

Antitrust Issues in Reverse Payment Settlements

Federal Trade Commission v. Actavis, Inc. et al.,

A Case Study

By Amanda Creedon

I. INTRODUCTION

Drug manufacturers often spend millions on research and development for drugs that never make it to market. As a result, manufacturers need to recoup these R&D costs in the sale of drugs that do make it to market. They often rely on the patent system, and the exclusivity it provides, to accomplish that recoupment. [1] Drug manufacturers have turned to reverse payment settlements to extend that exclusivity and generate higher profits from a particular drug. Reverse payment settlements arise in the context of generic drugs. A patentee will offer to pay a generic manufacturer, an alleged infringer, to delay the release of the generic drug to the market. [2] The payment is a purchase by the patentee to continue its exclusive right to sell its product; a right it already holds by virtue of the patent. For this reason, the practice is suspect of antitrust violations. [3]

In *Federal Trade Commission v. Actavis, Inc.*, the Federal Trade Commission (FTC) filed a complaint alleging that reverse settlement payments were unfair restraints of trade and therefore violated federal antitrust laws. [4] The Supreme Court held that reverse payment settlements in patent infringement litigation are not presumptively unlawful but can sometimes violate antitrust laws, to be determined on a case-by-case basis. [5]

The settlements are not immune from antitrust attack even if the agreement's anticompetitive effects fell within the scope of the exclusionary potential of the patent. [6]

II. BACKGROUND

The FDA approved Actavis' and Paddock's generic drugs in 2003, modeled after Solvay Pharmaceuticals' brand name drug Androgel. [7] In 2006, instead of bringing its drug to market and as part of settlement to paragraph IV [8] litigation between Solvay and the respondents, Actavis entered into an agreement with Solvay, agreeing not to bring the drug into the market until 65 months before Solvay's patent expired and to promote Androgel to doctors in exchange for \$9-10 million annually for nine years. [9] Solvay reached similar agreements with both Paddock and Par, settling for \$12 million and \$60 million, respectively. [10]

The FTC filed suit alleging Actavis and Paddock violated section five of the Federal Trade Commission Act, which prohibits "unfair or deceptive acts or practices in or affecting commerce," [11] by unlawfully agreeing to abandon their patent challenges, refraining from launching their generic product, and sharing in Solvay's profits. [12] These unusual settlements may have an adverse affect on competition, therefore both patent law policies and antitrust policies are relevant to determine if these settlements are legal.

III. DISCUSSION & ANALYSIS

A. *HOLDING*

The Supreme Court held that reverse settlement payments were not presumptively illegal but should be examined on a case-by-case basis to see if they violate antitrust laws. [13] The court notes that the likelihood of reverse settlement payments bringing about anticompetitive effects depends on its size, its scale in relation to litigation costs avoided, its independence from other services for which it might represent payment, the lack of other convincing justification, and which industry it occurs in. [14]

Rather than measure the amount of restriction solely against the length of the patent's term or earning potential, which the Court of Appeals did, the Supreme Court chose to address traditional antitrust questions like anticompetitive effects and market power. The Supreme Court supports their ruling that these settlements are subject to antitrust policies by stating that what the holder of a valid patent could do, does not by itself answer the antitrust question. [15] These settlements tend to have an adverse effect on competition as the brand name company and generic company are forming a monopoly on this particular drug and preventing the low price generic from being made available to consumers. [16]

The court noted that the Hatch-Waxman Act, was not designed to allow deals between brand and generic companies to delay competition, [17] but was designed to speed the introduction of low cost generic drugs into the

market. [18] It has a general precompetitive nature to it, in that the first to file an ANDA generic manufacturer receives in the 180 days of exclusivity, and that when parties settle a paragraph IV filing, they must report the terms to the FTC and the Antitrust Division of the Department of Justice. [19] The period of exclusivity given to the generic drug company who is first to file can be worth several millions, providing them incentive to bring their drug to the market quickly. [20] Reverse payment settlements prevent these low cost generics from being available to the public quickly, and the public must continue to pay the high price of the brand name drug.

B. Five Considerations

The Supreme Court gave five reasons why the Federal Trade Commission should be given the opportunity to prove an antitrust claim. [21] First, reverse settlements have potential for adverse effects on competition, as the payment is an extension of exclusive right to sell the brand name drug, giving a share of the monopoly profits to the generic company. [22] The court proposed that the patentee would have to pay millions in continued litigation if they did not settle this way, and the lost revenue from continued litigation would flow to consumers in the form of lower prices. [23] The court also noted that the generic entering the market before the patent expires would bring about competition, thereby further lowering prices for the consumer's benefit. [24]

Second, the court reasoned that these anticompetitive effects might sometimes prove unjustified under the rule of reason. [25] Possible valid justifications for these settlements are when the amount is no more than a rough approximation of the litigation expenses saved or when the settlement represent other services the generic has promised to perform, such as promoting the patented item. [26] It may be unjustified if the brand name is using this payment and its monopoly profits to avoid patent invalidation or a finding of noninfringement that would allow the generic to enter the market and lower prices for that drug. [27]

Third, where this type of settlement threatens unjustified anticompetitive harm, it is the patentee who likely possesses the power to bring that harm about in practice. The harm here is an artificially high price for drugs consumers need access to. [28]

Fourth, an antitrust action is likely to prove more feasible than the Eleventh Circuit believed. [29] An unexplained reverse payment would normally suggest that the patentee had serious doubts about the patent's survival, which suggests they would rather split the profits with the generic company than face the competitive market. [30] The consequence of having to face the competitive market is what underlies a claim of antitrust unlawfulness. [31]

Fifth, the fact that this settlement risks antitrust liability does not prevent litigating parties from settling their lawsuit. The antitrust question

is why they chose reverse settlement payments over other potential settlements. [32] If the answer is a desire to maintain and share in patent-generated monopoly profits, without other justifications, then the settlement is likely to violate antitrust laws. [33]

These five considerations outweigh the desirability of settlement that led the Eleventh Circuit to provide an almost automatic antitrust immunity to reverse settlement payments. [34]

IV. RAMIFICATIONS

The court held that reverse settlement payments are not presumptively illegal but should be examined for possible antitrust violations as they have both pros and cons in their effect on consumers. [35] The monopoly that can be formed between brand name and generic drug companies in extending the brand name drug's exclusivity through these settlements can produce unjustified anticompetitive harms, making them subject to antitrust scrutiny as well as patent law policies. [36]

The pros are these settlements extend patents which provide incentives to drug manufacturers to take risks associated with developing new drugs. [37] These innovative drugs are contributing to society by supplying new drugs to treat diseases and conditions patients are continually suffering from, improving improvement in medical treatment. [38] Drug companies holding valid patents see these settlements as a way to exercise their rights under patent laws to exclude others from infringing on

their patents and reducing litigation costs, allowing them to continued profits, which they use to produce innovative, beneficial drugs. [39]

The argument against these settlements is that they increase the cost of drugs available to the public by delaying generic entry into the market. [40] Payment for staying out of the market keeps prices at patentee-set levels, the benefit of which is split by the drug company that owns the patent and the generic company that has agreed to stay out of the market, while the consumer loses. [41] This rising cost of prescription drugs is a large factor of the growing healthcare cost that is a central issue the United States is attempting to confront today. [42] A 2010 analysis by the FTC found that reverse payment settlements cost consumers 3.5 billion annually. [43] Consumers may not have access to the drugs they need because of the high prices, especially low-income or elderly patients or those with chronic diseases that need long term care. [44] The amount of cost to consumers needs to be weighed against the benefit of the introduction of new drugs into the market.

An additional possible argument is that the Court actually expanded consumer access to affordable healthcare because it stripped brand name drug manufacturers from complete immunity from antitrust scrutiny when they enter into these agreements.⁴⁵ Therefore, if drug manufacturers can be charged and held accountable for their antitrust behavior, the consumer will benefit if the reverse settlement payment is deemed unlawful and the generic

drug enters the market. Although it is true that these settlements are not presumptively lawful and immune from antitrust liability, the Court focused on the fact that reverse settlement payments are not presumptively unlawful because they may be adversely affecting competition and adversely, not expanding, consumer's access to affordable drugs and healthcare.

The adverse effects these settlements have on competition, high drug prices, and increasing healthcare costs needs to be taken into account with the incentive to drug manufacturers to produce innovative drugs that are beneficial to society, which is potentially why the court deemed these not presumptively unlawful but to be determined on a case-by-case basis. Courts must weigh these two policy arguments when deciding if a specific reverse settlement payment violates antitrust laws and may be injurious to the public.

SOURCES

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- [3]. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 .
- [4]. *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2223 (2013) (hereinafter "Actavis").
- [5]. *Id.*
- [6]. *Id.*
- [7]. *Id.* at 2229.

[8]. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[9]. *Actavis*, 133 S. Ct. at 2229.

[10]. *Id.*

[11]. 15 U.S.C § 45(a)(1).

[12]. *Actavis*, 133 S. Ct. at 2230; *see* FTC Act cite.

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[14]. *Id* at 2237.

[15]. *Id* at 2225.

[16]. *Id.* at 2226.

[17]. *Id* at 2234 citing 146 Cong. Rec. 18774 (2000).

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[23]. *Id* at 2234.

[24]. *Id.*

[25]. *Id* at 2235-36.

[26]. *Id* at 2236.

[27]. *Id.*

[28]. *Id.*

[29]. *Id.*

[30]. *Id.*

[31]. *Id.*

[32]. *Id.* at 2237.

[33]. *Id.*

[34]. *Id.*

[35]. *See id.* at 2223-37.

[36]. *See id.*

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[41]. *Id.*

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[43]. *Id.*

[44]. Kyle Virtue, *supra* at 122.

[45] Ralph B. Kalfayan & Vic A. Merjanian, *Ensuring Access to Affordable Medication: The Supreme Court's Opinion in F.T.C. v. Actavis, Inc.*, 22 Competition: J. Anti. & Unfair Comp. L. Sec. St. B. Cal. 120, 120 (2013).