements, it is difficult to see the FTC believing any would likely be lawful. That hardly seems like a fair reading of Actavis.

To be sure, the FTC does appear to challenge the commercial bona fides of the side deal, commenting (somewhat ironically given the Commission's penchant for dismissing the relevance of high drug development costs) that "[f]ewer than 1% of drugs in pre-clinical development ultimately receive FDA approval," and noting that development of the products in question "has been significantly delayed."[42] But it separately urges that the side deal is unlawful because the side deal payment was an inducement for the generic to settle. Some might see the structure of the Endo complaint as an effort to fish for a favorable ruling (or even favorable language) on the FTC's preferred basis for opposing side deals. Regardless, the factual distinction remains that the side deal has been alleged not to reflect fair value.

The Teikoku stipulated order also reflects the FTC's preferred basis for finding side deals illegal, expressly making irrelevant whether any "value in return" was provided by the generic for monies it received.[43] A similar feature was present in the FTC's 2015 settlement with Cephalon and Teva and FTC staff were suggesting publicly that the terms of the order should be understood as setting a

standard for industry conduct.[44] As Markus Meier, currently assistant director of the FTC's Healthcare Division and acting deputy director of the Bureau of Competition, told Law360 at the time, despite the fact that future deals might not be identical in all respects, "there's ... a meaningful potential that this settlement will set a standard for the industry. The question is: Are other companies going to fall in line or not?"[45]

"Reverse Payment" Settlements Attendant to "Product Hops" Are Unlawful

The Endo complaint alleges that Endo engaged in "product hopping" through its discontinuation of Opana ER's old formulation prior to generic entry, so that patients would switch to a new "crush-resistant" dosage form that would not be subject to the generic substitution laws upon the generic's subsequent entry.[46] Even though consumers who had been "switched" to the reformulated version of Opana ER were free to buy the generic of the original formulation the day it was available, the FTC alleges that the rate of switching was slowed because the generic substitution laws were not available to facilitate the transition.[47] While this conduct is alleged to have "harmed consumers," the "product hop" does not itself appear to be challenged as illegal. The Second Circuit's recent decision in in New York v. Actavis concerning the Alzheimer's drug Namenda supports the argument that frustration of the generic substitution laws can be part of a viable antitrust claim.[48] But an essential element of the Second Circuit's holding — that, unlike more typical patient populations, moderate-to-severe Alzheimer's patients who took Namenda would be "very reluctant" to switch to the generic of the prior formulation[49] — appears absent here.

Conclusion

The FTC's challenge to the no-AG agreements in the Endo complaint is no surprise. As we have learned, though, the notable aspects of commission actions lie in the quieter passages — the statement of the elements of a violation, the allegations said to satisfy those elements, and the selection of issues that the commission persists in pursuing despite apparent judicial losses. The courts of appeals and the Supreme Court have not yet provided enough clarity to suggest that the unsettled state of the law will soon end, or that each new FTC filing will not repay a detailed examination.

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[1] Jamie Towey, "Quo Vadis Post-Actavis? FTC Competition Blog," posted March 30, 2016, available at https://www.ftc.gov/news-events/blogs/competition-matters/2016/03/quo-vadis-post-actavis.

[2] Federal Trade Commission v. Endo Pharmaceuticals Inc. et al., No. 2:16-cv-01440-PD (dated March 31, 2016), available at https://www.ftc.gov/system/files/documents/cases/160331endocmpt.pdf ("Endo Complaint").

[3] Federal Trade Commission v. Actavis, 133 S.Ct. 2223 (2013).

[4] See Endo Complaint ¶ 64. Many factors can affect the calculus of generic profitability after a branded product's loss of exclusivity, including the brand's own pricing behavior. We do not intend by use of the term "market" to imply that, as the FTC routinely alleges, a branded drug and its generic equivalent(s) constitute a "market" for antitrust purposes. That determination will depend on the facts.

[5] Facts described in this section and the next two are as alleged in the FTC's complaint, and may thus be subject to vigorous dispute.

[6] Id. ¶ 39.

[7] Id. ¶ 40.

[8] Id. ¶¶ 43-46.

[9] Id. ¶ 51.

[10] Id. ¶ 50.

[11] Id. ¶¶ 50, 53.

[12] Id. ¶¶ 56-59. Endo maintains that the crush-resistant reformulation of Opana ER and subsequent market withdrawal of the original formulation reflected an effort to deter drug abuse, and on that basis urged FDA post-withdrawal not to approve ANDA's based on the NDA for the original formulation. In a much-discussed action, FDA ultimately disagreed, and approved the ANDAs. See Determination that Opana ER (Oxymorphone Hydrochloride) Drug Products Covered by New Drug Application 21-610 Were Not Withdrawn from Sale for Reasons of Safety or Effectiveness, 78 FR 38053-01 (June 25, 2013).

[13] Id. ¶¶ 60-61.

[14] Id. ¶ 61.

[15] Id. ¶ 69.

[16] Id. ¶¶ 87-90.

[17] Id. ¶ 88.

[18] Id. ¶ 105.

[19] Id.

[20] Id. ¶ 107.

[21] Id. ¶ 108.

[22] Id. ¶ 110.

[23] Id. ¶¶ 113-114.

[24] Id. ¶ 115.

[25] Id. ¶¶ 116-117.

[26] Id. ¶¶ 117, 119, 122.

[27] Id. ¶ 119.

[28] Id. ¶¶ 123-136.

[29] Stipulated Order, Federal Trade Commission v. Teikoku Pharma USA, Inc. et al. (dated March 30, 2016), available at http://reaction.orrick.com/rs/ct.aspx?ct=24F76F1FD2EB47A9CCDD89ACD42A931ADFF755D1BAE16EAB2AD74C5751D5FB28FF4F1A98D79B080 ("Teikoku Stipulated Order").

[30] Teikoku Stipulated Order, "Definitions" ¶ 23.

[31] Id. The Teikoku Stipulated Order expressly states that agreements relating to the dates on which a generic may be sold under a subsequent agreement are not considered to be "payments." Other exceptions allow for the extension of pre-existing agreements and settlements of different claims, so long as such actions are not independently inconsistent with the order.

[32] See In the Matter of Endo Pharmaceuticals Inc., File No. 141-0004 (Dissenting Statement of Commissioner Maureen K. Ohlhausen), available at https://www.ftc.gov/system/files/documents/public_statements/942513/160331endostatement.pdf.

[33] See, e.g., In re Loestrin 24 Fe Antitrust Litig., No. 14-2071, 2016 WL 698077, *8 (1st Cir. Feb. 22, 2016) (rejecting the lower court's holding that Actavis only prohibited reverse payments in cash, and finding instead that the Supreme Court was concerned with more broadly defined above-market deals).

[34] King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp. (Lamictal), 791 F.3d 388, 403 (3d Cir. Jun. 26, 2015).

[35] SmithKline Beecham Corporation, dba GlaxoSmithKline v. King Drug Company of Florence, Inc., No. 15-1055 (March 2, 2016).

[36] Lamictal, 791 F.3d at 403 (no-AG agreement may be anticompetitive "when it represents an unexplained large transfer of value from the patent holder to the alleged infringer"); In re Wellbutrin XL Antitrust Litig., CV 08-2431, 2015 WL 5582289, at *16-17 (E.D. Pa. Sept. 23, 2015) (no-AG agreement not tied to the cessation of litigation may not implicate Actavis).

[37] Endo Complaint ¶¶ 63, 172.

[38] Id. ¶ 172.

[39] See Actavis, 133 S. Ct. at 2236 ("[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement"), 2237 ("the likelihood of a reverse payment bringing about anticompetitive effects

depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."). Other appellate courts have likewise concluded that side deals can violate the antitrust laws only when they provide compensation in excess of the value of services rendered. See, e.g., In re Loestrin, 2016 WL 698077 at *11-*12; Lamictal, 791 F.3d 388, 404 and 408.

[40] As we have noted in earlier client alerts, this position was reflected in the 2015 settlement of the Cephalon litigation. See Robert P. Reznick, David M. Goldstein, Richard S. Goldstein, and Howard M. Ullman, "Cephalon and Teva's $1.2 Billion Consent Order with the FTC: Is it Really a Harbinger of Things to Come?," available at https://orrick.com/Events-and-Publications/Pages/Cephalon-and-Tevas-1-Billion-Consent-Order-with-the-FTC.aspx ("Cephalon Client Alert").

[41] Id. ¶ 86 (emphasis added)

[42] Endo Complaint ¶¶ 78, 87(f).

[43] Teikoku Stipulated Order, "Definitions" ¶ 23.

[44] See Cephalon Client Alert, supra n. 40.

[45] M. Lippman, "FTC Health Care Chief: $1.2B Cephalon Deal A Strong Warning," Law360 (May 28, 2015).

[46] Endo Complaint ¶¶ 55-59.

[47] Id.

[48] See New York v. Actavis plc, 787 F.3d 638, 655 (2d Cir. 2015); Robert P. Reznick, David M. Goldstein, Richard S. Goldstein, and Howard M. Ullman, "8 Product-Hopping Takeaways from Namenda Ruling," Law360, June 11, 2015, available at https://orrick.com/Events-and-Publications/Documents/Law360-8-Product-Hopping-Takeaways-From-Namenda-Ruling-June2016.pdf.

[49] New York v. Actavis, 787 F.3d at 656.