THE ANTITRUST CHALLENGE TO PATENT SETTLEMENTS

Stanford Law School Conference
On Intellectual Property Law

Thomas B. Leary
September 14, 2006

This outline will generally follow the format submitted by Mark Schildkraut, in order to highlight areas of agreement and differences.

I. THE BIG REASONS THE COURTS HAVE BEEN REJECTING CHALLENGES TO SETTLEMENTS

The four reasons listed in the Schildkraut outline accurately capture the principal themes in the court decisions that dismiss private damage claims and/or reject the position taken by the Federal Trade Commission in the Schering opinion. 1/ There are, however, counter-arguments for each.

(i) Courts want to encourage settlements.

This is clearly true, and perhaps particularly true for complex patent litigation. The question, however, is whether the Hatch-Waxman Act 2/ –– with its incentives for patent litigation and rewards for successful challenges –– mandates same relaxation of this general policy.

(ii) Courts do not believe that litigants must act in the public interest when settling litigation.

This is also clearly true. The question, however, is whether an agency like the FTC, with a mandate to enforce a statute, should ignore the statutory objectives when it draws conclusions about likely competitive effects. The argument goes, as follows: payments for delayed entry would be per se illegal, were it not for

---

1/ Schering-Plough Corp., No. 9297 2003 WL 22989651 (F.T.C. Dec. 8, 2003), vacated, Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S.CT. 2929, 74 U.S.L.W. 3130, 74 U.S.L.W. 3714, 74 U.S.L.W. 3722 (U.S. Jun 26, 2006) (NO. 05-273).

2/ Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585.

the preclusive power of a patent; the parameters of patent protection are, however, matters that Congress can modify, if it chooses; and in Hatch-Waxman Congress has chosen to modify the usual parameters by creating special incentives for both sides to encourage patent litigation and thereby facilitate earlier generic entry. Facilitation of generic entry thus becomes a particularly important pro-competitive value that the FTC must take into account..

(iii) Accepting the theory of the challenges would require rejection of settlements where damages were compromised.

A short answer might be that Hatch-Waxman provides a mechanism for patent litigation to proceed before the patent holder has incurred damages, and compromise of damages is simply not an issue in Hatch-Waxman settlements.

This is not a complete answer because it still might be argued that the FTC's position could have a carry-over effect on other patent litigation. In further response, however, there is no suggestion that the FTC would attempt to do so. The FTC has relied heavily on special economic considerations that explain its jaundiced view of reverse payments from patentees to generic challengers, namely, the fact that the patentee's profit without competition exceeds the profit of both the patentee and the generic, after entry. This means that both parties will be better off if the generic accepts money in return for delayed entry. In fact, it means that a generic may do better by settling than by winning its case outright –– an outcome that not only defeats the underlying objective of Hatch-Waxman but also is qualitatively different from an agreement to pay reduced damages.

(iv) Risk Aversion.

Presumably, this comment means that because Hatch-Waxman contemplates patent litigation before generics are exposed to serious damage liability, the normal risk/reward calculations of patentees are modified, and they face downside litigation risks that exceed the upside potential gains. It is therefore only natural that they would want to buy their way out. This may well be true. But, again, Congress has the right to modify the normal risk/reward calculations if it chooses. In addition, if patentees are uncomfortable with the Hatch-Waxman regime, they can litigate under the normal rules –– but, they will forego the automatic 30 month stay. They evidently have not been attracted to that option, at least up to now. If reverse payments are essentially legal per se, patentees can continue to benefit from the 30 month stay and buy off the first challenger if litigation prospects do not appear favorable. Delayed entry by the first challenger can then block any others. Not bad.

In addition to these four considerations, there is probably a fifth. We all agree on the proposition that consumers have not been damaged by delayed entry if the patent actually is valid and infringed. In a private suit for damages, like Tomoxifen, 3/ the subsequent patent litigation history undoubtedly affected the court's views on the legality of the settlement ex ante. It is possible to accept the FTC's view of reverse payments, and still argue that the ultimate holding in Tomoxifen is correct.

3/ In re Tamoxifen Citrate Antitrust Litigation, 429 F.3d 370 (2d Cir. 2005).

II. ADDITIONAL PROBLEMS FOR ANTITRUST/IP AFFICIONADOS

(i) Difficult to reconcile condemnation of reverse payments with the right of patent holders to exclude.

The FTC does take account of the right to exclude. Remember that agreements by a potential competitor to defer entry are per se illegal standing alone. The FTC recognizes the power of a patent (a) by essentially immunizing any agreement to delay entry within the patent period, provided there is no reverse payment, and (b) by suggesting that reverse payments could be justified in some circumstances. The FTC does reject –– in this context and in others –– the extreme position that a patentee can impose any terms it wants on a potential entrant, within the scope of its patent monopoly. A patentee is not free to impose a price-fix either.

(ii) Cannot be reconciled with the Guidelines on Intellectual Property, which permits patent holders to exclude if it is more likely than not that the patent is valid and infringed.

In the Hatch-Waxman context, the FTC is trying to implement the will of Congress in an admittedly imperfect way. For reasons outlined in the Schering opinion, the agency does not want to undertake a mini-trial on the merits of a patent claim in the midst of an antitrust case. The biggest problems are that (a), post-settlement, the parties most knowledgeable on the matter are now on the same side, and that (b), unlike courts that decide private-damage actions, the FTC normally has to take a position before the patent merits have been adjudicated

elsewhere. The FTC believed (and, I suspect, still believes) that its approach is superior to a rule that would immunize virtually all payments for delay within the scope of the patent. And, the history of Hatch-Waxman settlements suggests that reverse payments are not essential for settlements. 4/

(iii) Focuses on intent evidence rather than effect evidence.

Not really. The FTC's approach does focus on likely effects –– i.e. the payment must have been traded for "something´–– but does allow for justifications, based on objective criteria rather than subjective intent. For example, payment for delay may permit a generic to compete more effectively once it does enter. By analogy, delay coupled with a reduced royalty may permit the same thing.

(iv) Ignores the reduction in output that might be caused by generic entry.

This could well be true. However, right or wrong, Congress has made a policy choice to encourage generic entry. The FTC does not have the power to second-guess this policy choice. This argument is similar to a claim that encouragement of early generic entry will reduce incentives for innovation in the pharmaceutical industry. This could well be true, too. But, the opinion of the FTC, or of a court, on this issue is simply irrelevant once Congress has chosen to accept that risk.

4/ In fiscal 2004, for example, none of the fourteen settlements reported to the FTC contained a reverse payment. See FTC, Summary of Agreements filed in FY 2004: A Report by the Bureau of Competition (2005), at http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf.

III. CONCUSION

In conclusion, I suspect that Marc Schildkraut and I would agree on one thing: this particular war is not over. Private actions continue to be filed, and recent public statements 5/ suggest that the FTC is still dug in. It will be interesting to see where and how the agency will move next.

5/ See, e.g., Prepared Statement of the Federal Trade Commission Before the Special Committee on Aging of the United States Senate on Barriers to Generic Entry, July 20, 2006, at http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf.