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In January of 1997, Bayer Laboratories paid Barr Laboratories $398.1 million in exchange for Barr's promise to refrain from marketing a generic version of Bayer's antimicrobial drug ciprofloxacin hydrochloride (Cipro) until December 2003.[1] At first appearance, a branded pharmaceutical company paying a generic competitor to stay out of the market sounds exactly like the kind of anticompetitive practice that antitrust law is meant to prevent. However, the issue becomes significantly more complicated when the payment is made as part of a patent-litigation settlement. Over the past several decades, pharmaceutical companies that produce brand-name drugs have settled patent litigation by making large payments (or providing something else of value) to potential rivals in exchange for the abandonment of suits that, if successful, would increase market competition.[2] As part of the settlement, the rival generic pharmaceutical company typically agrees to stay off the market for a period of time that may or may not cover the life of the patent.[3] These "pay-for-delay" settlements have been the subject of considerable controversy among certain agencies, courts, and commentators.[4]

Although courts generally encourage settlement, pay-for-delay settlements are unusual in that the plaintiff in the original suit (the patent holder) is paying the defendant (the challenger claiming patent invalidity) to end the suit.[5] These reverse payment settlements are a byproduct of the Hatch-Waxman Act, which was intended to allow generic drugs to enter the market with greater ease and speed by letting them bypass clinical trials if the generic drug could be shown to be bioequivalent to the already approved brand-name drug.[6] The Hatch-Waxman Act was also intended to promote competition between generic and branded drug manufacturers by allowing generic manufacturers to challenge the validity of brand name drug patents without incurring the cost of entry or risking damages from possible infringement.[7]

Under Hatch-Waxman, the first generic firm to file an Abbreviated New Drug Application (ANDA) with FDA asserting that the brand-name patent is either invalid or not infringed is entitled to a "bounty," which allows them to enter the market with a 180-day exclusivity period, effectively creating a duopoly along with the brand-name provider.[8] This exclusivity period is available only once, to the first ANDA applicant.[9] Because a key source of profits for a generic manufacturer is the exclusivity period, the bounty provides a substantial boost to the incentive to challenge.[10] In response to the ANDA, the branded firm may file suit to establish that the generic drug is infringing on their patent. Because generic manufacturers risk almost nothing in challenging branded patents, and branded manufacturers often face losses in the billions of dollars if their patent is found to be unlawful, it is often in the interest of the brand manufacturer to settle.[11]

The settlement of these suits arguably creates an antitrust violation because the settlement still allows the generic manufacturer to enjoy the 180 day exclusivity period upon entering the market, thus removing the bounty from the table.[12] By removing the bounty, the settlement eliminates the primary incentive for other generics manufacturers to challenge the branded patent. Throughout the past decade, the FTC has held reverse payment settlements to be antitrust violations for this very reason, arguing that by keeping generics out of the market, branded firms deprive customers of competitive prices.[13] The federal courts have generally disagreed with the FTC's argument, with the majority holding such settlements to be legal under the Sherman Act.[14]

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Initially, federal circuit courts divided over the legality of reverse payment settlements. In the case of *Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.*, the Sixth Circuit held that reverse payment settlements violated the Sherman Act.[15] However, several months later, Seventh Circuit judge Richard Posner rejected this view in dicta while sitting as a district court judge.[16] Additionally, both the Eleventh and Second Circuits have held reverse payment settlements to be legal, focusing their holdings on the exclusionary rights of patent holders.[17] The legality of a settlement between Bayer and Barr over generic Cipro was also litigated in federal court; with the Federal Circuit holding that reverse payment settlement agreements are essentially legal.[18] The Supreme Court, without comment, denied certiorari to hear the case despite urgings for review by consumer advocates and thirty-two states.[19]

The legality of the reverse payment settlement between Bayer and Barr was also litigated in California state court, with the initial holding matching federal precedent.[20] Although a San Diego superior court judge certified the class action lawsuit, the superior court ultimately granted summary judgment in favor of the defendant pharmaceutical corporations.[21] On appeal, the California Fourth Circuit upheld the ruling of the lower court, holding that reverse payments were legal under California's antitrust law, the Cartwright Act.[22] A petition for review was then submitted to the California Supreme Court, supported by California Attorney General Kamala Harris who argued against the California Fourth Circuit's holding.[23] On February 15, 2012, the California Supreme Court granted the petition for review.[24]

A judgment holding reverse payments illegal in California could have national implications, as drug manufacturers who engage in reverse payment settlements could face legal repercussions in California courts.[25] Although it is not yet known which way the California Supreme Court will decide in this matter, opponents of reverse payment settlements are hailing the court's grant of review as a significant victory.[26]

[1] Timothy A. Cook, Note, *Pharmaceutical Patent Litigation Settlements: Balancing Patent & Antitrust Policy Through Institutional Choice, 17* Mich. Telecomm. & Tech. L. Rev. 417, 418 (2011).
[2] *See generally* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem,* 81 N.Y.U. L. Rev. 1553 (2006).
[3] J. Thomas Rosch, *Pay-For-Delay Settlements, Authorized Generics, and Follow-On Biologics: Thoughts on the How Competition Law Can Best Protect Consumer Welfare in the Pharmaceutical Context,* 2009 WL 4047975 (F.T.C.) (2009).
[4] *See generally* Gerald Sobel, *Considerations of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements,* 20 Fed. Circuit B.J. 47 (2010)*; see also* FTC, *Reporter Resources: Pay-for-Delay: When Drug Companies Agree Not to Compete,* http://www.ftc.gov/opa/reporter/competition/payfordelay.shtml (last visited Apr. 20, 2012).
[5] *See generally* Patentlyo, *Reverse Payment Settlements Return to the Supreme Court,* http://www.patentlyo.com/patent/2011/01/reverse-payment-settlements-return-to-the-supreme-court.html (last visited Mar. 9, 2012).
[6] *See* 130 Cong. Rec. 24425 (1984) (statement of Rep. Waxman); 21 U.S.C.A. § 355(j)(2)(A)(iv).
[7] Cook, *supra* note 1, at 428.
[8] *Id.* at 426-27.
[9] *Id.* at 427.
[10] Hemphill, *supra* note 2, at 1605.
[11] FTC, *FTC Report Examines How Authorized Generics Affect the Pharmaceutical Market: Finds Brand-Name Firms Use Leverage Of Authorized Generic Entry to Delay Competition,* http://www.ftc.gov/opa/2011/08/genericdrugs.shtm (last visited Apr. 20, 2012).
[12] Rosch, *supra* note 3, at 1-2.
[13] *Id.* at 2.
[14] *See Cook, supra* note 1, at 430-37; *see also* Rosch*, supra* note 3, at 2-5.
[15] *See La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (In re Cardizem CD Antitrust Litig.)*, 332 F.3d 896, 908 (6th Cir. 2003) *(*holding that pay-for-delay agreements are, "at [their] core, . . . horizontal agreement[s] to eliminate competition in the market . . . [and] a classic example of a per se illegal restraint of trade.").
[16] *See Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (challenging the Sixth Circuit's reasoning in *Cardezum*, and arguing that a ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options, and may therefore be inherently anticompetitive).
[17] *See Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187 (3d Cir. 2006) *(*holding that a payment by a patent-holding brand-name pharmaceutical company to a generic competitor cannot be the sole basis for an antitrust law violation unless the exclusionary effects of the agreement exceed the scope of the patent's protection); *see also Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (stating that the court's correct focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection).
[18] *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (holding that reverse payment settlements are legal unless a plaintiff can prove either (1) that the brand's patent infringement lawsuit constituted fraud before the Patent and Trademark Office or fell within the "sham" litigation exception to the *Noerr-Pennington* Doctrine, or (2) that the settlement terms were outside of the scope of the brand's patent).
[19] *Id., cert. denied,* 129 S. Ct. 2828 (June 22, 2009) (No. 08-1194.); Greg Stohr, *Bayer's Cipro Accord Won't Be Questioned by U.S. High Court*, BLOOMBERG NEWS (Mar. 7, 2011) http://www.bloomberg.com/news/2011-03-07/bayer-s-cipro-settlement-won-t-be-questioned-by-u-s-high-court.html.
[20] *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165 (Cal. Ct. App. 2011).
[21] *Id.*
[22] *See id.* (the reasoning put forth by the court borrowed heavily from the Eleventh and Second Circuit Court decisions regarding reverse payments).
[23] Alison Frankel, *California Supreme Court to hear pay-for-delay case v. Bayer,* THOMPSON REUTERS (Feb. 16, 2012) http://newsandinsight.thomsonreuters.com/Legal/News/2012/02_-_February/California_Supreme_Court_to_hear_pay-for-delay_case_v__Bayer/.
[24] *In re Cipro Cases I & II,* 134 Cal. Rptr. 3d 165 (Cal. Ct. App 2011), *review granted*, 269 P.3d 653 (Cal. Feb. 15, 2012) (No. S198616).
[25] Bernice Yeung, *State Court to Examine 'Pay-for-Delay' Deals by Drugmakers*, CALIFORNIA WATCH (Mar. 2, 2012) http://californiawatch.org/dailyreport/state-court-examine-pay-delay-deals-drugmakers-15133.
[26] *Id.*