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When IP Settlements Create Antitrust Headaches

Agreements involving generic companies are especially vulnerable to government scrutiny.

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Although courts generally encourage mediation and settlement, negotiated settlement agreements in intellectual property disputes can create antitrust problems.

These settlements, which may include exclusive licenses, cross-licenses and pooling arrangements, are often agreements between horizontal competitors. Federal Trade Commission and U.S. Department of Justice guidelines appreciate that exclusive licensing and cross-licensing settlements may be an "efficient means to avoid litigation." Still, they will consider whether a settlement diminishes or has a tendency to diminish competition among "entities that would have been actual or likely competitors in a relevant market in the absence of the cross-license" or other exclusive licensing arrangements.

The relationship between IP and antitrust is inherently one of tension. Patent law provides for a legal right to exclude others (often would-be competitors) from making, using, selling or importing a patented invention for the term of the patent. Copyright similarly restricts the use of creative works, though not with respect to the underlying content. Both protections were designed to promote innovation, and both require that the rights holder make the creation or innovation known to the public.

When an IP holder exercises its rights to exclude under patent or copyright law, designing a settlement ostensibly within the scope of its patent or copyright, is it necessarily immune from antitrust liability? Some would argue the answer should be yes, but Congress has not included such immunity in the U.S. Patent or Copyright acts.

Consider *FTC v Actavis*. The U.S. Supreme Court held that reverse-payment patent settlements, where the resolution involves the patent holder paying a sum to the defendant, are subject to antitrust scrutiny under a traditional antitrust rule-of-reason analysis. The focus of the antitrust examination is on whether the reverse payment is so large that it cannot be justified as a legitimate fair-value or nuisance-value amount.

In *Actavis*, the questionable reverse-payment settlement was a pay-for-delay agreement made in the context of a would-be generic drug company's dropping both its efforts to enter the market prior to the expiration of the asserted patent and its allegations that the patents would not be infringed by the substitute drug.

In a recent class action over a patent settlement between Bayer A.G. and Barr Laboratories Inc., the California Supreme Court held that reverse-payment settlements are not immune from antitrust scrutiny under state law. (*In re Cipro Cases I & II*). The California Supreme Court relied on the U.S. Supreme Court's decision in *Actavis*, which rejected the scope of the patent as a definitive test under federal law, holding that, even if the terms of the reverse-payment settlement fall within the patent's apparent exclusionary scope, the settlement is not automatically immune from antitrust considerations.

In similarly rejecting the scope of the patent test under state law, the California court noted that "an invalidated patent carries with it no … right [to exclude others]."

Accordingly, a settlement that cuts off the challenge to a patent's validity should not effectively establish that patent's legitimacy. The California Supreme Court warned that "purchasing freedom from the possibility of competition, whether done by a patentee or anyone else, is illegal."

COMPETITIVE: Judge Ronnie Abrams found that a settlement between Takeda and three other drugmakers did not run afoul of antitrust laws.

This past September, the Southern District of New York held that the challenged settlements of a patent dispute between Takeda Pharmaceuticals and three generic drug manufacturers were not illicit reverse payments warranting scrutiny under the Sherman Act, because there was no plausible basis for holding that the settlements reduced competition for the drug.

In individual settlement agreements with each manufacturer, these generics did not receive any cash payments; rather a generic manufacturer was allowed to enter the market with a generic product almost four years before the expiration of the disputed patents. Further, each agreement also contained an acceleration clause that enabled the generic to enter the market as soon as any another generic manufacturer entered the market.

The plaintiffs argued that the acceleration clauses were anti-competitive because other generic manufacturers were discouraged from entering the market, knowing that three other manufacturers waited in the wings. As a preliminary matter, U.S. District Judge Ronnie Abrams ruled that even without cash payments, these settlements are subject to *Actavis* rule-of-reason scrutiny, but she noted that if no other generic entered the market before the expiration date, the effect of the clauses would be neutral, and if another generic manufacturer did enter early, the effect would be "indisputably pro-competitive" because the clauses would trigger more generics to enter the market.

To plaintiffs' speculation on how generics would have acted in the absence of the acceleration clauses, the court stated that "the mere possibility that the absence of an acceleration clause may result in more diverse generic competition is insufficient for plaintiffs to plausibly state a reverse payment [antitrust claim] here. *Actavis* requires only that a brand manufacturer not unlawfully restrict competition; it does not demand that the brand maximize competition."

The inquiry into whether a given settlement and its particular terms are anti-competitive is highly fact-intensive. The rule-of-reason analysis weighs the anti-competitive effects of a settlement agreement against the pro-competitive benefits. If the settlement has the practical effect of excluding competitors, it is vulnerable to antitrust attack.

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