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Pharmaceutical Pay-for-Delay Agreements In Decline Since 2013

Between 2005 and 2013, the amount of pharmaceutical "*pay-for-delay*" agreements increased dramatically, from three (3) to 40.[1] *Pay-for-delay* agreements, also known as *reverse payments*, allow brand-name pharmaceutical companies to delay generic competition to a brand-name drug by paying a generic competitor to hold its competing product off the market for a defined period of time.[2] The *Federal Trade Commission* (FTC), which has been fighting these agreements since 2001,[3] stated that these pay-for-delay agreements cost consumers an average of $3.5 billion in higher drug costs per year.[4] Following an Eleventh Circuit decision in 2005, where the court held that pay-for-delay agreements "*cannot be the sole basis for a violation of antitrust law*,"[5] pay-for-delay agreements reemerged, increasing steadily each year until 2013, when they began to decrease significantly in response to the June 2013 U.S. Supreme Court decision *Federal Trade Commission v. Actavis, Inc.*[6] The Supreme Court held that pay-for-delay agreements are neither presumptively valid or presumptively in violation of federal antitrust law, but should be examined under a "*rule of reason*" analysis to determine whether the agreement results in anticompetitive effects.[7] This decision makes it possible for pay-for-delay agreements to be the basis for a violation of antitrust law, and has caused the number of these agreements to decrease; however, brand-name pharmaceutical companies are still using a number of other strategies to potentially stifle competition for their branded products.[8] This *Health Capital Topics* article will briefly describe pay-for-delay agreements, the history of such agreements pre-*Actavis*, and the evolution of the competitive environment surrounding pharmaceutical patent disputes post-*Actavis*.

Pay-for-delay agreements arise in patent litigation when a generic pharmaceutical company pursues *Food and Drug Administration* (FDA) approval of a generic version of a brand-name drug.[9] Under the *Drug Price Competition and Patent Term Restoration Act of 1984*, commonly referred to as the *Hatch-Waxman Act*, a generic pharmaceutical company may seek market entry prior to the expiration of the brand-name drug's patents.[10] If a patent protects the brand-name drug, the generic pharmaceutical company may: (1) contest the validity of the patent; or, (2) argue that its new product does not infringe the brand-name drug's patent.[11] If the generic pharmaceutical company can successfully prove its case on either ground, the FDA will then approve the generic version for sale to the general public.[12] The first generic company to file its application and receive FDA approval under the *Hatch-Waxman Act* obtains 180 days of marketing exclusivity,[13] during which it is the only generic version of the brand-name drug on the market. This procedure provides generic pharmaceutical companies with an incentive to challenge brand-name patents,[14] while also potentially reducing the profitability of the brand-name drug, since the brand-name pharmaceutical company is likely to be forced to lower the price of the brand-name drug to remain competitive.[15] In response to this incentive, brand-name pharmaceutical companies often attempt to enter into a *pay-for-delay* agreement to avoid the risk of generic competition by paying the generic pharmaceutical company to delay putting its product on the market, usually until the brand-name drug's patent has expired.[16]

"*[M]ost if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation*,"[17] and prior to 2005, FTC investigations and enforcement actions against pay-for-delay agreements helped deter their use.[18] However, in 2005, the U.S. Court of Appeals for the Eleventh Circuit rejected a rule of law that would automatically invalidate pay-for-delay agreements, stating that pay-for-delay agreements "*cannot be the sole basis for a violation of antitrust law*."[19] For example, the number of pay-for-delay agreements increased from three (3) in fiscal year 2005 to 40 in fiscal year 2012.[20] This substantial increase in the number of pay-for-delay agreements was largely due to a circuit court split as to whether pay-for-delay agreements violated federal antitrust law.[21] Some circuits held that pay-for-delay agreements were *per se* antitrust violations (i.e., the agreements are, in and of themselves, illegal), while other circuits ruled that these agreements were legally permissible *unless* they granted exclusivity that exceeded the scope of the patent.[22] It was not until the Supreme Court decision in *Actavis* that there was a definitive ruling as to whether pay-for-delay agreements violate federal antitrust law.[23]

In *Actavis*, the FTC filed a complaint claiming that the pay-for-delay agreement between Solvay Pharmaceuticals, Inc. and two generic pharmaceutical companies, Actavis and Paddock, violated federal antitrust laws.[24] In 2006, Solvay paid Actavis and Paddock millions of dollars annually to keep generic

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versions of its daily testosterone replacement therapy drug, AndroGel, off the market until 2015.[25] The companies argued that these payments were compensation for other services performed, such as promotion of AndroGel by the generic companies, but the FTC contended that these payments were compensation for agreeing not to compete against Solvay.[26] The court ruled in favor of the FTC, stating, "*…there is reason for concern that settlements taking this form tend to have significant adverse effects on competition*."[27] The court concluded that pay-for-delay agreements may violate antitrust law; however, such agreements should be evaluated for possible violations based on a substantive "*rule of reason*" analysis, rather than a presumptive "*quick look*" approach.[28] The court stated:

> "*…the likelihood of a reverse payment bring about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services which it might represent payment, and the lack of any other convincing justification*."[29]

After the *Actavis* decision, the FTC reported that pay-for-delay agreements began to decrease, from 40 agreements in fiscal year 2012, the last complete year before the *Actavis* decision, to 21 agreements in fiscal year 2014.[30] While the FTC may view the decrease in the number of pay-for-delay agreements as a positive in their objective to end such agreements, it remains unclear as to whether this decrease will be indicative of long-term decreases in pay-for-delay or other anticompetitive agreements,[31] as the number of overall settlements between brand and generic pharmaceutical companies in fiscal year 2014 was consistent with recent years.[32]

The *Actavis* decision may lead to an increase future investigation and litigation of pay-for-delay agreements.[33] As noted by the FTC in 2014, settlements between branded and generic companies are still prevalent.[34] *Actavis* provided some clarity regarding the antitrust inquiry to be applied in deciding pay-for-delay cases; however, the Court failed to discuss alternative forms of settlements between brand-name pharmaceutical companies and generic manufacturers involving drug patent disputes, such as those involving an overt monetary payment, that may result in equally anticompetitive outcomes.[35] Future litigation surrounding pay-for-delay agreements, as well as other agreements between brand-name and generic pharmaceutical companies, may provide further clarity as to the trajectory of the competitive environment in the pharmaceutical industry and are worthy of monitoring.

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