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CLIENT ALERT

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

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Today, the Federal Trade Commission sued Endo, Impax, Watson, and others for "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. These two drugs represented approximately 64 percent of Endo's total annual revenues. According to the FTC, this is the first time the agency has brought a case "challenging an agreement not to market an authorized generic – often called a 'no-AG commitment' – as a form of reverse payment."

As alleged in the complaint, Endo agreed not to launch an authorized generic as part of the agreement. According to FTC Chairwoman Edith Ramirez, settlements that include a no-authorized-generic 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." According to the FTC, the first harm occurs when the generic company takes a payment to delay entry into the market, which has been held anticompetitive in a series of cases known as "pay for delay." This case will focus on the second harm, namely the "no authorized generic" provision.

A "no authorized generic" provision is valuable to both the branded drug holder, in this case Endo, and the generic company. It is valuable to Endo because there is only one generic competitor on the market. It is valuable to the generic company because there would be no other generic competition, so that the price should be higher for the generic during the statutory-authorized 180 day exclusivity period.

Since the Supreme Court in *Federal Trade Commission v. Actavis Inc.* ruled that "reverse payment" settlement arrangements in the pharmaceutical industry—that is, a payment from the brand patent owner to the generic infringer—can sometimes violate the antitrust law, at least one Circuit Court has ruled that such "no authorized generic" provisions could violate the antitrust laws. Last year in *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp* the Third Circuit found that a "no authorized generic" settlement provision should be subject to antitrust scrutiny "because it may represent an unusual, unexplained transfer of value from the patent holder to the alleged infringer that cannot be adequately justified."

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