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Going Beyond *Actavis*: New State Legislation to Punish Potentially Anticompetitive Patent Settlements

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The California Legislature recently passed, and Governor Gavin Newsom signed into law, AB 824 (Wood), Preserving Access to Affordable Drugs (the "Act"). The Act seeks to curtail and penalize "reverse payment" patent settlement agreements. Such agreements arise most frequently under the federal Hatch-Waxman Act, but AB 824 also applies to agreements settling patent litigation concerning biologics and biosimilars. The Act provides that the California Attorney General may recover from defendants as penalties the greater of $20,000,000 or three times the harm caused by the alleged reverse-payment settlement, in addition to whatever damages are available to the State under existing California laws.

Consistent with efforts by the Federal Trade Commission ("FTC") and private plaintiffs, the Act represents a further attempt to push the analysis of "reverse payment" settlement agreements away from the traditional, flexible rule of reason analysis prescribed by the Supreme Court in *FTC v. Actavis*, and toward a set of black and white rules and presumptions that favor government enforcers and private plaintiffs in ways that are inconsistent with that decision.

The Act provides that the California Attorney General may recover from defendants as penalties the greater of $20,000,000 or three times the harm caused by the alleged reverse-payment settlement.

As a result, the legislation may impose liability on parties that settle patent litigation in ways that are not demonstrably anticompetitive. While restricting the traditional rule of reason inquiry, the Act also leaves intact preexisting California laws, and therefore may exacerbate the considerable uncertainty and inconsistency in courts' analysis of alleged "reverse payment" settlements, in particular in cases brought by private plaintiffs.

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SCRUTINY OF "REVERSE PAYMENT" SETTLEMENTS UNDER FEDERAL AND CALIFORNIA LAW

The settlement of patent litigation can create tension between the policies underlying antitrust law and those underlying patent law.

On the one hand, federal and state antitrust laws are designed to enhance consumer benefit by preserving competitive markets, in which rivals compete for consumer loyalty, spurring innovation, choice, and lower prices. One way they do that is by preventing firms from abusing monopoly power, even if the monopoly power has been lawfully earned.

On the other hand, patent law is designed to incentivize innovation by providing inventors with temporary monopoly power (the right to exclude others from making or selling the patented good), after which their invention is contributed to the public domain.

As a result, patents traditionally have been viewed as providing a net economic benefit, and the settlement of a patent dispute that permits the challenger (a potential generic entrant, for example) to compete prior to expiration of the patent as pro-competitive. Only if such a settlement agreement included restraints on competition would it implicate antitrust issues, and such restraints, like any restraints built into a facially pro-competitive agreement, would have to be analyzed under the rule of reason.

However, when Congress enacted the Hatch-Waxman Act to encourage the development of generic drugs and to incentivize challenges to the validity of pharmaceutical patents, it changed the balance of risks inherent in traditional patent infringement litigation. Before the Hatch-Waxman Act, a patent holder could sue an infringer only after the infringer had started to make, use, or sell an allegedly infringing product.

As a result, the infringer incurred several risks – such as the risk of investment loss and damages for actual infringement (potentially enhanced for willful infringement). The Act, however, introduced a process unique to pharmaceuticals by which the potential generic entrant would commit an "act of infringement" by sending a notice challenging the patent that it anticipated infringing with its not-yet-approved or marketed product. This process removed many of the risks to the challenger of traditional patent infringement litigation (the obligation to invest in a product and market it at risk of an infringement action and exposure to significant damages), and changed the balance of economic risk to the detriment of the patent holder.

The risk of loss in a Hatch-Waxman patent dispute, therefore, is disproportionately on the patent-holder: If it wins, it merely preserves the status quo after spending millions on litigation; if it loses, the "reward" for its innovation – temporary market exclusivity – is cut short.

The risk of loss in a Hatch-Waxman patent dispute, therefore, is disproportionately on the patent-holder.

Thus, the Hatch-Waxman Act created a significant economic incentive for the patent holder to transfer some value to the patent challenger beyond simple early entry in order to settle such cases, leading to what has come to be known as "reverse" payments (so called because, unlike traditional patent settlements where payment from the infringer to the patent holder was made to compensate for past infringement damages, these payments went the other way). This incentive may be particularly acute when the generic firm is a so-called "first filer" because such firms generally receive six months exclusivity against other generics; accordingly a settlement with a first filer may postpone entry of other potential generic entrants.

The FTC has long sought to curtail patent settlement agreements that include a "reverse payment." That effort derives from an attractively simple view: that a "reverse payment" is a payment from an incumbent (the patent-holder) to a potential entrant (the generic challenger) to stay out of the market.

In 2013, after a number of years of litigation, the Supreme Court's decision in *FTC v. Actavis*[1] resolved a split in the circuits and attempted to pave a path for increased antitrust scrutiny of alleged "reverse payment" settlement agreements. Attempting to steer a course between the FTC's proposed "quick look" analysis, which relied on presumptions of illegality, and the "scope of the patent test" applied

by most circuits up to that time, which effectively presumed patent settlements lawful if they did not affect competition in products not covered by the allegedly infringed patent, the Court ruled that such agreements would be evaluated under the full rule of reason test. Without the benefit of presumptions concerning patent validity/invalidity, federal courts have struggled to articulate a workable rule of reason test in the "reverse payment" context.[2]

Following *Actavis*, in *In re Cipro Cases I & II*,[3] the California Supreme Court also rejected the "scope of the patent" test and articulated its own rule of reason test governing antitrust scrutiny of alleged "reverse payments" under the state's principal antitrust statute, the Cartwright Act. Akin to Justice Breyer's observation in *Actavis*, the *Cipro* court observed: "Some patents are valid; some are not. Sometimes competition would infringe; sometimes it would not." Accordingly, the court cited as the relevant benchmark in evaluating the state of competition "but for" a competitive reverse payment patent settlement the "average period of competition" that would have obtained in the absence of the settlement.

Despite its embrace of the "average period of competition," however, the *Cipro* court structured the rule of reason applicable to reverse payment patent settlements to presume a settlement is anticompetitive where there is a reverse payment of any size. The court articulated the rule of reason applicable to alleged "reverse payment" settlement agreements as follows:

- First, to make out a prima facie case that a challenged agreement is an unlawful restraint of trade, a plaintiff must show the agreement contains both a limit on the generic challenger's entry into the market and compensation from the patentee to the challenger.

- Second, the defendants bear the burden of coming forward with evidence of litigation costs or valuable collateral products or services that might explain the compensation.

- Third, if the defendants do so, the plaintiff has the burden of demonstrating the compensation exceeds the reasonable value of these.

- Fourth, if a prima facie case has been made out, the defendants may come forward with additional justifications to demonstrate the settlement agreement nevertheless is procompetitive.

- Fifth, a plaintiff who can dispel these justifications has carried the burden of demonstrating the settlement agreement is an unreasonable restraint of trade under the Cartwright Act.

KEY PROVISIONS OF AB 824, EFFECTS, AND OPEN QUESTIONS

Although it would appear to most observers that the courts had already addressed "reverse payment" settlements and the details of implementation of *Actavis* and *Cipro* were being worked out in ongoing litigation, the California legislature concluded that it was necessary to formalize the illegality of reverse payment settlements. It enacted AB 824 by large majorities in both the Assembly (64 to 1) and Senate (31 to 8), and the bill was signed into law by Governor Newsom on October 8, 2019.

AB 824's provisions are largely consistent with the test articulated by the California Supreme Court in *Cipro*.

First, the Act provides that an agreement that resolves patent settlement litigation is presumed to have anticompetitive effects if either: the generic firm receives anything of value; or the generic agrees not to compete for any period of time. The Act restricts the meaning of "anything of value" to exclude entry-date-only settlements and settlements with like effect.

AB 824's provisions are largely consistent with the test articulated by the California Supreme Court in *Cipro*.

Second, similar to the rule of reason articulated in *Cipro*, the Act provides that the presumption may be rebutted by a preponderance of the evidence that: the value received by the generic firm is fair and reasonable compensation for good or services; or the agreement has directly generated procompetitive effects that could not be achieved by less restrictive means and that such procompetitive effects outweigh the anticompetitive effects of the agreement.

Several of AB 824's other provisions restate principles articulated in *Cipro* concerning what the factfinder may and may not presume:

- The factfinder shall not presume: (i) that any patent – asserted or unasserted – is enforceable and infringed or otherwise would have precluded the generic challenger from entering the market before expiration of that patent; or (ii) that an agreement provision permitting entry prior to expiration of any patent means that the agreement is procompetitive.

- The factfinder shall presume that the relevant product market consists of the brand firm alleging patent infringement and the generic firm accused of infringement and any other biological product that is licensed as biosimilar or is an AB-rated generic to the reference product.

However, the Act goes beyond *Cipro* in significant ways. Most notably, the Act provides that the Attorney General may recover a minimum penalty of $20 million for a violation, and up to three times the value of the alleged reverse payment reasonably attributable to the violation based on California's share of the market for the brand drug at issue.

While AB 824 does not purport to modify the Cartwright Act, the Unfair Practices Act, or the Unfair Competition Law, it states that any violator "shall be liable for any damages, penalties, costs, fees, injunctions, or other remedies that may be just and reasonable and available" under those laws. The application of the Act to private damages actions under the Cartwright Act is therefore unclear.

For instance, while California courts have yet to address the issue, all or nearly all federal courts that have addressed the issue have rejected arguments that a plaintiff need not offer evidence of patent invalidity or non-infringement patent in order to prove causation – i.e., earlier generic entry – in a "but-for" scenario of continued litigation.[4] The Act purports to alter a rule of reason analysis but it is unclear whether it forecloses evaluation of patent merits in the context of causation. Thus, in private actions, in particular, we expect that there will be disputes regarding the Act's application. The results of such disputes may bring California law out of line with federal law and that of all other states, significantly complicating litigation. Among other issues, it would prevent courts from administering a single nationwide jury trial in a reverse payment case.

The Act's treatment of reverse payments that approximate future litigation costs is restrictive. While there is considerable debate about the circumstances and extent to which "reverse payment" settlement agreements actually reduce the availability of generic drugs and thus have anticompetitive effects,[5] even the FTC recognizes that settlements that involve a "reverse payment" that is less than the brand firm's expected litigation costs may be procompetitive. The FTC's February 2019 settlement agreement with Teva Pharmaceutical Industries Ltd. illustrates this.[6] Under the terms of the settlement Teva agreed not to enter into any "reverse payment" settlement agreement for 10 years. However, the agreement expressly permits Teva to settle patent litigation for up to $7 million, as a proxy for possible litigation costs. While AB 824 restricts "anything of value" to exclude compensation for future litigation costs, the Act requires that such litigation costs be well documented by forecasts in advance of settlement, and if forecasts are not available, future litigation costs are capped at just $250,000.

Last, the Act may be contemplated to cover prospective conduct only, but it is not clear from the text that the Act would not apply settlements that pre-date the Act's enactment. Even if under California law new legislation is presumptively prospective,[7] the silence here will create uncertainty with regard to ongoing litigation.

The passage of AB 824 indicates that the application of antitrust law to patent settlements remains an unsettled area.

Further uncertainty exists regarding the geographic scope of the Act. While most courts have applied California law with respect to California purchasers in challenges to pharmaceutical settlements (even if the settlements were made elsewhere), plaintiffs have increasingly argued that California law should apply to nationwide classes of purchasers. This is an unresolved issue but one

that could significantly increase the impact of AB 824.

CONCLUSION

The passage of AB 824 indicates that the application of antitrust law to patent settlements remains an unsettled area. We expect ongoing litigation of these matters, and potentially an increase in attempts by plaintiffs to apply California law.

Notes

1. *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013).
2. Following *Actavis*, a handful of courts have articulated a rule of reason test. The test offered by the U.S. Court of Appeals for the Third Circuit in *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 412 (3d Cir. 2015), is illustrative: First, to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition. Second, the burden then shifts to the defendant to show that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason. Finally, the plaintiff will have the opportunity to rebut the defendant's explanation.
3. *In re Cipro Cases I & II*, 61 Cal. 4th 116, 348 P.3d 845 (2015).
4. *See, e.g.*, *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 167 (3d Cir. 2017); *In re Nexium (Esomeprazole) Litig.*, 842 F.3d 34, 62-64 (1st Cir. 2016); *Apotex, Inc. v. Cephalon, Inc.*, 255 F. Supp. 3d 604, 614 (E.D. Pa. 2017).
5. Economists have differing views on whether and to what degree a rule prohibiting reverse payments in excess of avoided litigation costs would restrict procompetitive settlements. *See, e.g.*, Aaron Edlin et al., Activating Actavis, 28 ANTITRUST 16 (2013); Barry C. Harris et al., Activating Actavis: A More Complete Story, 28 ANTITRUST 83 (2014); Aaron Edlin et al., Actavis and Error Costs: A Reply to Critics, 14 ANTITRUST SOURCE 1 (2014).
6. (Proposed) Stipulated Revised Order for Permanent Injunction and Equitable Monetary Relief, *available at https://www.ftc.gov/system/files/documents/cases/teva_proposed_stipulated_revised_order.pdf.*
7. *See McClung v. Employment Dev. Dep't*, 34 Cal. 4th 467, 475, 99 P.3d 1015, 1021 (2004).