

Redefining the Border Between Intellectual Property and Antitrust: Implications of *FTC v. Actavis*

Introduction

The interface of intellectual property (particularly patent) rights and antitrust has challenged legal counselors in the US since at least the early 1930s. Earlier this month, the United States Supreme Court revisited this topic, dusting off and reinterpreting its older precedents in issuing the opinion *Federal Trade Commission v. Actavis, Inc., et al.*, Case No. 12-416, 570 U.S. __ (June 17, 2013). The *Actavis* decision would be noteworthy for its intended impact alone on reverse-payment settlement agreements in the pharmaceuticals industry, making those settlements more open to antitrust challenge. The opinion has broader implications, however, for the basic intersection of intellectual property law and antitrust. Fundamentally, the majority's move away from the scope of the patent test towards a more antitrust-focused analysis will impact not only reverse-payment settlements, but may shape other significant antitrust issues involving intellectual property. Such issues range from major policy initiatives like the likely inquiry into so-called "patent trolls" or patent assertion entities (PAEs), to the daily work of how practitioners evaluate patent license agreements. The Court's opinion will obviously require careful consideration of how the antitrust laws apply to patent infringement settlements, and in particular reverse-payment settlements in the pharmaceutical industry. Companies facing licensing demands by PAEs will find evaluations of the antitrust and competitive implications of such demands to be informative. As we discuss below, perhaps most surprising is that some relatively standard patent licensing terms – that might have seemed secure from antitrust review before this decision when falling within the scope of a patent – may require more careful analysis following it.

Background

Case History

Federal Trade Commission v. Actavis, Inc. involved the Federal Trade Commission's (FTC) challenge to a patent infringement settlement. Solvay Pharmaceuticals obtained a patent and Food and Drug Administration (FDA) approval to market the brand-name drug AndroGel. Actavis, Inc. and Paddock Laboratories later separately applied to the FDA under the Hatch-Waxman Act to market generic versions of AndroGel. Such applications constitute patent infringement. Solvay Pharmaceuticals thus initiated patent infringement complaints against Actavis and Paddock. Before a decision on the merits of Solvay's patent, the parties settled. Under the terms of the settlement, Actavis and Paddock agreed not to bring their generic products to market until an agreed-upon date prior to Solvay's patent expiration. In exchange, Solvay agreed to pay US\$12 million to Paddock and an estimated US\$19 - US\$30 million annually for nine years to Actavis. Because the patentee is paying the alleged infringer, this settlement is known as a "reverse-payment" settlement agreement.

The FTC sued the settling parties, alleging that the settlement agreement violated §5 of the FTC Act (15. USC §45). The district court found that the settlement agreement did not violate the antitrust laws and dismissed the complaint. On appeal, the Court of Appeals for the Eleventh Circuit affirmed the district court's ruling. It held that "a reverse-payment settlement is immune from attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." (*FTC v.*

Watson Pharmaceuticals, Inc., 677 F.3d 1298, 1312 (2012)). The court did recognize that agreements through which one competitor pays a potential competitor not to enter the market are typically prohibited by the antitrust laws. However, "reverse-payment settlements of patent litigation present atypical cases because one of the parties owns a patent." (677 F.3d at 1307). Considering the public policy favoring settlement of disputes and the patent holder's "lawful right to exclude others from the market" (677 F.3d at 1307), the court affirmed the dismissal. The FTC sought certiorari, which was granted.

The Supreme Court's Decision

In a 5-3 decision, a majority of the Supreme Court disagreed with the Eleventh Circuit and reversed and remanded the case for a rule-of-reason analysis of the settlement agreement. While not fully endorsing either party's arguments, the Supreme Court chose not to follow the "bright line" scope of the patent test and instead directed the lower courts to analyze the potential anticompetitive effects of the settlement.

In addressing the intersection between patent law and antitrust, the Court found that the "exclusionary potential of the patent" could not "immunize the agreement from antitrust attack." Slip op. at 8. Rather, courts must consider both patent law and antitrust policies to determine the scope of the protection afforded by the patent.

This was the principal point of debate between the majority and the dissent, and the decision was debated directly based on older precedents addressing whether a patent holder, acting within the scope of its patents, was shielded from antitrust challenge. The majority, for example, emphasized that reference "simply to what the holder of a valid patent could do does not answer the antitrust question." Slip op. at 8. Rather, the effects of challenged conduct must be measured "against procompetitive antitrust policies as well." Slip op. at 9. The majority appears to contemplate that any action apparently within the facial scope of a presumptively valid patent can be tested under the antitrust laws at least with an argument that the patent is not valid, or the conduct at issue not really within the scope of the patent, thus opening up an antitrust challenge to the conduct in question. Slip op. at 8 ("The patent here may or may not be valid, and may or may not be infringed."). It is in fact unclear from the majority opinion whether antitrust challenge may be brought against conduct that falls within a valid patent: "Whether a particular restraint lies 'beyond the limits of a patent monopoly' is a *conclusion* that flows from the analysis. . . ." Slip op. at 10. The dissent highlighted this point specifically, observing that the majority "seems to have in mind a regime where courts ignore the patent, and simply conduct an antitrust analysis of the settlement without regard to the validity of the patent." Slip op. (dissent) at 5.

Intellectual Property Law and Antitrust Implications

This decision will likely reach beyond brand-generic settlements in the pharmaceuticals industry. Broader implications from the ruling will also affect general intellectual property law issues. Both the majority and the dissent relied and shed new light on older antitrust decisions involving patents, making clear that the *Actavis* decision would apply to patent pools, cross-licensing arrangements, and more routine patent licensing decisions.

Patent "Trolls" or Patent Assertion Entities

One thing that the majority and dissent appeared to agree on is that agreements between holders of separate patents can sometimes be reviewed under the antitrust laws. While their rationales were somewhat different, each made clear that a decision to combine or pool patents would not be insulated from antitrust review simply because the patents themselves were valid and enforceable and any license offered fell within the scope of those patents.

For example, in discussing a 1963 decision, the majority relied on *United States v. Singer*

Manufacturing Co. (374 U.S. 174 (1963)), a case involving a patent settlement whereby "all three firms settled their patent-related disagreements while assigning the broadest claims to the firm best able to enforce the patent against yet other potential competitors." Slip op. at 10 (*citing Singer Mfg. Co.*, 374 U.S. at 190-192). The majority did not question the antitrust judgment against the defendants and cited the case for the proposition that the validity and scope of the patents at issue did not protect the arrangement. Slip op. at 10. The dissent believed that the case was rightly decided simply because the patent laws did not permit such an arrangement. Slip op. (dissent) at 6. But, notwithstanding the semantic differences, the dissent did not disagree that an agreement among patent holders was subject to review, regardless of whether the patents were valid. For trolls or PAEs, this clearly means that agreements with patent holders to acquire or pool their patents are subject to antitrust review.

That review, moreover, is likely to be informed by the Court's further view that patent protection from antitrust challenge turns "in important part" on the "the public interest in granting patent monopolies [that] exists only to the extent that the public is given a novel and useful invention in consideration for its grant." (*citing Singer Mfg. Co.*, 374 U.S. at 199). Moreover, the majority observed that the antitrust laws might be violated by an agreement among patent holders to cross-license valid and enforceable patents if "the patent holders thereby . . . 'curtailed the manufacture and supply of an unpatented product.'" Slip op. at 11-12 (*citing Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163, 174 (1931)).

These observations will likely come into play and support the increased antitrust scrutiny being brought to bear on the activities of trolls and PAEs. According to FTC Chairwoman Edith Ramirez, in announcing her intent to study the anticompetitive potential of these organizations, "there is mounting evidence that PAE activities may have an adverse impact on competition and consumers." (*FTC's Ramirez Calls for Comprehensive Study of Patent Trolls*, June 20, 2013.) One can expect the scope of the patent test not to be an impediment to that review. Antitrust reviewers will undoubtedly ask whether a PAE, once it has acquired the rights to a patent, is furthering the public interest in the "novel and useful invention" mentioned above, and weigh any such benefit against the potential impact of the patent troll enforcement activity on "manufacture and supply of . . . unpatented product[s]." Slip op. at 11-12.

Will Other Licensing Activities be Subject to Antitrust Laws?

The potential impact of *FTC v. Actavis* is not limited to high profile enforcement matters such as that focused on reverse-payment settlements and patent troll activities. Indeed, the majority cites *United States v. Line Material Co.* (333 U.S. 287 (1948)) and *Standard Oil Co. (Indiana)* (283 U.S. 163 (1931)) as two cases in which cross-licensing agreements were analyzed for anticompetitive effects. As summarized in the majority opinion, "these cases . . . seek to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets antitrust law policy strongly favoring competition." Slip op. at 12. One fundamental concern of the dissent is that the majority was reinterpreting these older cases, which had in the dissent's view "made very clear that patent settlements – and for that matter, any agreements related to patents" were not subject to antitrust review if the agreement was within the scope of the patent. Slip op. (dissent) at 8.

While one would expect that traditional antitrust principles would protect various terms and conditions used in licensing agreements from antitrust review, the opinion may well be read to suggest that such standard clauses in patent licensing agreements as "field of use" restrictions will face greater scrutiny. For example, the ABA's standard antitrust treatise now comfortably declares: "A field of use restriction that goes beyond the scope of the patent grant may, however, raise more significant antitrust concerns." ABA Section of Antitrust Law, Antitrust L. Dev. 1098 (7th ed. 2012). Under *Actavis*, the question needs to be asked now whether a field of use restriction "within the scope of the patent" raises significant antitrust concerns in particular circumstances.

Conclusion

For intellectual property and antitrust counselors in the US, the implications from *Actavis* will need to be carefully considered. Even more care needs to be exercised in settling patent disputes between competitors or potential competitors. The activities of PAEs or patent trolls warrant closer antitrust scrutiny. And terms and conditions in licensing agreements, even where unilaterally negotiated by a single patent holder, may no longer be protected from challenge under the antitrust laws. Licensing agreements embodying terms or arising in circumstances that might raise significant antitrust issues if employed outside of the patent licensing context now clearly warrant some careful consideration in the patent licensing context, even if they fall within the scope of the patent.

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