CPI COMPETITION POLICY INTERNATIONAL

CPI Antitrust Chronicle
June 2012 (2)

Reverse Payment Settlements: Presumptively Bad or Usually Acceptable

C. Kyle Musgrove & Richard Ripley
Haynes and Boone LLP

www.competitionpolicyinternational.com

Reverse Payment Settlements: Presumptively Bad or Usually Acceptable

C. Kyle Musgrove & Richard Ripley[1]

I. INTRODUCTION

In April 2012, the Federal Trade Commission ("FTC") suffered yet another rebuke of what FTC Chair Jon Leibowitz has characterized as "one of the Commission's top competition priorities," *i.e.,* stopping "reverse payment" settlements in drug patent litigation. The Eleventh Circuit's decision in the AndroGel case[2] presents an opportunity to review the concept of "reverse payment" settlements, the agency's persistent condemnation of these agreements, the courts' near-unanimous endorsement of the concept, and assess which side holds the better hand.

II. HATCH-WAXMAN ACT: A BRIEF HISTORY

The Hatch-Waxman Act provides a simplified pathway to approval for generic pharmaceuticals by permitting a generic manufacturer to file an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") prior to the expiration of a brand-name manufacturer's patent. The generic manufacturer can rely on the safety and efficacy studies conducted by the brand-name manufacturer to gain FDA approval of a generic by proving its bioequivalence with the brand-name pharmaceutical.

Under the Act, an ANDA applicant must make one of four certifications with respect to any patents associated with the brand-name pharmaceutical and listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"). The reverse payment settlements flow from litigation precipitated by a "Paragraph IV" ("PIV") certification, under which the ANDA applicant attests that the patent covering the brand-name drug is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.[3] After that certification, the ANDA applicant has 20 days to notify the patent holder.

To forestall FDA approval of the ANDA, the patent holder has 45 days to bring suit effectively challenging the certification; *i.e.*, alleging that the patent would be infringed by the proposed generic. When an action is filed, the FDA is enjoined from finally approving the ANDA until the earlier of 30 months from the notice letter or a final decision or settlement that states that the patent is invalid or not infringed. In addition, the Act affords the first ANDA applicant that files a substantially completed application containing a Paragraph IV certification

[1] Messrs. Musgrove and Ripley are partners with Haynes and Boone LLP, where they practice IP and antitrust litigation, respectively. They would like to thank Lindsay Volpenheim for her assistance with this article.

[2] *FTC v. Watson Pharm., Inc.,* No. 10-12729, 2012 WL 1427789, at *1 (11th Cir. April 25, 2012).

[3] 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)..

for a particular drug a 180-day "exclusivity period" that provides a 6-month window where it is the only generic under an ANDA on the market.[4] Thus the Act motivates ANDA applications and rewards litigation where that application is based on a PIV certification.

Reverse payment settlements resolve the litigation on terms that obligate the brand-name manufacturer to pay the generic applicant a sum to resolve the claim that the brand-name firm originally brought. These settlements also usually set a date on which the generic can enter the market, which can range from the expiration of the patent to a period months or years prior to the expiration date.

III. THE FTC: REVERSE PAYMENTS = PRESUMPTIVELY BAD

The FTC contends that such settlements reflect collusion between brand-name and generic manufacturers that stifles innovation and competition. The agency released a recent study estimating that reverse payment settlements in the pharmaceutical industry cost American consumers $3.5 billion annually.[5]

In a 2009 speech, FTC Chairman Jon Leibowitz charged that the effects of reverse payment settlements are at odds with the goals of the Hatch-Waxman Act.[6] Chairman Leibowitz asserted that these settlements leave generic manufacturers competing to be the first to get paid off rather than the first to come to market. Additionally, he asserted that these settlements discourage innovation of new drugs by making it profitable for brand-name manufacturers to protect weak patents for their existing pharmaceuticals by paying-off the generic manufacturers to abandon their patent challenges. In short, the FTC believes that reverse payment settlements often are vehicles that brand-name manufacturers use to avoid a judgment that their patent was invalid or would not be infringed by the generics, thereby protecting monopoly profits.[7]

IV. THE COURTS: REVERSE PAYMENTS = USUALLY ACCEPTABLE

Notwithstanding a single early victory,[8] this position has not found success in the courts. Three of the four circuits to consider the issue—Federal, Second, and Eleventh—have upheld the concept of reverse payment settlements as a legitimate exercise of patent rights. These circuits have held that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement does not violate antitrust laws so long as the settlement's anticompetitive effects fall within the scope of the exclusionary potential of the patent.[9]

This conclusion reflects a balance of two established legal tenets embodying conduct that in certain contexts raises antitrust concerns. First, a patent by its very nature is anticompetitive to the extent that it enables the patent holder to exclude rivals from the market. The Patent statute,

---

[4] 21 U.S.C. § 355(j)(5)(B)(iv).

[5] Fed. Trade Comm'n, Pay-for-Delay: How Drug Companies Pay-Offs Cost Consumers Billions (2010).

[6] Jon Leibowitz, Chairman, Fed. Trade Comm'n, *Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform* (June 23, 2009).

[7] *Watson.,* 2012 WL 1427789, at *1.

[8] *In re Cardizem*, 332 F.3d 896, 991 (6th Cir. 2003).

[9] *In re Ciprofloxacin*, 544 F.3d 1323, 1335 (Fed. Cir. 2008); *In Re Tamoxifen*, 466 F.3d 187, 212 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005).

however, views this grant of exclusivity as a reward for those who pursue innovation and, thus, benefits the public. Courts generally will respect the monopoly that a patent provides barring proof of fraud or invalidity, and this tolerance has extended to reverse payment settlements.

In its most recent challenge to reverse payment settlements, the FTC argued that a patent would have no exclusionary potential if the patent holder was not likely to win the patent challenge, thus the objective strength of the underlying patent claims should be considered in determining legality of the settlement.[10] The FTC urged "a rule that an exclusion payment is unlawful if, viewing the situation objectively as [sic] the time of the settlement, it is more likely than not that the patent would not have blocked the generic entry earlier than the agreed-upon entry date."[11] The court rejected that attack on patent monopoly, holding that the "exclusionary potential of the patent" is defined by the patent claims regardless of the strength of those claims or the likelihood of a success in the underlying patent challenge.[12]

The court also held that the FTC's position cut against the judicial policy favoring settlements.[13] Courts value settlements as a way to avoid costly, time-consuming litigation. Given the unpredictable and extensive nature of patent litigation, even a patent holder who is likely to succeed in the patent challenge has incentives to settle the patent challenge to both avoid the chance of losing and to cap costly litigation. Courts give great deference to settlements, even those between competitors or potential competitors.

V. PRESUMPTIVELY BAD OR USUALLY ACCEPTABLE?

So who has the better of the argument? Are reverse payment settlements an acceptable competitive limitation under long-standing patent law principles or are they a contrived bottleneck that should be considered presumptively unlawful?

The data on which the FTC relies to buttress its stance does not provide much assistance in answering this question. The core premise of the FTC's position is that the generic drugs subject to such settlements are entering the market later than they otherwise would because of the compensation that the generic receives. The FTC study estimated that settlements containing compensation paid to the alleged generic infringer "on average prohibit generic entry for nearly 17 months longer than agreements without payments." This estimate, which involved a comparison of 218 settlements (152 without compensation and 66 with compensation) covering FY 04-09, has several vulnerabilities.

First, the estimate calculates the time difference in prohibition dates, a date prior to which the generic cannot market the drug under the agreement. It does not compare when the generic would have been **capable** of entering the market in the pay versus no-pay context. This is material because the only settlements that the FTC reviewed were those resolving PIV litigation. A PIV certification does not itself permit or require the generic to be in the market; consequently the prohibition dates may be immaterial given the remaining processes the generic must

[10] *Watson,* 2012 WL 1427789, at *11.
[11] *Id.*
[12] *Id.*
[13] *FTC v. Watson Pharm., Inc.,* No. 10-12729, 2012 WL 1427789, at *12-13 (11th Cir. April 25, 2012).

complete (FDA approval, manufacturing set up, *etc*.) before it is capable of offering the product to consumers in competition with the brand-name drug.

Next, the monetary loss to consumers that the FTC extrapolates from the estimated delay is inflated. The study poses a hypothetical in which a brand-name drug is priced at $300 and the generic at $30, or 10 percent of the brand-name price. But according to a 2008 study by the National Association of Chain Drug Stores, the average price of a brand-name drug was $137.90 and the average price of a generic drug was $35.22, or 25 percent of the brand-name drug. Plugging these values into the FTC hypothetical, the fictitious consumer savings drop by 62 percent. Although nearly all data can be slippery to some degree, these overstatements arguably impugn the credibility of the FTC's estimates.

Finally, the FTC study implies that settlements are likely not about the generic avoiding the risk of defeat because generics prevailed in 73 percent of the patent litigation resolved by a court decision between 1992 and 2002 (22 out of 30 cases).[14] This is a materially higher generic success rate than that calculated by RBC Capital Markets Corp in 2010. RBC analyzed 370 court rulings in drug patent litigation for the period 2000-09 (which includes the post-*Schering* increase in reverse payment settlements). It found that the success rate for generics in litigation resolved by court decision was only 48 percent during that decade.

Further, of the seven generic firms that accounted for the vast majority (78 percent) of Paragraph IV cases brought during this time only one company (Sandoz) had a success rate exceeding 25 percent, and it only accounted for 7 percent of the total Paragraph IV cases. The generic success rate, however, increases dramatically to 69 percent when settlements are included. Of the seven top generic firms, only one (Apotex) had a success rate below 60 percent when settlements are included. These data call into question the bona fides of the FTC's dismissal of settlements as effective risk management vehicles that facilitate generic entry more often than litigation to a decision on the merits.

The FTC's position does not fare much better at the policy level. The agency's position is based on the core contention that reverse payment settlements largely protect bogus patents, a conclusion reached because of the perceived overpayment in exchange for continued exclusivity.

This core contention concerns validity, not infringement, and thus directly confronts the presumption of validity of patents generally, as well as indirectly questioning the performance of the PTO in vetting drug patent applications. But the increase in reverse payment settlements in recent years is generally acknowledged to be the result of the approval of the concept in the 2006 *Schering* decision, not some proliferation of bad drug patents. There is no definitive data demonstrating that pre-*Schering* litigation resolved by a court decision in favor of the generic on the issues of validity has decreased materially (which would suggest a shift of the resolution for patents on questionable validity from a court decision to a settlement).

The agency also asserts that these settlements erect anticompetitive entry barriers by creating a "bottleneck" in the FDA approval process for subsequent generics by effectively

[14] Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002).

"parking" its 180-day exclusivity period. This downplays the forfeiture provisions added to the Act in 2003 that expressly authorize methods by which subsequent ANDA applicants can enter.[15]

Further, the FTC's position does not give due consideration to investment made with respect to the patent estate. From the patent holder's perspective, these settlements permit it to preserve some of the value of that investment. Outside the Hatch-Waxman context, courts routinely rely on this type of investment to refute a claim that the exclusion of a competitor is the result of collusion. The unresolved status of both validity and infringement underscore the settlement's importance in addressing the patent holder's investment while, at the same time, enabling market access to generics at a time prior to the patent's expiration.

VI. CONCLUSION

Reverse payment settlements facilitate certainty by eliminating extensive and costly litigation, which has the potential to indefinitely block the market entry of generic manufacturers, both first and subsequent filers, for extended periods of time while the litigation occurs. Resolving litigation through the use of settlements sets a definite market entry date. As several courts have pointed out, a prohibition on reverse payment settlements would "reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive."[16]

Moreover, the *ex post* judicial analysis of these settlements that the FTC advocates in its recent *en banc* petition before the 11th Circuit would result in a mini trial on the very disputes that the settlement intended to resolve. Further, the standard that the FTC proffers would be available to private litigants (e.g., competitors, downstream purchasers, or consumer classes). From a judicial economy perspective, both the scope and substance of the proffered standard should be a non-starter.

Finally, any legislative efforts must tread lightly on the policies identified above; they are not susceptible to a one-size-fits-all remedy. The recent unsuccessful amendment to the Food and Drug Administration Safety and Innovation Act is an example of reactively attempting to terminate perceived excesses instead of thoughtfully assessing whether these overarching policies demand tolerance.

[15] 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

[16] *Schering-Ploug*, 402 F.3d at 1075 (quoting *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003)).