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The FTC's Continuing Challenge to Reverse Payment Patent Settlements in the Pharmaceutical Industry

By Helen Cho Eckert

I. INTRODUCTION

In early 2009, the Federal Trade Commission ("FTC") launched its latest challenge to reverse payment settlements in the pharmaceutical industry, *FTC v. Watson Pharmaceuticals* ("*Watson*").[1] In a press release accompanying *Watson*, the FTC announced that "'[t]oday's action reaffirms the Commission's commitment to protect American consumers from artificially high prescription drug prices that result when branded and generic pharmaceutical companies decide to collude rather than compete[.]' "[2] In a concurring statement, FTC Chairman Jon Leibowitz took it a step further, declaring that "eliminating these pay-for-delay settlements is one of the most important objectives for antitrust enforcement in America today."[3]

The FTC has consistently maintained its position that certain types of settlements of patent litigation between brand patent holders and allegedly infringing generic firms — whereby payment is made in exchange for delayed generic entry into the market — constitute anticompetitive conduct harmful to consumers.[4] *Watson* continues the FTC assault, adding to last year's previous challenge, *FTC v. Cephalon* ("*Cephalon*").[5]

While the FTC's position is at odds with a number of reported cases to date, and has been expressly rejected by the Eleventh Circuit in *Schering-Plough Corp. v. FTC*,[6] it has nevertheless become an important driver of the antitrust debate over the exercise of intellectual property rights. The issue of reverse payment settlements raises important, and often conflicting, considerations between the policies underlying the antitrust and patent laws. Such settlements between pharmaceutical companies implicate additional vital interests in the national healthcare arena. The debate over reverse payment settlements certainly did not end with *Schering-*

[1] Complaint, *FTC et al. v. Watson Pharmaceuticals, Inc. et al.*, No. 09-598 (C.D. Cal. Jan. 27, 2009) (Public Version), http://www.ftc.gov/os/caselist/0710060/090202androgelcmpt.pdf (*Watson* Complaint).

[2] Press Release, FTC, *FTC Sues Drug Companies for Unlawfully Conspiring to Delay the Sale of Generic AndroGel Until 2015* (Feb. 2, 2009), http://www.ftc.gov/os/caselist/0710060/index.shtm.

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[3] Press Release, FTC, *Concurring Statement of Chairman (then Commissioner) Jon Leibowitz: FTC v. Watson Pharmaceuticals et. al.* (Feb. 2, 2009), http://www.ftc.gov/os/caselist/0710060/index.shtm.

[4] *E.g.*, Press Release, FTC, *FTC Sues Cephalon, Inc. for Unlawfully Blocking Sale of Lower-Cost Generic Versions of Branded Drug Until 2012* (Feb. 13, 2008), http://www.ftc.gov/opa/2008/02/ceph.shtm.

[5] *FTC v. Cephalon, Inc.*, No. 08-2141 (E.D. Pa. May 05, 2008).

[6] 402 F.3d 1056 (11th Cir. 2005).

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Plough. The FTC's new actions against *Watson* and *Cephalon* are the latest steps to advancing that debate.

This article begins with a brief overview of the statutory framework for understanding reverse payment settlements in the pharmaceutical industry. It discusses the FTC's past challenges to such settlements, the courts' rejection of such challenges thus far, and a brief discussion of the allegations in *Watson* and *Cephalon*. It then examines some of the policy considerations behind the FTC's position and closes with a modest recommendation as to how the competing antitrust and patent concerns might be harmonized.

II. ROLE OF THE HATCH-WAXMAN AMENDMENTS IN REVERSE PAYMENT SETTLEMENTS

In 1984, Congress passed the Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act (''Hatch-Waxman'').[7] Hatch-Waxman was intended to help curb rapidly escalating health care costs in the U.S. — particularly with respect to prescription drugs — by encouraging market entry of significantly lower-cost generic versions of pioneer drugs.[8] Hatch-Waxman does so through two main avenues.

First, it allows generic firms to bypass the traditional (and protracted) drug approval process by filing an ''Abbreviated New Drug Application'' (''ANDA'') which relies on safety and efficacy studies originally submitted for approval of the bioequivalent pioneer drug.[9]

Second, it incentivizes generic firms to enter the market before expiration of a brand firm's patents through a ''Paragraph IV'' certification, *i.e.*, a certification that the brand firm's patent is invalid or will not be infringed.[10] The first-to-file Paragraph IV generic applicant is rewarded for bearing the risk and expense of patent litigation with a 180-day exclusivity period, during which it can market its generic without competition from any other generic firm.[11] The 180-day period is triggered only by the earlier of: (1) the first commercial marketing of the generic drug; or (2) a court judgment determining that the pioneer patent in question is invalid or not infringed. The FDA may not approve other generic firms for market entry until after the 180-day exclusivity period of the first-to-file generic applicant has run.[12]

An overview of Hatch-Waxman and its effects, including its unintended ones, are critical to understanding how reverse payment settlements have come to be common resolutions to patent disputes within the pharmaceutical industry. The 180-day exclusivity period can only be triggered by one of the two provisions described above. This creates the potential for a single reverse payment settlement between the brand patent holder and the first-to-file generic applicant to foreclose all other competition by creating a bottleneck in the FDA approval process for subsequent generic applicants. The bottleneck occurs when the settling generic firm does not relinquish its first-to-file Paragraph IV status, while at the same time: (1) agreeing to delay its own ''first commercial marketing'' until the time agreed upon with the brand patent holder; and (2) avoiding a court judgment through voluntary settlement of the litigation.[13] If the 180-day period is never triggered, it can, in theory, never end, and all other generic firms are forced to wait on the sidelines while the brand patent holder continues to enjoy monopoly profits. While amendments made to Hatch-Waxman in 2003 provide for forfeiture of the 180-day period if the first-to-file generic does not market within reasonable, specified time periods, the possibility of a bottleneck foreclosing competition still remains.[14]

Another factor contributing to the prevalence of reverse payment settlements is Hatch-Waxman's reallocation of risks and rewards between the patent holder and the alleged infringer. In the traditional patent infringement context, the patent holder sues the alleged infringer after the infringer has already entered the market. As a consequence, the alleged infringer is exposed to the risk of potentially large damages, measured in terms of, *inter alia*, the patent holder's lost profits.[15]

However, in the Hatch-Waxman context, the filing of the Paragraph IV certification itself is the ''infringing'' act which triggers suit. Therefore, the alleged infringer is exposed to very little risk (no more than its litigation costs and the investment in obtaining FDA approval) but has the potential to reap substantial profits from its 180-day exclusivity period. On the other hand, the patent holder faces much the same risk it would have in the traditional infringement context — loss of its patent rights, future monopoly profits, and substantial investment in developing its pioneer drug — but no longer has the ''upside'' potential of winning lost profit damages or other measure of damages.[16]

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[7] Formally known as the ''Drug Competition and Patent Term Restoration Act of 1984,'' Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 *et seq.*).

[8] H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

[9] *See* 21 U.S.C. § 355(j) for provisions regarding ANDAs. The new ANDA provisions allow for tremendous savings in time, testing and development for generics. *See* Erica N. Anderson, Note, *Schering the Market: Analyzing the Debate Over Reverse-Payment Settlements in the Wake of the Medicare Modernization Act of 2003 and In re Tamoxifen Citrate Litigation*, 93 IOWA L. REV. 1015, 1031 (2008) (while the cost of researching, developing and obtaining FDA approval of a pioneer drug may be up to $1 billion, the cost of getting approval of a generic that is the bioequivalent of the pioneer drug is about $1 million).

[10] *See* 21 U.S.C. § 355(j)(2)(A)(vii) (provisions regarding paragraph IV certification). Because a Paragraph IV certification asserts that the branded drug's patents are invalid or will not be infringed, the ANDA filer must give notice of its application to the patent holder. The patent holder then has 45 days in which to bring a patent infringement suit, which prompts an automatic 30-month stay of the ANDA while the patent litigation ensues.

[11] *See* 21 U.S.C. § 355(j)(5)(B)(iv) (provisions regarding the 180-day exclusivity period).

[12] 21 C.F.R. § 314.107.

[13] *E.g.*, Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 516-17 (2007).

[14] *E.g.*, Anderson, *supra* note 9, at 1022-24.

[15] Indeed, the generic is exposed to enormous risk given that the average price-differentials between generic and brand versions of the same drug would mean that the patent holder's lost profits would likely exceed the generic's total revenues. *See* Steven W. Day, Note, *Leaving Room for Innovation: Rejecting the FTC's Stance Against Reverse Payments in Schering-Plough v. FTC*, 57 CASE W. RES. L. REV. 223, 229 (2006).

[16] *E.g.*, Day, *supra* note 15, at 231-32; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003) (*Cipro II*) (Hatch-Waxman's statutory scheme

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This statutory reallocation expands the already existing imbalance in economic incentives between the brand and generic firms. For example, while the average cost of developing and obtaining approval for a pioneer drug can be very high, the cost of developing a bioequivalent generic is generally orders of magnitude less.[17] In addition, because of the average price differentials between generics and brand drugs (generics are priced on average 20 to as much as 80 percent below the price of the brand drug), the profits that a generic firm anticipates making upon market entry are considerably less than the profits the brand firm stands to lose from those very same sales.[18] The convergence of all these factors — when added to the costs and burdens of litigation — may make it more profitable for both the patent holder and the alleged infringer to settle their patent dispute and share in the patent holder's ''monopoly'' profits rather than pursue direct competition.

III. PAST FTC ENFORCEMENT AIMED AT REVERSE PAYMENT SETTLEMENTS

The FTC's interest in pharmaceutical patent settlements began some years ago. In March 2001, the FTC issued an administrative complaint charging respondents Schering-Plough Corp. (''Schering''), Upsher-Smith Laboratories, Inc. (''Upsher'') and American Home Products Corp. (''AHP'') with violations of Section 5 of the Federal Trade Commission Act and Section 1 of the Sherman Act.[19] The FTC alleged that respondents entered into unlawful settlement agreements to delay the entry of low-cost generic versions of Schering's prescription drug, K-Dur 20.

In 1995, eleven years before expiration of Schering's patent, Upsher filed a Paragraph IV ANDA. Schering sued for infringement, and in June 1997, on the eve of trial, the parties allegedly agreed to a settlement wherein Schering paid $60 million in exchange for Upsher's agreement to delay entry of its generic until 2001. Similarly, when AHP filed a Paragraph IV ANDA, the ensuing infringement suit was allegedly settled with a payment of $30 million from Schering in exchange for delaying AHP's entry until 2004.

The FTC's final opinion held that although a settlement agreement which ''delays generic entry until some date before expiration of the pioneer's patent'' is not made illegal simply by the fact of delayed entry, the existence of a reverse payment is the critical fact leading to a finding of illegality:

> If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.[20]

Stopping short of declaring all reverse payment settlements *per se* illegal, the FTC held that a settlement must be evaluated as of the time it was entered into to determine whether it was unreasonable, *i.e.*, ''whether it likely delayed generic entry beyond the date that would have been provided in a differently crafted settlement.''[21] In reaching its conclusion, the FTC rejected respondents' arguments that the reverse payments were not *quid pro quo* for delayed entry, but rather, consideration for cross-licenses granted by the generics to Schering.

The FTC's Final Order enjoined the respondents from entering into any future patent settlements wherein an ANDA applicant received any consideration in exchange for an agreement not to research, develop, manufacture, or sell the ANDA product for any period of time, *unless* the consideration paid was no more than the lesser of the patentee's litigation costs or $2 million, *i.e.*, what the FTC believes to be the maximum reasonable reimbursement for litigation costs.[22]

On respondents' appeal to the Eleventh Circuit, the court reversed the FTC under a deferential substantial evidence standard. In contrast to the FTC, which regarded the reverse payment itself as a crucial component in finding liability, the court regarded the existence of the patent as the dispositive fact: patents, by their nature, ''create an environment of exclusion, and consequently, cripple competition.''[23] According to the Eleventh Circuit, although agreements to allocate markets and diminish competition are normally anticompetitive, the fact that one party owns a patent changes the analysis entirely. Accordingly, in the patent context, a reverse payment settlement does not violate the antitrust laws so long as its anticompetitive effect is no broader than the patent's lawful exclusionary power. The court questioned the FTC's ''logic'' in concluding that the *quid pro quo* for payment must have been deferred generic entry, criticizing the Commission's refusal to consider the unique circumstances created by Hatch-Waxman which make reverse payment settlements more justifiable.[24]

The FTC petitioned for certiorari and garnered significant support, including attorney generals from 34 states and Rep. Henry Waxman (D-Calif.), co-sponsor of the Hatch-Waxman Act. Significantly, the Depart-

affects the ''parties' relative risk assessments and explains the flow of settlement funds and their magnitude.'').

[17] *See supra* note 9.

[18] *See* Prepared Statement of The Federal Trade Commission On ''Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs,'' Presented by Richard A. Feinstein, Director, Bureau of Competition, Before the Subcommittee on Courts and Competition Policy of the Committee on the Judiciary, United States House of Representatives, at 12 (June 3, 2009), http://www.ftc.gov/opa/2009/06/payfordelay.shtm (last visited June 16, 2009).

[19] *In the Matter of Schering-Plough Corp., Upsher-Smith Laboratories, Inc., and American Home Products Corp.*, FTC No. 9297, http://www.ftc.gov/os/adjpro/d9297/index.shtm (*Schering-Plough*). *Schering-Plough* is not the FTC's first attack on reverse payment settlements in the pharmaceutical industry. *See, e.g., Abbott Labs*, Docket No. C-3945 (May 22, 2000), http://www.ftc.gov/os/2000/05/c3945complaint.htm (consent order).

[20] Opinion of the Commission, *Schering-Plough*, at 26 (Dec. 18, 2003) (*Schering-Plough* Opinion) (internal citations omitted).

[21] *Id.* at 31.

[22] Final Order, *Schering-Plough*, at 4 (Dec. 18, 2003).

[23] *Schering-Plough*, 402 F.3d at 1065-66.

[24] *Id.* at 1064, 1073-74. In reaching its holding, the court followed its earlier decision in *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003), wherein the lower court's finding that a reverse payment settlement was *per se* illegal was reversed because of the existence of a patent. The *Valley Drug* precedent no doubt played a significant role in Schering-Plough's decision to seek appeal in the Eleventh Circuit.

ment of Justice parted ways with its sister agency and urged the Court to deny certiorari because, in the DOJ's view, the facts of *Schering-Plough* did not provide a suitable vehicle for the Court to address the important and complex issues raised by the FTC's actions (4 PLIR 590, 5/19/06).[25] The Supreme court denied certiorari (4 PLIR 742, 6/30/06).

Other circuit and district courts to date have similarly ruled against the FTC's stance. For example, in *In re Tamoxifen Citrate Antitrust Litig.*, consumers and consumer groups challenged the legality of a settlement between the brand patent holder and the first-to-file generic applicant and alleged that the settlement unlawfully provided for the sharing of monopoly profits, which in turn enabled artificially high prices for tamoxifen and foreclosed competition from other generic firms.[26] In affirming the district court's Rule 12(b)(6) dismissal for failure to state a claim, the Second Circuit held that absent evidence that the underlying patent was procured by fraud, or that the patent infringement action was itself a ''sham,'' no cognizable antitrust injury arises from such a settlement, so long as competition is restrained only within the exclusionary scope of the patent itself.[27]

IV. FTC'S LATEST CHALLENGES

FTC v. Watson Pharmaceuticals et al. The FTC's latest attack on reverse payment settlements was launched against generic companies Watson Pharmaceuticals, Par Pharmaceuticals, Paddock Laboratories, and the brand patent holder Solvay Pharmaceuticals. Solvay produced the branded drug, AndroGel, a widely prescribed testosterone replacement drug. AndroGel is Solvay's top-selling drug, generating more than $400 million in U.S. sales in 2007 alone. In 2003, Watson and Paddock each filed ANDAs with the FDA to market generic versions of AndroGel, submitting Paragraph IV certifications that Solvay's patents (set to expire in 2020) were either invalid or not infringed. As the first-to-file, Watson was entitled to the 180-day exclusivity period.

In 2006, shortly after Watson obtained final approval from the FDA, Watson and Solvay agreed to settle their patent dispute with a co-promotion arrangement wherein Watson received a substantial share of Solvay's profits, in exchange for promoting AndroGel and delaying entry of its generic version into the market until 2015. Paddock and Solvay similarly settled their patent dispute, with Solvay paying Paddock $10 million annually in exchange for Paddock's agreement to co-promote AndroGel and delay its generic entry until 2015.

The FTC's complaint alleges violations of Section 1 of the Sherman Act, Section 5(a) of the FTC Act, California's Cartwright Act, and California's Unfair Competition Act against all defendants. Additionally, a Section 2 monopolization violation was alleged against Solvay. Notably, *Watson* was filed in conjunction with the Attorney General of the State of California, in order to redress injury to California's welfare (7 PLIR 145, 2/6/09). The case was originally filed in a California federal court, but was soon thereafter transferred to the Northern District of Georgia where it is currently pending.[28]

FTC v. Cephalon. Cephalon was brought as a single-firm Section 2 monopolization claim against the brand patent holder alone (6 PLIR 201, 2/22/08). The complaint alleged that Cephalon, faced with imminent competition from four would-be generic competitors, compensated each of them to abandon patent challenges and agree to delay entry of generic versions of Provigil until 2012 (Cephalon's last patent was set to expire in 2015). In doing so, Cephalon preserved its annual average of $800 million in ''monopoly'' profits, while also avoiding the heavy burden of proving that each of the four generic challengers infringed Cephalon's ''narrow'' patent. Without the compensation, the generics would have entered the market by June 2006. According to the FTC, for the promise of delayed entry, Cephalon paid over $200 million to the generic firms. Cephalon's settlements also created a bottleneck which precluded all other generic entry until the 180-day exclusivity period was triggered in 2012. The case is currently pending in the Eastern District of Pennsylvania.[29]

V. IMPORTANT POLICY ARGUMENTS BEHIND THE FTC'S APPROACH

Reverse payment settlements bring to the forefront significant, longstanding policy tensions at the intersection of antitrust and patent laws, with further complexity unique to the pharmaceutical industry interposed by Hatch-Waxman. While both antitrust and patent laws aim to enhance social welfare and innovation, they do so in different, often conflicting, ways. Antitrust laws protect maximum competition by prohibiting unreasonable restraints on the market whereas patent laws aim to encourage innovation by granting patent holders a legal right to exclude all competition. There are important policy arguments behind the FTC's position which emphasize competition for the benefit of consumer welfare over the interests of private litigants to exercise their patent — and settlement — rights as they see fit.

A. The FTC Claims that Reverse Payment Settlements Harm Consumer Welfare

The FTC's position on reverse payment settlements is consistent with its mandate of promoting competition and protecting consumer welfare. The FTC has focused a great deal of attention on healthcare, one of the fastest growing and most significant industries affecting consumer welfare.[30] To that end, the FTC opposes settlement agreements which delay generic entry, the

[25] Brief for United States as Amicus Curiae Supporting Respondents, *FTC v. Schering-Plough Corp.*, No. 05-273, 2006 WL 1358441 (U.S. May 17, 2006). The DOJ also criticized the FTC's ''high degree of suspicion of [] reverse payment settlement[s].''

[26] 466 F.3d 187, 196-197 (2d Cir. 2006).

[27] *Id.* at 212-13. *See also Valley Drug*, 344 F.3d 1294; *Cipro II*, 261 F. Supp. 2d 188, 257; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 523 (E.D.N.Y. 2005) (*Cipro III*).

[28] *FTC v. Watson Pharmaceuticals, Inc. et al.*, No. 09-955 (N.D. Georgia). On April 21, 2009, the State of California dismissed its claims without prejudice against all defendants, on jurisdictional grounds following the transfer to Georgia.

[29] *FTC v. Cepalon, Inc.*, No. 08-2141 (E.D. Penn.).

[30] Deborah Platt Majoras, *The FTC: Learning from History as We Confront Today's Consumer Challenges*, 75 UMKC L. Rev. 115, 120 (2006). Pharmaceutical sales in the U.S. topped $296 billion in 2006 alone. Standard & Poor's Industry Surveys, *Healthcare: Pharmaceuticals* (Apr. 24, 2008).

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immediate costs of which are allegedly borne by the average consumer through higher drug prices over a longer period of time.[31] From a consumer-price perspective, the best outcome for consumers — maximum competition and the benefits of early generic entry — cannot be ignored.[32] For example, generic drugs represent 54% of the total volume of prescription drugs sold in the U.S., but only 12% of the total dollars spent.[33]

According to the FTC, some substantive policing of private settlements is necessary to protect the interests of consumers who are directly affected by such settlements but have no seat at the bargaining table. The traditional adversary system cannot necessarily be counted upon to provide checks against patent settlement since both sets of settling parties seem to gain more from a reverse payment settlement than from continued litigation and ensuing competition.[34] In the FTC's view, private for-profit companies should not be given what is essentially *carte blanche* to craft settlements which maximize their profits to the detriment of consumers, all in the name of protecting untested patent rights. The FTC embraces this position in full recognition of the fact that the American legal process favors settlements, and that litigation is expensive, risky and a drain on companies' resources.

B. The FTC Claims that Reverse Payment Settlements are Contrary to the Policies Underlying Hatch-Waxman

Hatch-Waxman was enacted to lower soaring prescription drug costs by promoting generic entry into the market. It is Congress's resolution of the conflict between antitrust and patent laws — at least in the pharmaceutical context — to limit patent holder's rights in favor of providing lower-cost generic drugs to American consumers.

The FTC (and other critics of reverse payment settlements) argue that reverse payment settlements delay generic entry and allow the brand and generic firms to secure as profits what would have amounted to consumer savings had the generic entered the market sooner, in direct contravention of Hatch-Waxman's central purpose [35] Courts which allow such settlements — so long as they do not exceed the exclusionary scope of the patent — have essentially concluded that patent rights trump the competition that was a central thesis of Hatch-Waxman:

> In concluding that settlement agreements under which generic manufacturers are paid to keep their drugs off the market have pro-competitive justifications, the Eleventh Circuit [in *Schering-Plough*] turned the policies of the underlying federal legislation on its head. Although agreements such as those involved in this case may be an unfortunate, unintended consequence of the Hatch-Waxman Act, the Act was never intended to foster such agreements. The Act's intention was to promote competition by generic drug manufacturers, not to permit them to exact a portion of the brand-name manufacturer's monopoly profits in return for withholding entry into the market.[36]

C. The FTC Claims that the *Schering-Plough* Line of Cases Do Not Properly Balance Patent Rights and Antitrust Responsibilities

The principle asserted in the *Schering-Plough* line of cases, *i.e.*, that a settlement is lawful so long as it does not exceed the exclusionary scope of the patent, simply begs the central question at the core of the reverse payment debate, at least as the FTC sees it: does a payment, made to guarantee an otherwise not-guaranteeable right to exclude others, ''exceed the limits'' of the patent's exclusionary scope?

According to the FTC's position, *Schering-Plough* presents a Catch-22 for antitrust plaintiffs. Under the *Schering-Plough* standard, an antitrust plaintiff can only prove his case by establishing that the settlement went beyond the exclusionary scope of the patent to lawfully exclude competition. However, the exclusionary scope of the patent at issue can only truly be determined by examining the underlying merit of the patent, an examination which the settlement just avoided.

Schering-Plough purports to address this problem by equating the exclusionary scope of the patent with its expiration date.[37] But an assumption that all patents are valid and enforceable for the full life of the patent, *i.e.*, *per se* validity, ignores the probabilistic nature of patents and begs the very question at issue in patent disputes.[38]

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[31] *See* Paul F. Dehlner and Matthew C. MacIsaac, *The FTC's Ongoing Opposition to Reverse Payments*, Law 360, May 8, 2008, http://www.law360.com/articles/55670.

[32] One may argue, however, that the FTC's challenges to reverse payment settlements in the name of protecting consumer welfare is shortsighted: Although short-term consumer welfare may be promoted by expediting generic entry, the FTC's approach may harm long-term consumer welfare by taking away incentives for brand firms to develop the pioneer drugs of the future. *See* Day, *supra* note 15, at 261 (One study found that ''for every dollar saved by increasing access to generic drugs, consumers lose three dollars in health benefits due to losses in future innovation.'') (*citing* James W. Hughes, Michael J. Moore & Edward A. Snyder, Napsterizing Pharmaceuticals: Access, Innovation, and Consumer Welfare 28 (Nat'l Bureau of Econ. Research, Working Paper No. 9229, 2002)).

[33] Business Monitor International, *United States Pharmaceutical and Healthcare Report Q3 2008* (June 1, 2008).

[34] The profit that a generic firm anticipates making by entering the market is much less than the amount of profit the brand firm stands to lose from the same sales. Thus, both the generic and the brand are incentivized to share the difference between the brand's potential loss and the generic's potential gain. That difference represents the amount consumers stood to save absent the settlement. Accordingly, consumers are the ones who bear the ultimate costs of such settlements. *See, e.g.*, June 3, 2009 Prepared Statement of the FTC., *supra* note 18, at 10.

[35] *Id.* at 2; Brief of Representative Henry A. Waxman as Amici Curiae in Support of Petitioner, *FTC v. Schering-Plough Corp.*, No. 05-273, 2005 WL 2462026, at *2 (U.S. Sept. 30, 2004).

[36] *Id.*

[37] *See e.g., Schering-Plough*, 402 F.3d at 1066-68.

[38] *See e.g.*, Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 12-13 (2005) (a patent holder's power to exclude accused infringers from the market is never absolute until it obtains a final, successful court judgment on validity and infringement. ''Until that time, the patent's power to exclude competitors is tempered by the statistically high probability that either the patentee will fail to prove infringement or the accused infringer will demonstrate invalidity.''); Joseph Scott Miller, *Patent Ships Sail an Antitrust Sea*, 30 SEATTLE U. L. REV.

The FTC's argument proceeds along the following lines: patents enjoy a *presumption* of validity, but not *per se* validity. The Patent and Trademark Office grants patents (sometimes at an alarming rate) without first ensuring validity, and a significant portion of those patents are subsequently invalidated.[39] Under our patent system, the method used to test validity (and infringement) is through litigation. Patent holders always face the risk that their patents will be found invalid, stripping them of any right to exclude. Accordingly, a reverse payment settlement enables a patent holder to secure — through a monetary *quid pro quo* — a level of certainty not obtainable through the existence of its patent alone. And such certainty is secured at the expense of consumers, whose access to lower-priced, generic drugs is delayed, sometimes for many more years.[40] According to the FTC, the *Schering-Plough* line of cases ''disrupt the carefully balanced patent system by overprotecting weak and narrow patents; allowing patent holders to buy protection that their patents cannot provide; and ignoring consumers' interests in competition safeguarded by the antitrust laws.''[41]

VI. WHAT DOES THE FUTURE HOLD?

A. Amend Hatch-Waxman to Foreclose the Possibility of a Bottleneck

As discussed above, reverse payment settlements which create a bottleneck foreclosing all other generic competition appear to be contrary to Hatch-Waxman's central purpose.[42] The ability to foreclose all other competition through a single settlement may create a significant incentive for a type of collusion between the brand patent holder and the first-to-file Paragraph IV applicant:

> By effectively creating an insurmountable barrier to third party generic entry, it allows the settling parties to share in supracompetitive profits made possible by market exclusivity. In fact, were it not for the fear of antitrust liability, it would probably always be in the best interest of a branded drug company and the [first-to-file generic] to reach such an agreement. The profit margins available under monopoly conditions generally exceed those available in a market with two or more competitors, and with only a single potential generic competitor both parties would be better off sharing those profits than competing.[43]

While settlements present a win-win situation for the settling parties, they leave other important considerations unaddressed.

Congress was aware of the potential for brand and generic firms to ''game'' the system to delay generic entry and enacted amendments to Hatch-Waxman which included several provisions requiring forfeiture of the 180-day exclusivity period.[44] However, the 2003 amendments have not entirely foreclosed the possibility of a bottleneck and Congress may further amend Hatch-Waxman to finally close that door. Congress could make clear that dismissal of an action brought by a first-to-file generic applicant under Paragraph IV constitutes an automatic forfeiture of the 180-day exclusivity period.[45] This change alone would alter the settlement dynamic in reverse payment cases.

B. Take a Quick Look at the Underlying Patent Dispute

Fundamentally, however, the issues raised by reverse payment settlements require some mechanism for balancing legitimate patent rights with antitrust concerns. The FTC continues to press this point. The FTC's main objective, it appears, is to vindicate the proposition that the appropriate standard with which to judge the antitrust legality of reverse payment settlements must take into account the relative likelihood of success of the parties' claims had they not settled, *i.e.*, evaluate the probalistic validity of the patent and whether or not it was infringed. As discussed *supra*, the prevailing court standard that a settlement may not exceed the lawful exclusionary scope of the patent merely begs the ultimate question raised by the FTC. Only through some mechanism for examining the validity and strength of the patent can one determine whether a settlement exceeds the exclusionary scope of the patent.

Some analysts have suggested that an abbreviated analysis of the relative likelihood of the parties' potential patent claims would enable courts to parse out those settlements which were entered into for anticompetitive purposes from those that are the lawful and legitimate by-products of the Hatch-Waxman environment.[46] While certainly more cumbersome than the *Schering-Plough* approach, a ''quick look'' patent analysis may be the best tool available to the courts to strike the appropriate balance between promoting maximum competition while preserving legitimate patent rights.

VII. CONCLUSION

Given the prevalence of reverse payment settlements in the pharmaceutical industry, coupled with the importance of healthcare costs to consumer welfare, pharmaceutical companies should be prepared for a continuing battle over these settlements. Indeed, the tide appears to be turning. Both the House and Senate currently have bills working through the committee process (H.R. 1706 and S. 369, respectively) which would bar would-be generics from accepting any consideration for

395, 397-98 (2007) (a patent gives the holder the power to bring an enforcement action to try to exclude others from competing against it. ''Patent litigation to prevent [competition] is not self-executing: in any enforcement action, the patentee bears the burden of proving liability'').

[39] Indeed, generics prevailed in 73% of pharmaceutical patent infringement suits which resulted in a decision on the merits between 1999 and 2000. June 3, 2009 Prepared Statement of the FTC, *supra* note 18, at 13.

[40] *Id.* at 2.

[41] *Id.* at 6.

[42] Holman, *supra* note 13, at 518.

[43] *Id.*

[44] *See* 21 U.S.C. § 355(j)(5)(D).

[45] Prepared Statement of the FTC before the Special Committee on Aging, United States Senate on Barriers to Generic Entry, at 8 (July 20, 2006), http://www.ftc.gov/os/2006/07/index.shtm (urging Congress to adopt this approach).

[46] *See, e.g.*, Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 698-99 (2004) (asserting that intellectual property settlement agreements, at least in the reverse payment context, ''should not be accorded per se treatment under the antitrust laws and should be approved so long as the patentee has a strong ex ante likelihood of succeeding on the merits of its infringement claim and thereby excluding the infringing use from the market.'').

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settlement of patent disputes.[47] And the FTC, with Chairman Leibowitz taking the lead, remains diligent in its opposition to reverse payment settlements on both the litigation and legislative fronts.[48] Just this month, the FTC testified before a House subcommittee, urging Congress to support H.R. 1706.[49] Likewise, President Obama's budget proposals indicate that the new administration will support limitations on these settlements and Christine Varney (the new head of the Justice Department's Antitrust Division) has also indicated her intent to oppose such settlements and ''align'' the positions of the Justice Department and the FTC.[50]

Close scrutiny is being paid to reverse payment settlements by other governments as well. In January 2008, the European Commissioner for Competition launched dawn raids on the offices of at least six major pharmaceutical companies.[51] EU investigators are examining whether ''generics companies have accepted payments from brand-name drug companies as part of patent litigation in exchange for delaying the release of their cheaper product.''[52] In November 2008, the EU Competition Directorate released its Preliminary Report on its investigation of the pharmaceutical industry, asserting that generic entry occurred later than could be expected in many instances and that such delayed entry had significant repercussions for public health and consumers.[53] The EU's Final Report is expected sometime this summer.

In this environment, the FTC, the EU and the courts will need to find an efficient mechanism for balancing the interests of both the patent and antitrust laws. Until that happens, uncertainty will continue to weigh upon these types of patent settlements.

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[47] H.R. 1706: Protecting Consumer Access to Generic Drugs Act of 2009 was voted on, with approval, by the Subcommittee on Commerce, Trade and Consumer Protection and forwarded to the Full Committee this month (7 PLIR 642, 6/5/09). S. 369: Preserve Access to Affordable Generics Act is scheduled to be considered by the Committee on the Judiciary soon.

[48] *See, e.g., supra* note 3.

[49] June 3, 2009 Prepared Statement of the FTC, *supra* note 18.

[50] President Obama explained in his recent budget that ''The Administration will prevent drug companies from blocking generic drugs from consumers by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market.'' Office of Mgmt. & Budget, Exec. Office of the President, Budget of the United States Government, Fiscal Year 2010 (2009) (proposed), at 28, http://www.whitehouse.gov/omb/assets/fy2010_new_era/A_New_Era_of_Responsibility2.pdf. (last visited June 16, 2009); Executive Nominations: Hearing Before the S. Judiciary Comm., 111th Cong. 38-39 (2009) (exchange between Sen. Herb Kohl, Member, S. Judiciary Comm., and Christine Anne Varney, Nominee, Assistant Att'y Gen., Antitrust Division, Department of Justice).

[51] Samuel Howard, *EU Steps Up Antitrust Probe of Drug Market*, Law 360, May 15, 2008, http://www.law360.com/articles/56369.

[52] European Commission on Competition, *Preliminary Report on Pharmaceutical Sector Inquiry* (Nov. 28, 2008), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/exec_summary_en.pdf.

[53] *Id.*

** Unless otherwise noted, all URLs listed herein were last visited on Feb. 19, 2009.