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Don't Hold Back: The FTC Attacks Endo for Agreeing to Delay Launch of an Authorized Generic





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The Federal Trade Commission seeks, in a recent lawsuit, to expand the reach of the antitrust laws for pharmaceutical manufacturers settling patent litigation to include agreements not to launch an authorized generic (a ''no-AG commitment''). On March 31, the FTC filed a complaint in the District Court for the Eastern District of Pennsylvania against Endo Pharmaceuticals, Inc. (''Endo''), Impax Laboratories, Inc. (''Impax''), Watson Laboratories, Inc. (''Watson''), and others, alleging that the companies violated Section 5(a) of the FTC Act[1] by entering into, among other things, no-AG commitments. The FTC alleges that these no-AG commitments constitute ''anticompetitive reverse-payment agreements orchestrated by Endo to prevent lower-cost generic competition to its two most important branded prescription drug products,'' Opana ER, an opioid drug, and Lidoderm, a lidocaine patch. The FTC alleges that these no-AG commitments in the Opana ER and Lidoderm settlement agreements are unlawful reverse payments. This is the first time the FTC has challenged a no-AG commitment as an allegedly ''unlawful reverse payment.''

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This case highlights the tension between antitrust laws and the Hatch Waxman Act with respect to no-AG commitments. Under the Hatch Waxman Act, a company seeking to market the generic version of a branded pharmaceutical may be entitled to 180 days of marketing exclusivity once it receives FDA approval if it is the first to challenge the branded pharmaceutical's patent.[2] This company is referred to as the ''first filer.''

[1] The FTC brought the majority of its claims under the FTC Act, but it also brought a single claim under Section 7 of the Clayton Act.

[2] The company may file an Abbreviated New Drug Application (''ANDA'') with the FDA, in which the company must demonstrate to the FDA that its generic version of the drug is

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During the exclusivity period, no other generic pharmaceutical company will receive approval from the FDA to market a generic version of that drug, that is, this 180-day exclusivity is a period in which the FDA will not approve other later-filed generic applications. But this exclusivity extends only to other Abbreviated New Drug Applications, that is, other generics, and does not extend to the brand company, which is already authorized by the FDA to market that drug. This permits (but does not require) the brand name company to offer its product as an ''authorized generic,'' distributing the generic drug itself or licensing another company to do so with the goal of recouping some of the anticipated lost profits that would result from the first-filer's entry into the market. As a result, it is not uncommon to have two generic versions of the drug on the market during the 180-day exclusivity period – the first filer's generic and the authorized generic.

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In this case, the FTC alleges that Endo agreed on at least two occasions to enter into no-AG commitments that constitute an illegal reverse payment under the antitrust laws. The first agreement was with Impax where, among other things, Endo agreed (i) not to launch an authorized generic (of certain strength drugs) of its extended release opioid product, called Opana ER, during the 180-day exclusivity period and (ii) to make various forms of payment[3] to Impax. In return, Impax allegedly agreed to a license entry date for its generic product that was still before patent expiry, but represented a delayed entry of 2 ½ years according to the FTC. The second agreement was with Watson where, among other things, Endo also agreed (i) not to launch an authorized generic of its Lidoderm product during the first 7 ½ months of Watson's generic sales and (ii) to provide Watson with branded Lidoderm patches allegedly at no cost and valued at between $96 million and $240 million. In return, Watson allegedly agreed to a license entry date for its generic product that was still before patent expiry, but represented a delay in the launch of its generic version of Lidoderm for more than a year according to the FTC.[4] The FTC alleges that neither agreement made economic sense and only served to ''ensure that Endo would not face generic competition'' for either drug. As a result, the FTC alleges that ''patients were denied the opportunity to purchase lower-cost generic versions of Opana ER and Lidoderm, forcing them and other purchasers to pay hundreds of millions of dollars a year more for these medications.''

This case also highlights the competitive implications of the entry of an authorized generic. The FTC alleges that the first-filer's generic product may be offered at a 20% to 30% discount to the branded product during the 180-day exclusivity period, but that prices for the first-filer's product for this period are on average even lower if an authorized generic is launched. The FTC notes ''the retail prices are 4% to 8% lower and wholesale prices are 7% to 14% lower . . .'' for the first filer when there is authorized generic competition. In addition to this alleged price erosion, the FTC argues that the authorized generic can be expected to take a substantial market share from the first filer during its 180-day exclusivity period, resulting, it alleges, in an overall revenue loss from the authorized generic competition of 40% to 52%. Accordingly, the FTC concludes that the lack of authorized generic competition achieved here by the no-AG commitments resulted in doubling generic revenue during the relevant 180-day exclusivity periods.

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While this is the first time the FTC brings such a reverse payment case for a no-AG commitment, private plaintiffs have brought similar claims. Last year in *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, (3d Cir. 2015), the Third Circuit found that a ''no authorized generic'' settlement provision should be at least subject to antitrust scrutiny to determine whether it is unlawful ''because it may represent an unusual, unexplained transfer of value from the patent holder to the alleged infringer that cannot be adequately justified.'' The Third Circuit noted that, ''[i]t seems to us that no-AG agreements are likely to present the same types of problems as reverse payments of cash. The no-AG agreement here may be of great monetary value to. . . .the first-filing generic.'' *Id.* at 404.

In deciding whether this ''no-AG commitment'' violates the antitrust laws, the district court will be applying a rule of reason antitrust analysis, as set forth by the

equivalent to the brand-name drug. As the Complaint notes, the company must include a ''paragraph IV certification'' in its ANDA stating that the ''patents for the brand-name drug are invalid, unenforceable and/or will not be infringed by the generic drug.''

[3] According to the Complaint, there was a payment that had two components: (1) Endo guaranteed that Impax would receive supracompetitive profits by being the only seller of generic Opana ER during its first 180 days on the market and (2) a co-promotion and development agreement where Endo paid Impax $40 million.

[4] Apparently unbeknownst to all but Endo, according to the Complaint, the period of delayed entry of the Opana ER generic bought Endo the time it needed to gain FDA approval for Reformulated Opana ER. This Reformulated Opana ER had been modified so that it was crush resistant and, therefore, less likely to be abused. So, by the time that the first-filer launched its generic, the patient population on Opana ER had been switched to Reformulated Opana ER. This is significant because the prescription drug laws in all 50 states only permit a pharmacist to switch from a generic drug to a branded drug if the drug is listed as a generic for the drug prescribed. Here, the first-filer's generic drug was **not** a generic for Reformulated Opana ER. This cut the first-filer's revenue even further and triggered an undisclosed further payment under the agreement that FTC also argues is an unlawful reverse payment.

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Supreme Court in *FTC v. Actavis*, 133 S. Ct. 2223 (2013). In *Actavis,* the Supreme Court held that unexplained, large payments from the holder of a patent on a drug to an alleged infringer to settle patent litigation could, in some instances, violate the antitrust laws. The *Actavis* Court provided some initial guidance on how to structure rule-of-reason litigation in a reverse payment case. The Court explained that such antitrust questions must be answered ''by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents.'' *Actavis*, 133 S. Ct. at 2231. The *Actavis* Court set forth a three-step analytical structure for the rule-of reason analysis. First, to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition. *See Id.* at 2235-36. ''[T]he 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.'' *Id.* at 2237. Second, the burden then shifts to the defendant to show ''that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.'' *Id.* at 2235-36. Third, the plaintiff will have the opportunity to rebut the defendant's explanation. Both the FTC and the pharmaceutical manufacturers will be vying to tip the *Actavis* rule of reason analysis in their favor. It remains to be seen whether these no-AG commitments can survive *Actavis* scrutiny.

The FTC brought this case in the Third Circuit, relying on this recent jurisprudence, to contend that these particular no-AG commitments in Opana ER® and Lidocaine® settlement agreements are unlawful reverse payments under *Actavis*. And statements from the FTC would suggest that ''no-AG commitment'' cases may be a new priority. FTC Chairwoman Edith Ramirez recently stated that settlements that include a no-AG commitment ''harm consumers twice – first by delaying the entry of generic drugs and then by preventing additional generic competition in the market following generic entry.'' This case will focus on whether the ''no authorized generic'' provisions here are unlawful reverse payments under *Actavis*, and it can be expected that this case will further shape the ever-changing boundaries of reverse payments under *Actavis*.