The Effect of FTC Challenges to Pay-For-Delay Agreements: Brand-Name and Generic Companies Abandon Large Cash Payments and Other Forms of Reverse Payments

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Each year, brand-name pharmaceutical companies spend millions of dollars researching and developing new drugs. Despite the huge sums spent, only a handful of the drugs developed become candidates for further safety and efficacy investigation. Even fewer are ultimately submitted to the U.S. Food and Drug Administration (FDA) for approval. By the time the FDA approves a drug, brand-name pharmaceutical companies have spent tens of hundreds of millions of dollars (if not more) to obtain FDA approval to market the drug. To protect this investment, brand-name pharmaceutical companies obtain patents covering their drug, which the company is required to list in the electronic Orange Book.

Under the Hatch-Waxman Act, a generic company may seek to market a generic version of a brand-name drug before the expiration of the patents listed in the Orange Book for the drug if it files an Abbreviated New Drug Application (ANDA) that includes a Paragraph IV certification.[1] In most cases where the ANDA includes a Paragraph IV certification, the brand-name company will file a patent infringement lawsuit against the generic company. If the generic company prevails in the lawsuit, the FDA will be able to approve the ANDA before the patents would have otherwise expired and the generic company will be authorized to enter the market. The impact to the brand-name companies by the entry of the generic drug is decreased revenues due to lower drug prices and a significant decrease in the sales of the brand-name drug.

Brand-name pharmaceutical companies have shown a willingness to "put their money where their mouth is" to protect the market of their blockbuster drugs. By entering into reverse-payment settlement agreements, also known as "pay-for-delay" agreements, brand-name companies pay generic manufacturers to delay entry into the market. The form of these agreements is relatively simple. Generic manufacturers are paid a fraction of the money that they would have made from early entry into the market in exchange for terminating costly patent litigation. Brand-name companies eliminate the risk that a generic manufacturer will enter the market before its patents expire. With so much money at stake, pay-for delay agreements appear to make financial sense for both brand-name companies and generic manufacturers.

Proponents of the pay-for-delay agreements assert that the compensation provided to generic manufacturers represents the litigation costs saved by entering into a settlement agreement. Opponents of these agreements, including the Federal Trade Commission (FTC), argue that, while brand-name companies and generic manufacturers share the benefits of the high pharmaceutical prices, ultimately it's consumers who lose.[2] Specifically, they claim that pay-for-delay agreements cost consumers billions of dollars each year.[3] Thus, not only are these agreements morally wrong, but also potentially anti-competitive.

The FTC's vigorous prosecution of brand-name and generic companies that enter into reverse-payment settlement agreements was made possible by the Medicare Prescription Drug, Improvement and Modernization Act (the MMA), which requires brand-name and generic drug manufacturers to file certain agreements with the FTC and the U.S. Department of Justice (i.e., MMA filings).[4] After initial setbacks in the lower courts, the Supreme Court validated the FTC's antitrust arguments in *Federal Trade Comm'n v. Actavis, Inc.*,[5] when it ruled that reverse-payment settlement agreements could sometimes violate antitrust laws. The Court outlined five sets of considerations that led to its conclusion. First, a reverse payment agreement has the potential for significant adverse effects on competition.[6] Second, the anticompetitive consequences of making such a payment will sometimes prove unjustified, particularly where a reverse payment does not reflect traditional settlement considerations such as avoided litigation costs or fair value for services.[7] Third, where a reverse payment brings with it the threat of unjustified anticompetitive harm, the patent owner may possess the power to effectuate that harm.[8] Specifically under this third consideration, the Court noted that "at least the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power, namely the power to charge prices higher than the competitive level." Fourth, courts, by examining the size of the reverse payments, may answer the antitrust question without litigating the validity of the patent.[9] Fifth, the fact that a large and unjustified reverse payment agreement risks antitrust liability does not prevent litigating parties settling their lawsuit in other ways.[10] The Court concluded that these considerations outweighed the drug companies' argument that the desire to promote settlements justified granting automatic antitrust immunity to reverse payment settlements.

Since the Court's ruling in 2013, the FTC has aggressively targeted pay-for-delay agreements as allegedly violating antitrust laws. The FTC is not alone, however, in its attempts to void pay-for-delay agreements. Direct purchasers have joined the fight by filing several lawsuits against brand-name companies and their generic competitors.[11] The goal is to void any agreement that may potentially stifle competition between a generic manufacturer and a brand company to the detriment of consumers.

In addition, *Actavis* has strengthened the FTC's bargaining power to negotiate settlement agreements with pharmaceutical companies to resolve antitrust litigation regarding reverse-payment settlements. For example, in 2015 the FTC reached a settlement that resolved its antitrust suit against Cephalon, Inc. (Cephalon).[12] The lawsuit, filed in 2008, alleged that Cephalon illegally blocked generic competition to its popular sleep-disorder drug Provigil. The FTC alleged that Cephalon entered into a series of agreements with generic drug manufacturers to forego marketing and selling their generic products for six years. As part of the settlement agreement with the FTC, Cephalon and Teva, which had acquired Cephalon in 2012, agreed to pay $1.2 billion to a settlement fund for the purpose of compensating direct purchasers who overpaid as result of Cephalon's allegedly anticompetitive conduct. In addition to a financial penalty, Cephalon and Teva agreed to a prohibition on entering into any type of patent settlement agreements that included: 1) payment by the NDA holder to the ANDA filer and 2) an agreement by the ANDA filer not to research, develop, manufacture, market or sell a generic product for any period of time. Although neither company admitted any liability or wrongdoing, the FTC celebrated the settlement as "an important step in the FTC's ongoing effort to protect consumers from anticompetitive pay for delay settlements."[13]

On March 30, 2016, the FTC filed its most recent lawsuit over alleged anti-competitive agreements between Endo Pharmaceuticals, Inc. (Endo) and several generic pharmaceutical companies. The FTC alleged in the complaint that Endo orchestrated anticompetitive reverse-payment agreements to prevent lower-cost generic competition of two of its most important branded prescription drugs: Opana extended release (ER) and Lipoderm. The FTC found two agreements problematic. The first was a settlement agreement between Endo and Impax Laboratories (Impax) in which Endo agreed to pay Impax to abandon a lawsuit involving Endo's patents and forego entering the market with a generic version of Opana ER for two and one-half years. In the second agreement, Endo and its partner Teikoku Pharma USA, Inc. (Teikoku) agreed to pay Watson Laboratories (Watson) to abandon its patent challenge and delay entry of its generic version of Lipoderm into the market. As a component of both agreements, Endo agreed to refrain from marketing authorized generic (AG) versions of its brand-name drugs.[14] The FTC argued that the purpose and effect of each agreement was undoubtedly anticompetitive. The FTC alleged that, as a result of the delay in generic competition, patients and other direct purchasers were forced to pay hundreds of millions of dollars a year more for each of Opana ER and Lipoderm.

The FTC's challenges to these reverse-payment settlement agreements and its landmark victory in *Actavis* have reshaped how brand-name and generic drug manufacturers settle patent disputes. For example, recent MMA filings show that *Actavis* appears to have had an impact on how brand-name and generic drug manufacturers structure their settlement agreements.

First, in the wake of Actavis, the number of potentially unlawful reverse-payment settlement agreements seems to be declining. Before *Actavis*, this number had been steadily increasing from three in fiscal year (FY) 2005 to 40 in FY 2012. Starting in early 2013, this number has declined. In FY 2014, 21 potentially unlawful reverse-payment agreements were filed with the FTC. Approximately half of these agreements involved cash payments to generic companies under $5 million. These cash payments are relatively small and might be justified as saved litigation cost, which is one of the considerations the Supreme Court identified in *Actavis*.[15]

Second, most settlement agreements do not involve any compensation to the generic company. While this has been a constant trend since MMA filings went into effect, there has been a noticeable increase in the number of settlement agreements that do not involve any compensation to generic companies. The FTC estimates that about 80% of the settlement agreements that were filed in FY 2014 did not involve any such compensation.[16]

Third, commitments by the brand company not to sell an authorized generic seem to be declining. The FTC has argued that no-AG commitments harm consumers twice by: (1) delaying the entry of a

generic product that keeps the price of the branded drug from falling during the period of delay; and (2) reducing the number of generic competitors that ultimately enter the market, which results in higher prices for the generic drug. The number of no-AG commitments has declined substantially over the last two fiscal years from 19 in FY 2012 to four in FY 2013 and five in FY 2014.[17]

As the FTC continues to devote significant resources to police the settlement agreements between brand-name and generic drug manufactures against potential antitrust violations, brand-name and generic drug manufactures have woken up to the reality that brand-name companies cannot simply make cash payment to generic drug manufacturers or agree to no-AG commitments. Instead, these companies need to fashion creative ways that avoid raising antitrust concerns by the FTC.

References

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3. Id.
4. Medicare Prescription Drug, Improvement and Modernization Act 21 U.S.C. § 384 (2003)
5. Federal Trade Comm'n v. Actavis, Inc., 133 S. Ct. 2223 (2013)
6. Id. at 2234.
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11. King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp., 791 F.3d 388 (3d. Cir. 2015)
12. Federal Trade Commission, "FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected By Anticompetitive Tactics." 2015
13. Id.
14. An authorized generic is the generic version marketed by the brand-name company of its own brand product drug, which it can market at any time, including during the first filer's 180-day exclusivity period. No ANDA is required by the brand-name company because it already has approval to sell under its NDA.
15. Jamie Towey and Brad Albert, Is FTC v. Actavis Causing Pharma Companies to Change Their Behavior?, January 2016.
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