Pay-to-Delay: How to Prevent Competition and Get Away With It

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I. Introduction

On December 5, 2014, in Boston, Massachusetts, a jury verdict provided a ray of hope for brand-name drug producers hoping to avoid future competition in the pharmaceutical market. The trial was closely watched, as it was the first class action suit tried since the United States Supreme Court ruled in *F.T.C. v. Actavis* that the proper method for challenging patent settlements under antitrust laws was a Rule-of-Reason analysis. Applying new precedent, the jury in *In re Nexium (Esomeprazole) Antitrust Litigation* found that an agreement between AstraZeneca PLC (“AstraZeneca”) and Ranbaxy Laboratories Ltd. (“Ranbaxy”) to delay Ranbaxy’s launch of a generic version of AstraZeneca’s patented heartburn drug Nexium was anticompetitive, but that there was no injury. The jury found that, while AstraZeneca had market power, because Ranbaxy wasn’t yet prepared to offer a competitive product in the market, the agreement could not cause any anti-competitive harm. Since there was no anticompetitive effect, there could be no competitive injury to the consumer.

II. Background

The application of a Rule-of-Reason analysis, which allowed the jury to hold AstraZeneca and Ranbaxy harmless for their agreement not to compete, stems from the United States Supreme Court’s holding in *F.T.C. v. Actavis*. In that case, the Supreme Court reviewed a reverse-payment settlement. A reverse-payment is an agreement in which a brand-name drug

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1 133 S. Ct. 2223 (2013).
manufacturer (such as AstraZeneca) may pay a generic competitor (such as Ranbaxy) to settle a patent infringement lawsuit filed under the Hatch-Waxman Act. The agreement may require that the generic drug manufacturer stay out of the market for that particular drug for a specified period of time. In Actavis, the Court resolved a circuit split, and determined that the proper analysis to review Hatch-Waxman–related patent settlements was a Rule-of-Reason analysis.

The Court concluded that such agreements could violate the Sherman Act, but not always. The Court rejected both the “quick look” approach argued by the F.T.C. and the “scope of the patent” test urged by the defense. Instead, the Court held that a Rule-of-Reason analysis was appropriate to determine if the settlement’s effects were so anticompetitive as to violate the Sherman Act’s prohibition on the establishment or maintenance of monopolies.

In Actavis, Actavis and other generic pharmaceutical manufacturers filed with the Food and Drug Administration (“FDA”) for the right to market generic drugs modeled after a product already patented by Solvay named AndroGel. The FDA eventually approved Actavis’ generic product, among others. Solvay sued, claiming patent infringement. But instead of Actavis and the other generic manufacturers paying for breaking the law and infringing on Solvay’s patent, it was Solvay that paid, in a reverse-payment agreement. The F.T.C. challenged the agreement in court, alleging that Solvay paid the generic manufacturers millions of dollars in exchange for

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4 Actavis, 133 S. Ct. at 2230.


6 Actavis, 133 S. Ct. at 2237. The Court reviewed settlement’s “size . . . scale in relation to the payor’s anticipated future litigation costs . . . independence from other services for which it might represent payment, and the lack of any other convincing justification” to determine its legality. Id.

7 Id., at 2229.

8 Id.

9 The amount was substantial: “Solvay agreed to pay millions of dollars to each generic—$12 million in total to Paddock; $60 million in total to Par; and an estimated $19–$30 million annually, for nine years, to Actavis.” Actavis, 133 S.Ct. at 2229.
agreeing not to introduce their generic versions of AndroGel for a period of years. The Court made much of the unusual nature of the form of settlement that a reverse-payment takes, and held that it would not make legal sense to only measure a reverse-payment’s anticompetitive effects against patent law policy and not against procompetitive antitrust policies as well.\textsuperscript{10} While the Court acknowledged that such a settlement may fall within the scope of the exclusionary potential of the patent, it did not agree that the fact that one of the parties held an exclusive patent made whatever settlement related to that patent immune from antitrust analysis.\textsuperscript{11}

\textbf{III. Application of Actavis in In re Nexium Antitrust Litigation}

Congress passed the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act,\textsuperscript{12} in 1984 in order to expedite the entry of non-infringing generic competitors into the pharmaceutical market.

In 1999, AstraZeneca filed a New Drug Application (“NDA”), where it sought approval from the FDA to market a new heartburn drug named Nexium, and obtained that approval in 2001. Four years later, Ranbaxy filed an ANDA and notified AstraZeneca that it sought to manufacture a generic version of Nexium under a paragraph IV certification that it would not infringe on any of AstraZeneca’s valid patents. As expected, AstraZeneca filed a suit against Ranbaxy in November of 2005 under the Hatch-Waxman Act, claiming that Ranbaxy’s generic version of Nexium would infringe on six patents. Several other generic manufacturers, including Dr. Reddy’s and Teva, followed in filing ANDAs to market Nexium generics, and AstraZeneca continued to bring patent infringement claims in response to these paragraph IV filings.

\textsuperscript{10} \textit{Id.} at 2231.

\textsuperscript{11} \textit{Id.} at 2230.

After completion of discovery, but before the district court could make any rulings on the merits of the case, AstraZeneca and Ranbaxy entered into a reverse-payment agreement on April 14, 2008. Under this agreement, AstraZeneca agreed to end its proceedings against Ranbaxy, and the court entered a consent judgment the same day that the thirty-month stay on FDA approval of Ranbaxy’s generic Nexium expired. The agreement required that Ranbaxy admit that AstraZeneca’s Nexium patents were valid, that its generic would infringe upon AstraZeneca’s patents, and to delay the launch of its generic equivalent to Nexium until May 27, 2014. In exchange for this agreement not to compete, AstraZeneca agreed to pay Ranbaxy over $1 billion. AstraZeneca went on to secure the bottleneck against generic competition by making similar agreements with Teva and Dr. Reddy’s. These agreements created the basis for the claims brought in In re Nexium Antitrust Litigation.

The class action pursuing treble damages in In re Nexium Antitrust Litigation consisted of two sets of plaintiffs: Direct Purchasers (such as unions, pharmacies, and insurance companies) and End-Payors (everyday consumers who were prescribed Nexium for heartburn). The suit alleged that AstraZeneca’s reverse-payments were anticompetitive because their operation produced a six-year time span in which AstraZeneca would not have to compete with generic drugs based on Nexium’s formula. The suit alleged that, but-for the reverse-payment agreements, a generic ANDA filer would have obtained FDA approval and reached the market by shortly after April 14, 2008. The plaintiffs alleged that the reverse-payment agreements effectively allowed AstraZeneca to buy off its putative competitors and ensure a six-year monopoly. The damages sought by plaintiffs totaled approximately $10 billion.

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13 In re Nexium Antitrust Litigation, 968 F. Supp. 2d at 381.  
14 Id. at 385.
On September 4, 2014, Judge William G. Young, for the United States District Court for the District of Massachusetts, denied motions for summary judgment and cleared the way for the suit to go to trial. While Dr. Reddy’s settled immediately before trial and Teva settled out of the suit during the trial, Ranbaxy and AstraZeneca remained to defend their actions in court. The court determined in pre-trial motions that the Supreme Court’s ruling in *Actavis* was controlling in reviewing the legality of a reverse-payment agreement, and that a Rule-of-Reason analysis was necessary to show that a reverse-payment agreement violated federal antitrust law.\(^\text{15}\)

Over the six-week trial, plaintiffs argued that AstraZeneca’s agreements with Ranbaxy contained an unexplained large reverse-payment designed to delay generic entry. The plaintiffs relied on the argument that, had the agreement not been entered into, the introduction of a generic Nexium copy to the market would have been accomplished by as early as mid-2008. Plaintiffs claimed that this de facto ensured a supra-competitive price, as AstraZeneca would have had to reduce the price of Nexium to remain profitable in the presence of a generic competitor. However, this was complicated by the fact that the court, in pre-trial motions, ruled that at the time of the reverse-payment Ranbaxy did not have a generic ready to go to market, and that there was insufficient evidence for a jury to find as a matter of law that Ranbaxy could have obtained FDA approval at an earlier date. Defendants focused on the fact that no generic manufacturer, at the time of the agreements, was positioned to bring a generic Nexium copy to market, much less had received FDA approval. Ultimately, the jury found this argument persuasive, though perhaps not in the manner the defendants would have preferred.

On December 5, 2014, the jury reached a verdict. In that verdict, the jury split the decision between the parties. While the jury found that the reverse-payment agreement in question was “large and unjustified” as the Supreme Court held in *Actavis* was necessary to show

\(^{15}\) *Id.* at 386.
illegality,\textsuperscript{16} the jury ultimately concluded that the agreement was not unreasonably anticompetitive. The jury found persuasive the defendants’ argument that no generic manufacturer was positioned, with regard to regulatory approval or marketing capacity, to challenge Nexium in the market at the time of the agreements.\textsuperscript{17} Because of this determination, the jury found that the class of plaintiffs could not have been injured, because AstraZeneca was not technically avoiding competition when no competition existed.

IV. Impact

The impact of the jury’s verdict cannot be overstated: if a major company in the pharmaceutical industry, with market power, enters into a reverse payment agreement prior to the generic competitor being ready to enter the market, it may legally essentially lock out competition and secure itself a monopoly for a period of years. It is unsurprising, as a result, that plaintiffs immediately filed for a new trial.\textsuperscript{18} This is a direct result of the Supreme Court’s decision in \textit{Actavis}; by requiring that trial courts entertain a full Rule-of-Reason analysis, brand-name manufacturers now have a blueprint on which to model future reverse-payment agreements so as to resist antitrust challenges. In moving for a new trial, the plaintiffs argued that the jury instructions were improperly framed and claimed the support of the FDA in seeking a new trial.\textsuperscript{19} As of this writing, the court has not yet ruled on the plaintiffs’ motion for a new trial, but an appeal is possible if the court denies plaintiffs’ Rule 59 motion. The decision to appeal, however, is complicated by the possibility that a reviewing First Circuit Court of Appeals could create

\textsuperscript{16} \textit{Actavis}, 133 S. Ct. at 2237.


precedent based on the trial court’s findings, and cement the pharmaceutical monopoly loophole, at least in the First Circuit. How the plaintiffs choose to proceed will shape the application of future Rule-of-Reason analyses of reverse-payment agreements.