

Hatch-Waxman Patent Settlements: The Battle for a Benchmark

BY JAMES C. BURLING

WHILE THE FEDERAL COURTS are gravitating toward minimal antitrust intervention into patent settlements between pioneer and generic drug manufacturers (“Hatch-Waxman settlements”), acknowledging legitimate competing values in patent law and settlement policy, the Federal Trade Commission continues to urge special antitrust constraints upon such settlements. However, two recent circuit court decisions—*Schering-Plough v. FTC* in the Eleventh Circuit,¹ and *In re Tamoxifen Citrate Antitrust Litigation* in the Second Circuit²—have rejected the FTC’s view that any settlement including compensation from the pioneer drug patent holder to a generic drug challenger (a so-called “reverse payment”) and “delayed” generic entry is virtually per se illegal. Rather, these decisions hold that any settlement less exclusionary than the patent at issue is presumptively valid.

The Commission has petitioned the Supreme Court to review the judgment of the Eleventh Circuit in *Schering-Plough*,³ and the petition remains pending as this article goes to press. The Court requested the views of the Solicitor General, who initially declined to petition the Supreme Court on behalf of the FTC, and thus can be expected to offer, at best, lukewarm support for the FTC’s position.⁴ Though a denial of certiorari would not prevent the FTC from continuing to advance its position against Hatch-Waxman patent settlements, it presumably would end the Commission’s primary means of challenge. Because 15 U.S.C. § 45(c) provides that a Commission decision may be appealed to any circuit where the respondent does business, parties aggrieved by future adverse FTC orders almost certainly would seek review in either the Eleventh or Second Circuit.⁵

Of course, if the Supreme Court grants certiorari in *Schering-Plough* (or *In re Tamoxifen Citrate*), then the resulting decision from the Court should provide definitive guidance for Hatch-Waxman patent settlements. Important indicia for granting certiorari, however, are absent. Notwithstanding an earlier Sixth Circuit decision holding a

Hatch-Waxman settlement per se illegal,⁶ there is no real split among the circuits.⁷ Indeed, there is an emerging consensus in favor of the principles articulated by the Eleventh Circuit.⁸ Also, consistent with statutory requirements and judicial precedent, the Eleventh and the Second Circuits have identified an appropriate policy balance of the patent, antitrust, and settlement principles that collide under the Hatch-Waxman framework.

In this article, the FTC’s “reverse payment” position, as most recently set out in both its petition and reply in *Schering-Plough* and its amicus brief *In re Tamoxifen Citrate*, is measured against the three policy goals (antitrust, patent, and settlement) that must be reconciled in judging Hatch-Waxman settlements. That evaluation shows, not surprisingly, that the FTC has assigned an overriding priority to antitrust concerns, impinging upon competing patent and settlement principles. The FTC seeks to justify the special rules it would impose upon these settlements by reference to the Hatch-Waxman Act and its 2003 “Medicare Modernization Act” (MMA) amendment. That justification remains open to serious question as neither the statutory language nor any necessary inference from that legislation lends substantial support to the FTC’s position.

The FTC’s Hatch-Waxman Settlement Challenges, *Schering-Plough*, and *Tamoxifen*

The Commission’s first two challenges to Hatch-Waxman “reverse payment” patent settlements resulted in consent orders prohibiting similar settlements in the future.⁹ Both matters involved substantial cash payments to generic companies and their agreements to delay market entry. In these consent orders and in public statements thereafter, the Commission set out its view that Hatch-Waxman settlements delaying generic entry and including any payment from the patent holder to the generic were highly suspect, if not per se illegal.¹⁰ The Commission believed that such “reverse payments” (flowing from plaintiff to defendant) plainly constituted a quid pro quo for delayed generic entry.

The *Schering-Plough* matter was the first such action fully litigated by the Commission, in the course of which the FTC more fully articulated its position on Hatch-Waxman settlements. *Schering-Plough* held a formulation patent (expiring September 5, 2006) for a potassium supplement, K-Dur 20.¹¹ In August 1995, Upsher-Smith filed an ANDA. *Schering*

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timely brought suit for patent infringement, and in June 1997 the parties settled. Upsher-Smith agreed not to market any generic version of K-Dur 20 until September 2001; Schering-Plough agreed to pay Upsher-Smith \$60 million; and Schering-Plough received licenses to five unrelated Upsher-Smith products. In December 1995, a second generic manufacturer, ESI-Lederle, filed its ANDA. Schering-Plough timely filed a patent infringement suit, and in June 1998, the parties settled. ESI agreed not to market any generic version of K-Dur 20 until January 2004, and not to market more than one such generic for an additional two years; Schering agreed to pay ESI \$5 million for its legal fees and up to \$10 million contingent upon the FDA's approval of ESI's generic; and Schering agreed to pay an additional \$15 million in return for licenses to several unrelated ESI products.¹²

On March 30, 2001, the FTC brought an administrative complaint against Schering-Plough, Upsher-Smith, and ESI,¹³ asserting that Schering-Plough's payments to Upsher-Smith and ESI, respectively, exceeded the fair value of the cross-licensed products, and constituted reverse payments to secure delay in generic drug entry. After extensive evidentiary proceedings, the Administrative Law Judge dismissed the complaint on June 27, 2002, finding both settlements lawful by reasoning presaging the Eleventh Circuit's later analysis.¹⁴ The ALJ "ruled that the theories advanced by the FTC, namely, that the agreements were anticompetitive, required either a presumption (1) that Schering-Plough's '743 patent was invalid; or (2) that Upsher-Smith's or ESI's generic products did not infringe the '743 patent. The ALJ concluded that such presumptions had no basis in law or fact."¹⁵ The ALJ "found that the presence of payments did not make the settlements anticompetitive, per se," but rather that the "exclusionary power of the patent itself must be assessed."¹⁶

The Commission largely rejected the ALJ's findings and analysis, concluding that the payments were not legitimate consideration for licenses but rather were reverse payments made to procure delay in generic drug competition.¹⁷ The Commission held that the payments were illegal because they delayed entry beyond the dates that would have been agreed upon in a hypothetical settlement without reverse payments.¹⁸

On March 8, 2005, the Eleventh Circuit vacated the FTC's decision and order: "[T]he size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy."¹⁹ The court held that neither per se nor rule of reason analysis was applicable, reiterating a three-part test it had articulated in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*: "[T]he proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."²⁰ The Eleventh Circuit concluded that the FTC had applied an incorrect baseline for measuring the competitive impact of a Hatch-Waxman settlement, improperly relying upon a hypothetical settlement

with an entry date that "would have been" agreed upon as a benchmark against which to measure any alleged "delay" in generic entry.²¹ The court found no proof that a different settlement with an earlier generic entry date was possible or that continued litigation would result in earlier generic entry dates, and held that the settlements at issue did not violate the antitrust laws because the agreed "delay" in entry was within the exclusionary potential of the patent.²²

In *In re Tamoxifen Citrate*, the Second Circuit similarly rejected a slightly modified version of the FTC's position asserted by private plaintiffs in a multidistrict class action brought by a variety of third-party payers and consumers of tamoxifen citrate, a breast cancer drug.²³ The plaintiffs challenged a "reverse payment" settlement between pioneer drug/patent-holder Zeneca and generic drug manufacturer Barr Laboratories. In affirming dismissal of the complaint, the Second Circuit endorsed the reasoning of the Eleventh: "[S]imply because a brand-name pharmaceutical company holding a patent paid its generic competitor money [in the settlement of patent litigation] cannot be the sole basis for a violation of the antitrust law' unless the 'exclusionary effects of the agreement exceed the scope of the patent's protection.'"²⁴ The plaintiffs have sought panel rehearing and rehearing en banc of the decision, and the FTC has filed a brief *amicus curiae* in support of those efforts.

Balancing Competing Goals

Analysis of Hatch-Waxman patent litigation settlements begins with recognition that there are at least three principles in play. First, antitrust law condemns unreasonably anticompetitive agreements—those that would diminish market output and increase price. Second, patent law shares with antitrust the long run goal of increased innovation, leading in turn to increased competition. But in the near term, the patent reward for innovation grants a right to exclude competition, a result at odds with antitrust principles. In the particular context of pioneer and generic drugs, the Hatch-Waxman Act itself worked a compromise of competing antitrust and patent goals.²⁵ The Act was intended to speed the entry of generic drugs to spur competition, but at the same time to preserve the incentive to innovate fostered by the patent laws.²⁶ Finally, courts repeatedly have articulated a policy in favor of settlement, especially in regard to patent litigation, noting the efficiency and repose thereby accomplished.²⁷ These three competing goals cannot be reconciled simply by logic. Rather, to assess Hatch-Waxman patent litigation settlements, the courts must balance the competing policies set out in legislation and case law, and apply that balance to identify the appropriate benchmark against which to measure Hatch-Waxman settlements.

For these reasons, the Eleventh Circuit in *Schering-Plough* was quite right to reject both per se treatment and the truncated rule of reason approach advocated by the Commission.²⁸ As commentators and some courts have observed, standard antitrust analysis does not work well for evaluating

antitrust issues in the context of patent settlements.²⁹ Many such settlements—involving “delayed” entry of the challenger, or division of markets—would be per se illegal outside the patent context. We already know that the exclusion or delayed entry of a significant competitor is anticompetitive. As the Eleventh Circuit observed in both *Valley Drug* and *Schering-Plough*: “What is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects.”³⁰ “Our conclusion, to a degree, and we hope that the FTC is mindful of this, reflects policy.”³¹

In the end, it is the identification of the intended policy balance and of the settlement benchmark that follows that will dictate whether any particular settlement violates the antitrust laws. This is an exercise in discerning and reconciling antitrust concerns with existing patent and settlement policies evident in statutory and case law, rather than developing policy in a vacuum. The FTC urges an admittedly hypothetical settlement benchmark, where litigation risk assessment (validity and infringement) must be mediated in settlement only by the “currency” of entry date modification (or, put another way, by adjusting the patent term): a 100 percent risk of invalidity/non-infringement is settled by allowing immediate generic entry; a zero percent risk by

exclusion until patent expiration; and any intermediate risk by proportionate entry along the time line of remaining patent life. Assuming the primacy of antitrust considerations, the FTC would require that the parties settle on terms most immediately favorable for consumers. In contrast, the Eleventh and Second Circuits have given deference to countervailing patent and settlement goals.

Patent Goals

In *Schering-Plough*, the Eleventh Circuit placed a heavy emphasis on patent interests. The presumption of patent validity is stated expressly in the Patent Act.³² The presumption can be overcome, but only by “clear and convincing” evidence of invalidity—the highest standard in civil litigation.³³ The Eleventh Circuit’s test of measuring any settlement against the exclusionary potential of the patent simply applies that presumption: The benchmark against which to measure a settlement is the “but for” world of patent validity, and exclusion of the generic until patent expiration. The Second Circuit followed suit in *In re Tamoxifen Citrate*: “[In a ‘reverse payment’ settlement], so long as the patent litigation is neither sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.”³⁴

The Hatch-Waxman Regulatory Framework

THE 1984 AMENDMENTS to the Food, Drug, and Cosmetic Act (Hatch-Waxman Act) set out the generic drug approval process and made specific adjustments to the rights of patent holders for “pioneer” (or “branded”) drugs. 21 U.S.C. §§ 301 *et seq.* The Act streamlines the FDA’s approval of generic drugs by requiring that a generic manufacturer need only demonstrate “bioequivalence” to a previously approved pioneer drug (effectively relying upon the safety and efficacy studies for the pioneer drug).

To expedite resolution of patent issues that might affect the approval or launch of generics, holders of patents covering an approved drug must list such patents in an FDA publication commonly known as the Orange Book. As part of its Abbreviated New Drug Application (ANDA) for generic drug approval, the applicant must certify that any unexpired patent for the pioneer drug is either invalid or will not be infringed. *Id.* § 355(j)(2)(A)(vii)(I)–(IV). This so-called Paragraph IV certification requires the generic company to notify the patent holder of its intent to market the generic upon ANDA approval.

After such Paragraph IV notification, the patent holder has 45 days to file a patent infringement suit, which triggers an automatic 30-month stay of final ANDA approval (unless the lawsuit is earlier resolved against the patent holder). *Id.* § 355(j)(5)(B)(iii).

The Act also provides that the first generic manufacturer to file an ANDA containing a Paragraph IV certification obtains 180 days of marketing exclusivity, during which the FDA cannot approve any other ANDA. *Id.* § 355(j)(5)(B)(iv). Prior to the 2003 MMA amendment described below, the 180-day exclusivity period commenced upon the earlier of the date the first filer marketed its generic or the date of a final decision from the trial court adverse to the patentee (or, if timely appealed, the date the Federal Circuit declared the patent invalid or not infringed). *Id.*

The Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, attempted to reduce certain perceived abuses of the Hatch-Waxman Act. Principal provisions include: a limitation upon the number of automatic 30-month stays that can apply to any particular drug; modification of the triggers for the 180-day marketing exclusivity for the first ANDA-filer, including forfeiture of exclusivity for failure to market under certain circumstances; a requirement that pioneer-generic (and certain other) patent settlements must be filed with both the FTC and the Department of Justice; and forfeiture of 180-day exclusivity for any generic found to be the subject of an illegal settlement agreement.

—JCB

The FTC, however, has sought to attack this presumption collaterally, by inference rather than by straightforward evidence of patent invalidity.³⁵ In *Schering-Plough*, the Commission advanced its usual argument that a large “reverse” settlement payment constitutes an acknowledgement of the patent’s weakness³⁶ (or of likely non-infringement). The FTC contends that if the parties conclude that the patent is weak, then a settlement must adjust the remaining patent life proportionally to reflect that weakness. It is of course undeniable that such a “substantial” payment, without more, logically may be probative as to patent validity. However, it is a long hike from that premise to the conclusion that the presumption of patent validity should be vitiated by such a payment; and to insist that *any* risk of invalidity or non-infringement translate in settlement only to a shortened patent term.

To begin with, the logic of the FTC’s assumption that any payment to the generic constitutes a quid pro quo for delay is far from ironclad. It is almost certain that some portion, and potentially all, of a payment is due to risk aversion by the patent holder. For example, a pioneer drug company might well prefer three years of certain product exclusivity to the litigation alternative of a 50 percent chance of zero years of exclusivity and a 50 percent chance of eight years of exclusivity. The generic challenger might determine that a 50 percent chance of near term entry is worth trial. Yet, the FTC would condemn any payment made to the generic to drop its challenge in exchange for a license to enter in three years, even though the analysis it espouses would suggest four years as an appropriate settlement.

There has been extensive commentary supporting the notion that cash settlement payments may be justified by risk aversion or other valid reasons.³⁷ While the FTC’s view that reverse-payment-equals-delay may be a permissible inference, it is certainly not a necessary one, and therefore provides a very unstable foundation for the nearly irrebuttable presumption that the FTC would apply.

The FTC denies that it has made the presence of a substantial reverse payment a virtual *per se* test for illegality. Rather, it suggests that such a payment should shift the burden to the settling parties to explain why it is not a payment to delay entry.³⁸ In *Schering-Plough*, the FTC found that the parties failed to make such a showing.³⁹ The Eleventh Circuit viewed the FTC’s test as tantamount to *per se* illegality, and rightly so.⁴⁰

Although the FTC invokes *California Dental Association* and *PolyGram* to support burden shifting where it has established a *prima facie* case of likely anticompetitive effects,⁴¹ it has established no such thing under its reverse payment approach. In Hatch-Waxman settlement cases, the issue should not be whether earlier generic entry provides greater competition, as that is a truism. Rather, the issue should be whether earlier generic entry was *legally* possible. Only then should the possibility of such entry serve as a benchmark against which to measure “delay.” A *prima facie* showing of “delay” against this benchmark requires demonstration

(meaning *proof*, not assumption) that the parties in fact could have settled in a manner allowing entry at an earlier time or that the patent litigation would have ended in a way that allowed entry at an earlier time. As the FTC has elected not to try to prove either, it cannot claim to have established a *prima facie* case necessary for burden shifting. Moreover, it is far from clear what factual showing could be made by the settling parties under the FTC’s burden shifting approach to “prove” the payment was *not* one for delay. Where the *prima facie* case is established by a hypothetical rather than evidence-based entry benchmark, marshalling “offsetting” evidence requires the almost impossible task of proving a negative—that a settlement including an earlier entry date could not have occurred.

In a second and more recent effort to justify its effort to limit Hatch-Waxman settlements—first arising in its *Schering-Plough* petition⁴²—the FTC has relied on the observation that patents generally are “probabilistic” to argue that the particular patent covering the pioneer drug faces at least some risk of invalidity.⁴³ Based on broad patent studies showing that many challenged patents are invalid, the FTC argues that every patent should be assumed to be at risk of invalidity. However, such “evidence” about the overall results of patent challenges would certainly not be probative or even admissible in any patent infringement trial, much less sufficient to overcome the presumption of validity.⁴⁴

The FTC is on somewhat stronger ground in urging that where a generic asserts non-infringement, rather than invalidity, patent holders are not entitled to any presumption. Although it has not taken pains to urge this distinction in prior cases, the FTC has made it a particular point in *Schering-Plough*, which it characterizes as primarily involving disputed infringement.⁴⁵ Thus, says the FTC, because there is no presumption of infringement, and indeed a burden on the patent holder to show it, the Eleventh Circuit’s settlement benchmark of exclusionary potential of the patent is wrong when applied to cases alleging non-infringement, and possibly backwards.⁴⁶ Yet *Schering-Plough* apparently offered considerable evidence of infringement, and likely established a *prima facie* case.⁴⁷ The FTC, for reasons of its own, chose not to argue contrary evidence. In patent litigation, if the patent holder offers *prima facie* evidence of infringement, and the infringer offers nothing, the patent holder wins. At least in those cases—as in *Schering-Plough*—where there is an unchallenged *prima facie* showing of infringement, courts hardly can be faulted for using the potential exclusionary power of the patent as a settlement benchmark for both validity and infringement challenges.⁴⁸

Finally, in regard to patent concerns, there is intractable tension between the FTC’s effort to “adjust” patent grants to reflect risk and the standard of proof employed in civil litigation.⁴⁹ A patent that is 51 percent or more likely to be valid will be found entirely valid by a jury or court employing the accepted standard of proof. However, by the FTC’s logic, under which validity risk probabilities must translate into

