

In order to justify government intervention against a firm that has been successful in the market, a court must be able to do better than merely observe conduct that is consistent with an anticompetitive explanation and then let a jury decide the issue by a “preponderance” of the evidence.³⁴

Note that the Ninth Circuit’s safe harbor approach accommodates this criticism more than the D.C. Circuit’s structured approach. *Tyco* avoids a jury question if the defendant produces uncontroverted evidence of some improvement from the new product, even if in other, arguably more important, respects the new product may not be an improvement. In contrast, while the D.C. Circuit’s structured approach may be calculated to provide some “deference” to the innovator’s product design, that deference would appear to be largely illusory, particularly in the context of a jury trial applying a “preponderance of the evidence” standard.

In purely practical terms, the result under almost any test that does not utilize a safe harbor will depend on how high the bar is set for plaintiffs to defeat summary judgment on whether an improvement is “significant” or on the “predominant purpose” of a new product design.³⁵ If the

³⁴ HERBERT HOVENKAMP, *THE ANTITRUST ENTERPRISE* 47 (2005).

³⁵ One way to provide additional deference without resorting to a safe harbor would be to impose a higher evidentiary burden – such as “clear and convincing evidence” – to rebut the defendant’s improvement claim or to establish predatory intent. While the “convincing clarity” standard has been applied in patent law to claims of inequitable

existence of any quantum of conflicting evidence suffices to put these issues to a jury, then the danger of antitrust courts’ second-guessing product design decisions will inevitably suppress a certain amount of innovation. While the D.C. Circuit seems resigned to this outcome,³⁶ other courts wishing to avoid or minimize it might look to some variation of the Ninth Circuit’s safe harbor approach.

“REVERSE PAYMENT” PATENT SETTLEMENTS: RECENT CASES AND LEGISLATION

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The current White House administration and the Department of Justice (“DOJ”) have joined the Federal Trade Commission (“FTC”) in asserting that reverse payment settlements should be banned. While the White House

conduct, *see Kingsdown Medical Consultants v. Hollister, Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988) (*en banc*) (materiality and intent), it has generally not been a feature of antitrust jurisprudence. *But see Transamerica Corp. v. IBM*, 698 F.2d 1377, 1388 (9th Cir. 1983) (Plaintiff must prove predatory effect by “clear and convincing evidence” when prices exceed average total cost).

³⁶ *See Microsoft IV*, at 65 (imposing liability when a monopolist makes its products incompatible with those of rivals “will inevitably deter a certain amount of innovation.”).

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administration lobbied for banning reverse payment settlements in the health care reform act, the FTC and the DOJ challenged reverse payment settlements in the courts. Despite these efforts, courts are largely adhering to the reasoning undergirding the Eleventh Circuit's holding in *Schering-Plough*: a reverse payment settlement is not an antitrust violation so long as it does not exceed the exclusionary scope of the patent-in-suit.³⁸

The availability of these settlements to litigants has great implications. In patent litigation valued between \$1 million and \$25 million, a patent owner should expect to spend more than \$2 million litigating the patent through trial and appeal. Costs can climb above \$4 million where more than \$25 million is at stake.³⁹ While the rewards for successfully enforcing a patent may be large and beneficial, the risks are large as well: loss of the patent through invalidation means a loss in, among other things, current or potential licensing revenue enjoyed by the patent holder. Sunk costs for research, development, and bringing to market a product or process that may be the subject of the claims of the patent also raise the stakes of litigation. The risks and rewards involving pharmaceutical patent litigation are no exception, and may be higher in many respects.

Costs to bring a drug to market are substantial.⁴⁰ A new drug is essentially an

information good—once its formula is understood, it is generally easy and inexpensive for others to manufacture it without incurring similar research and development costs.⁴¹ Empirical evidence suggests that higher drug profits are positively correlated with greater research and development efforts.⁴² Pharmaceuticals have been associated with the case for strong patents because of the substantial research and development costs.⁴³

Price of Innovation: New Estimates of Drug Development Costs, 22 J. HEALTH ECON. 151 (2003). Under the Food, Drug, and Cosmetic Act, a drug company must demonstrate that a drug is safe and effective before the FDA will approve it for marketing. 21 U.S.C. § 355(d) (2009). That demonstration is made through a New Drug Application (NDA), which is a lengthy, expensive, time-consuming process that costs millions of dollars to the drug company, much of which is spent conducting necessary clinical trials. *Id.* § 355(b). Therefore, drug makers rely heavily on patent protection because a patent is generally considered necessary to recoup the costs of an initial investment in the drug. See Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 BROOKINGS PAPERS ON ECON. ACTIVITY (SPECIAL ISSUE) 783, 795-96, 819 (illustrating that pharmaceutical manufacturers value patents highly as appropriation means); see also *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 609 F. Supp. 2d 786, 811 n.23 (S.D. Ind. 2009) (providing examples of steep erosion of brand sales upon generic entry (loss of approximately 80% of sales within three weeks)).

³⁸ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006) (“*Schering-Plough*”).

³⁹ American Intellectual Property Law Association, *Report of the Economic Survey*

⁴⁰ Studies estimate it may cost a drug company \$802 million to bring a drug to market. Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The*

⁴¹ See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006). Drug companies, compared to innovators in other industries, cannot as easily rely upon a head start, complementary assets, and scale of production as means to preserve profits.

⁴² Carmello Giacotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195, 195 (2005).

⁴³ See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1615-17 (2003).

Congress has established an elaborate regulatory scheme permitting generic drug manufacturers to test the validity and scope of a pharmaceutical patent: if the patent holder's patent is found invalid or not infringed, the generic competitor may enter the market prior to the scheduled expiration of the patent.⁴⁴ This scheme spawns patent infringement lawsuits between a pharmaceutical patent holder and a generic drug manufacturer aspiring to enter the market. Such lawsuits, as with most patent litigations, often end in settlement.

Sometimes, settlement results in payments made to the accused infringer. Such payments have been called "reverse payments" because many believe that the natural direction in which payments should flow in settling a patent litigation is from the alleged infringer to the patentee-plaintiff. Critics of reverse payments primarily cite concerns for competition and consumer cost as reasons such payments should be explicitly ruled antitrust violations.⁴⁵ However, most courts that have considered the legality of reverse payment settlements

examined whether the agreements were within the exclusionary power of the patent, rather than finding such agreements violated antitrust law per se.⁴⁶

Recent Decisions Involving Reverse Payments

Although the FTC continues to assert that reverse payments are per se violative of antitrust law, the district courts continue to apply reasoning set forth in *Schering-Plough* and rule that reverse payments are not per se illegal. In *In re AndroGel Antitrust Litigation*, a district court dismissed antitrust claims brought by the FTC and purchasers of the drug at issue.⁴⁷ As part of the settlement of an ANDA patent litigation, the generics agreed to delay their entry into the market until 2015, five years before expiration of the patent.⁴⁸ In return, the patentee-pharmaceutical companies agreed to pay the generics millions of dollars to promote the brand name drug while the generics were waiting to enter the market.⁴⁹

⁴⁴ See 21 U.S.C. § 355 et seq. A more detailed summary of the Hatch-Waxman framework and earlier cases examining "reverse payment" settlements has appeared in these pages and elsewhere. See, e.g., Craig E. Countryman, *An Analysis of the Justice Department's New Position Regarding "Reverse Payment" Settlements*, The AIPLA Antitrust News—October 2009, and Robert G. Pluta, "Promoting the Progress" or Paying for Delay: Balancing Patent and Antitrust Law in the Age of Health Care Reform, 11 Engage 86 (March 2010).

⁴⁵ See generally Bigelow & Willig, "Reverse Payments" in Settlements of Patent Litigation: *Schering-Plough, K-Dur, and the FTC*, in THE ANTITRUST REVOLUTION 248 (Kwoka, Jr. & White eds., 2005).

⁴⁶ See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), cert. denied sub nom, *Ark. Carpenters Health & Welfare Fund v. Bayer, AG*, 129 S. Ct. 2828 (2009) ("Cipro"); *Schering-Plough*, 402 F.3d at 1056; *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003), cert. denied, 543 U.S. 939 (2004) ("Valley Drug"); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), amending 429 F.3d 370 (2d Cir. 2005), cert. denied, 127 S. Ct. 3001 (2007) ("Tamoxifen").

⁴⁷ *In re AndroGel Antitrust Litig.*, No. 1:09-MD-2084, 2010 U.S. Dist. LEXIS 16017, at *25 (N.D. Ga. Feb. 22, 2010) ("AndroGel"). The court, however, denied the defendants' motion to dismiss the direct purchaser plaintiff's sham litigation claim. See *Id.* at *30.

⁴⁸ *AndroGel*, 2010 U.S. Dist. LEXIS 16017, at *14-15.

⁴⁹ *Id.* at *15-16.

The *AndroGel* court acknowledged that neither the rule of reason nor a per se antitrust analysis is appropriate for patent settlements because patents, by their very nature, create anticompetitive effects.⁵⁰ The *AndroGel* court then applied the standard adopted in *Schering-Plough*, examining the extent to which the settlement exceeded the exclusionary scope of the patent, and measuring the resulting anticompetitive effects.⁵¹ In so doing, the court found that the agreements were within the exclusionary zone of patent, and dismissed the plaintiffs' claims that the reverse payment settlements violated antitrust laws.⁵²

In *In re K-Dur Antitrust Litigation*, a New Jersey district judge granted summary judgment in favor of the defendant drug manufacturers in a case brought by direct purchasers of a branded drug.⁵³ The direct purchasers argued that the appropriate legal standard to determine the legality of the settlement agreements was either a per se analysis or a "quick look" rule of reason analysis.⁵⁴ Rejecting these approaches, a special master appointed by the court applied the "scope of the patent" test adopted by the Second, Eleventh and

Federal Circuits.⁵⁵ The special master found that the agreement did not preclude the generic manufacturers from marketing products that fell outside the scope of the patent claims because any contractual restraint was coextensive with the reach of the patent.⁵⁶ Nothing in the agreement extended the life of the patent beyond its scheduled expiration date.⁵⁷ Ultimately, the court adopted the special master's recommendation that the reverse payment settlements did not exceed the exclusionary scope of the patents.⁵⁸ The case is currently on appeal before the Third Circuit.⁵⁹

In *In re Cephalon*, the FTC was unable to persuade a Pennsylvania district court to apply a per se analysis to the reverse payment settlements at issue in the defendants' motion to dismiss.⁶⁰ *Cephalon* was an opportunity for the FTC to argue for a per se standard in absence of a precedential opinion from the appellate court. Yet, after surveying precedents from other circuits, the district court applied the

⁵⁰ *Id.* at *19.

⁵¹ *Id.* at *20-21.

⁵² *Id.* at *24-25.

⁵³ *In re K-Dur Antitrust Litig.*, No. 01-1652, 2010 U.S. Dist. LEXIS 28918 (D.N.J. Mar. 24, 2010). Notably, the same reverse payments settlements at issue in this case were at issue in *Schering-Plough*.

⁵⁴ *In re K-Dur Antitrust Litigation*, Docket No. 733, No. 01-1652 (D.N.J. Feb. 2, 2010) (special master's opinion, p. 23) ("Under the framework proposed by DP Plaintiffs, settlement agreements involving reverse payments would be subject to a rebuttable presumption of illegality, which could be overcome by proof of a pro-competitive justification for the payment.").

⁵⁵ *Id.* at 46.

⁵⁶ *Id.* at 46-47.

⁵⁷ *Id.* at 41-42.

⁵⁸ *In re K-Dur Antitrust Litig.*, No. 01-1652, 2010 U.S. Dist. LEXIS 28918, at *11. The court also ruled that the underlying patent infringement lawsuits were not objectively baseless, and therefore, the defendants had not engaged in sham litigation.

⁵⁹ *In re K-Dur Antitrust Litigation*, Docket Nos. 733, Nos. 759-761 (D.N.J. Feb. 12-13, 2010) (Notice of Appeal filed by plaintiffs as to Order Adopting Report and Recommendations).

⁶⁰ *King Drug Co. of Florence v. Cephalon, Inc.*, No. 2:06-cv-1797, 2010 U.S. Dist. LEXIS 29905 (E.D. Pa. Mar. 29, 2010) ("*Cephalon*"). Despite its efforts, the FTC has been unsuccessful in persuading any court to adopt a per se approach when analyzing reverse payments.

“scope of the patent” test to determine whether the agreements violated antitrust law. The court reasoned that the test (i) accounts for the exclusionary power of a patent; (ii) permits a plaintiff to assert that the patent was procured by fraud; (iii) does not discourage settlements; and (iv) permits reverse payment settlements, which are seemingly a natural consequence of the Hatch-Waxman Act.⁶¹ The court, despite rejecting a per se approach, ultimately ruled that “sufficient facts have been alleged to establish that the agreements in question grant greater rights than those conferred under the patent.”⁶²

Meanwhile, the current White House administration, the DOJ, and the FTC argue that reverse payment settlements should be banned outright. The White House administration has indicated that eliminating such payments is one of the ways to help pay for health care reform.⁶³ The FTC chairman has indicated that reverse payments harm consumers, and therefore, should be per se illegal.⁶⁴ The DOJ has now

aligned itself with the FTC after arguing against a per se treatment of reverse payments in prior cases, and has recently advocated that the courts adopt a rebuttable presumption against the legality of reverse payment settlements.⁶⁵ In other words, any settlement in which a generic receives payment from a pharmaceutical-patentee would be deemed to violate the antitrust laws unless the payment is commensurate with any savings in litigation costs or differing expected outcomes of the litigation.⁶⁶ Given the views espoused in its

for Health Care Reform (The \$35 Billion Solution) (June 23, 2009), *available at* <http://www.ftc.gov/speeches/leibowitz/090623payfor delayspeech.pdf>.

⁶⁵ See Brief for the United States in Response to the Court’s Invitation, *Ark. Carpenters Health & Welfare Fund v. Bayer, AG*, No. 05-2852-cv (CON) (2d Cir. 2009); the DOJ position through the beginning of 2009 was analyzed in the January 2009 issue of *The AIPLA Antitrust News*. See Mel Orlans and Esther H. Steinhauer, *Reverse Payment Patent Settlements: The Ongoing Search for a Dispositive Rationale*, *The AIPLA Antitrust News*—January 2009. There, the authors explained how the DOJ’s views evolved over three *amicus* briefs opposing petitions for *certiorari*. In 2004, the DOJ advocated against a per se standard for reverse payments, arguing that a patentee’s right to exclude permits it to restrict the sale of infringing products. See *Andrx Pharm., Inc. v. Kroger Co.* (No. 03-779), Brief for the United States as Amicus Curiae (Supreme Ct. 2004). In 2006, the DOJ suggested that an appropriate standard would consider the objective likelihood of success in the underlying patent litigation. See *FTC v. Schering-Plough Corp.* (No. 05-273), Brief for the United States as Amicus Curiae (Supreme Ct. 2006). In 2007, the DOJ argued that per se treatment of reverse payment settlements imposes on a patentee’s right to exclude, and that a rule of reason analysis should be adopted. The DOJ further argued that the analysis should include a determination of the objective likelihood of success in the underlying patent litigation. See *Joblove v. Barr Labs., Inc.* (No. 06-830), Brief for the United States as Amicus Curiae (Supreme Ct. 2007).

⁶⁶ The current DOJ position, based on its solicited views in *Arkansas Carpenters*, was analyzed in the October 2009 issue of *The AIPLA Antitrust News*.

⁶¹ *Cephalon*, 2010 U.S. Dist. LEXIS 28918, at *47-51 (noting that “a per se prohibition on reverse payment settlements would reduce a generic manufacturer’s incentive to challenge patents.”).

⁶² *Id.* at *63. The court emphasized that it had no record from which to rule, and that it must view the facts in a light most favorable to the non-moving party.

⁶³ OFFICE OF MGMT. & BUDGET, EXECUTIVE OFFICE OF THE PRESIDENT, BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 2010, at 28 (2009) (proposed), *available at* [http://www.whitehouse.gov/omb/assets/fy2010_new_era/A New Era of Responsibility2.pdf](http://www.whitehouse.gov/omb/assets/fy2010_new_era/A%20New%20Era%20of%20Responsibility2.pdf).

⁶⁴ Jon Leibowitz, Chairman, Fed. Trade Comm’n, Address at the Center for American Progress: “Pay-for-Delay” Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers’ Wallets, and Help Pay

Arkansas Carpenters brief,⁶⁷ we can expect the DOJ to continue to advocate that reverse payments should be presumed illegal, hoping to create a circuit split that will prompt the Supreme Court to grant *certiorari* on the issue.

Reverse Payments in the Age of Health Care Reform

Certain members of Congress are also advocating for a ban on reverse payments. Congress considered an outright ban on reverse payments as part of its health care reform legislation, but the ban was removed from the bill before it was signed into law.⁶⁸ Congress had previously considered legislation banning reverse payments before it was included in the health care reform bill.⁶⁹ The proposed

See Craig E. Countryman, *An Analysis of the Justice Department's New Position Regarding "Reverse Payment" Settlements*, *The AIPLA Antitrust News*—October 2009. There, the author thoroughly analyzed the DOJ's suggested presumption and how the defendants might overcome the presumption. Currently, the DOJ is advocating for a subjective analysis of the parties' assessment of their positions in the underlying patent litigation to determine whether the reverse settlement agreement was commensurate with the expected outcome of the litigation.

⁶⁷ *See* Brief for the United States in Response to the Court's Invitation, *Ark. Carpenters Health & Welfare Fund v. Bayer, AG*, No. 05-2852-cv (CON) (2d Cir. 2009).

⁶⁸ Senator Kohl submitted S. 369 as a bipartisan amendment to the U.S. Senate health care legislation package. The amendment is not part of the health care reform acts that were signed into law in March 2010. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010); Health Care and Education Reconciliation Act, Pub. L. No. 111-152 (2010).

⁶⁹ *See* Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009); Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009).

Senate bill would have banned reverse payments by forbidding any person, in connection with the sale of a drug product, to directly or indirectly be a party to any agreement resolving a patent infringement claim in which (1) the [generic firm] receives anything of value; and (2) the [generic firm] agrees not to research, develop, manufacture, market or sell the [generic] product for any period of time.⁷⁰

The proposed Senate bill gives the FTC power to exempt and authorize any reverse payment agreements that act "in furtherance of market competition and for the benefit of consumers."⁷¹ Given that a ban on reverse payments was removed from the health care reform act, a stand-alone Senate bill has little hope of passing in the 111th Congress.

Congress did, however, pass legislation in the health care reform act that governs biosimilar versions of branded biologic drugs ("biosimilars").⁷² Biosimilars are biopharmaceutical products that are generic versions of branded biopharmaceutical products.⁷³ The biosimilars legislation is similar to the Hatch-Waxman Act in that it allows competitors to bring biosimilarsto market with greater ease and efficiency than branded biologic drugs. Manufacturers who

⁷⁰ S. 369, 111th Cong. (2009).

⁷¹ S. 369, 111th Cong. § 3 (2009); *see also* H.R. 1706, 111th Cong. (2009).

⁷² *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010); Health Care and Education Reconciliation Act, Pub. L. No. 111-152 (2010).

⁷³ Biopharmaceuticals are created using biological processes, such as growing cells, while pharmaceuticals are created using purely chemical processes.

file the first application for a given biosimilar enjoy an exclusivity period, just as first filers in the ANDA context are given exclusivity.⁷⁴ Several events can trigger the exclusivity period, including dismissal or delay of an underlying patent infringement lawsuit.⁷⁵ Therefore, litigants are precluded from using the exclusivity period to block other entrants—a maneuver that was possible under prior versions of the Hatch-Waxman Act. Nonetheless, the biosimilar legislation and the resulting patent litigation may motivate biopharmaceuticals and biosimilar manufacturers and retailers to reach settlement agreements that include reverse payments, presumably encouraging the FTC's challenge of such settlements. However, there likely is nothing unique in the examination of a biosimilar reverse payment that would alter the consistent analysis of courts that reverse payments do not violate the antitrust laws, so long as the scope of the patent is not exceeded by that settlement.

Critics of reverse payments charge that the settlement arrangements violate antitrust laws and are anti-competitive because they can delay a generic drug's entry into the market. Proponents of a "scope of the patent" test argue that the test provides a balance between the policy goals of antitrust and patent law, and that a per se ban will result in fewer settlements between pharmaceuticals and generics, chilling innovation by multiplying the already numerous challenges of drug development. Despite the recent assertions of the FTC and the DOJ, courts continue to hold that reverse payments settlements that remain within the exclusionary zone of the patent do not violate antitrust law.

⁷⁴ *Supra*, note 36.

⁷⁵ *Id.*

MOBILE COMPUTING: WHY YOU MAY NEVER SEE SOME GREAT APPS

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On July 31, 2009 the Federal Communications Commission (FCC) sent Apple,⁷⁶ Google⁷⁷ and AT&T⁷⁸ letters of inquiry relating to a recent incident that could have antitrust implications. The FCC is particularly concerned with ensuring that companies in the telecommunications industry operate in a fair manner. As cell phones and mobile devices become more complex, the FCC plays an increasingly important role to advocate against any unfair

⁷⁶ Letter from James D. Schlichting, Acting Chief, Wireless Telecommunications Bureau, Federal Communications Commission, to Catherine A. Novelli, Vice President, Worldwide Government Affairs, Apple Inc., Letter to Apple regarding Google Voice and related iPhone applications, WTB Orders (DA 09-1736) (Jul. 31, 2009) *available at*: http://hraunfoss.fcc.gov/edocs_public/attachmatch/DA-09-1736A1.pdf (last visited Dec. 7, 2009).

⁷⁷ Letter from James D. Schlichting, Acting Chief, Wireless Telecommunications Bureau, Federal Communications Commission, to Richard S. Whitt, Esq. Washington Telecom and Media Counsel, Google Inc., Letter to Google concerning Apple's rejection of the Google Voice for iPhone Application, WTB Orders (DA 09-1739) (Jul. 31, 2009) *available at*: http://hraunfoss.fcc.gov/edocs_public/attachmatch/DA-09-1739A1.pdf (Last visited Dec. 7, 2009).

⁷⁸ Letter from James D. Schlichting, Acting Chief, Wireless Telecommunications Bureau, Federal Communications Commission, to James W. Cicconi, Senior Executive Vice President-External and Legislative Affairs, AT&T Services, Inc., Letter to AT&T concerning Apple's rejection of the Google Voice for iPhone Application, WTB Orders (DA 09-1737) (Jul. 31, 2009) *available at*: http://hraunfoss.fcc.gov/edocs_public/attachmatch/DA-09-1737A1.pdf (last visited Dec. 7, 2009).