
Unprecedented State Law on Pharmaceutical “Reverse Payments” Goes Into Effect

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A new California law, Preserving Access to Affordable Drugs, AB-824 (the Act), which is aimed at curbing reverse-payment patent settlements, took effect on January 1. The Act codifies a presumption that any transfer of value from a branded to a generic pharmaceutical company settling patent infringement litigation, combined with a delay of the generic drug’s entry into the market, has an anticompetitive effect. The statute shifts the burden to the settling parties to affirmatively demonstrate either (1) that the payment by the branded company is fair and reasonable compensation solely for other goods or services that the generic company has agreed to provide, or (2) that the agreement has generated procompetitive benefits that outweigh its anticompetitive effects. The statute therefore makes reverse-payment settlement agreements more difficult to defend than they had been under prior case law. Importantly, nothing in the Act limits its application to settlements that were negotiated, completed or entered into in California or by California companies.

There is no comparable statute at the federal level or in any other state, making California’s reverse-payment law an unprecedented attempt to legislatively limit reverse-payment settlements. The law goes beyond the Supreme Court’s holding in *FTC v. Actavis*, which established a traditional “rule of reason” analysis. Late last month, the Eastern District of California denied a motion to enjoin enforcement of the statute, and that ruling is now on appeal to the Ninth Circuit. *Ass’n for Accessible Meds. v. Becerra*, No. 2:19-cv-02281 (E.D. Cal. Dec. 31, 2019).

Background

In 2013, the Supreme Court held that reverse-payment settlement agreements are to be analyzed under the traditional rule of reason antitrust framework. *Fed. Trade Comm’n v. Actavis*, 570 U.S. 136 (2013). Although the Supreme Court did not clarify how district courts are to apply the rule of reason in this specific context, the first step of the analysis traditionally requires the plaintiff to show that the restraint at issue produces significant anticompetitive effects within the relevant product and geographic markets. See *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018). The burden then shifts to the defendant to offer a legitimate procompetitive justification for the restraint. If the defendant carries that burden, the plaintiff has the final burden of demonstrating that the restraint is

not reasonably necessary to achieve that objective, or that the objective can be achieved in a substantially less restrictive manner. *Id.*

California's new law truncates that rule of reason analysis by establishing a presumption of anticompetitive effect anytime a reverse-payment settlement agreement meets two conditions: (1) a generic pharmaceutical company receives "anything of value" from a branded company claiming patent infringement, and (2) the generic company agrees to delay manufacturing or sale of its drug for some period, beyond the date when it could otherwise have entered the market. CAL. HEALTH & SAFETY CODE § 134002(a)(1). As a result, the statute shifts the burden to the settling parties to rebut the presumption of anticompetitive behavior by showing either (1) that the payment by the branded company is fair and reasonable compensation solely for other goods or services that the generic company has agreed to provide, or (2) that the agreement has generated procompetitive benefits that outweigh its anticompetitive effects. *Id.* at § 134002(a)(3).

"Anything of value" is defined broadly and encompasses common types of consideration used in brand-generic settlement agreements. Specifically, the Act provides that all such settlements are subject to the law *except* for those with certain forms of consideration, such as the right to market in the United States before the patent at issue expires, an agreement not to sue for patent infringement, and payments reflecting the branded company's avoided litigation expenses. *Id.* at § 134002(a)(2).

The Act's rules concerning the documentation of avoided litigation costs are particularly restrictive as well as unprecedented. While the Supreme Court in *Actavis* held that payments that do not exceed litigation costs did not raise antitrust concerns under federal law, the Court did not specify any caps on the amount, set out evidentiary requirements or require that the payments fall within a certain measure of the generic company's expected profits. *Actavis*, 570 U.S. at 156. The Act, however, provides that for settlements where the only value provided is equivalent to the patentee's avoided litigation costs, those costs must be documented in the branded company's written budget at least six months prior to settlement. HEALTH & SAFETY CODE § 134002(a)(2)(C). In addition, the compensation must be less than either \$7.5 million or 5% of the generic company's expected revenue from the first three years of sales, as documented in forecasts prepared by the generic company at least a year before settlement. *Id.* If there are no forecasts of sales revenue, the compensation cannot exceed \$250,000.

The Act is also noteworthy for two additional features. First, the law creates a presumption that defines the relevant product market as one comprising only the branded drug, the generic drug, and any other bioequivalent or biosimilar drug, practically assuring that the branded company will be deemed a monopolist. *Id.* at § 134002(c). Second, the Act imposes heavy civil penalties on companies found to violate the law, as well as parties who assist in violating the law. *Id.* at § 134002(e)(1)(A). The Act authorizes the California attorney general to recover the greater of \$20 million or three times the value received by the generic company in the settlement. *Id.* at § 134002(e).

Legal Challenge

In November 2019, the Association for Accessible Medicines (AAM), a trade organization that represents generic pharmaceutical companies, filed a lawsuit against the state of California, challenging the new law's constitutionality and seeking to enjoin its enforcement. *Compl., Ass'n for Accessible Meds.*, No. 2:19-cv-02281 (Nov. 12, 2019). AAM's primary argument was that the Act violates the "Dormant" Commerce Clause because by its own terms it reaches settlement agreements entered into outside of California or between non-California entities and can be enforced against all settlements so long as the drug at issue was sold in California. AAM argued that the Act burdened interstate commerce by regulating it more strictly than federal law does. AAM also argued that the law was unconstitutional because it was preempted by federal law (including the Hatch-Waxman Act, which does not proscribe reverse-payment settlements); that the law imposed excessive fines in violation of the Eighth Amendment; and that the law's burden-shifting scheme violated the Due Process Clause.

On December 31, 2019, the district court denied AAM's request to enjoin the Act. The court found that the law was not facially invalid (that is, all applications would not necessarily be unconstitutional) because it clearly could be applied lawfully to "settlement agreements contained within California." *Mem. & Order on Pl.'s Mot. for Prelim. Inj., Ass'n for Accessible Meds.*, No. 2:19-cv-02281, at 7 (Dec. 31, 2019). The court further reasoned that to the extent the law could be construed to regulate settlement agreements entered into outside of California, the challenge was not yet ripe for assessment because the plaintiff had not sufficiently shown that the Act "is likely to be enforced in an unconstitutional manner" or that a threat of enforcement has dissuaded any party from acting in a way that would violate the law. *Id.* at 10.

On January 3, AAM appealed the decision to the Ninth Circuit. Based on the current schedule, briefing is expected to be completed by the end of February.

Implications

California's new law could have significant ramifications for pharmaceutical companies considering entering into settlements involving "anything of value," including litigation cost avoidance payments, both because it potentially prohibits agreements that would not be illegal under *Actavis* and because it requires specific documentation of anticipated litigation costs. Importantly, the law remains in effect while AAM's appeal is pending. Significant questions remain as to how the courts ultimately will construe the reach of the Act, as well as how the Act will be enforced. For now, as AAM warned, the Act is likely to have an impact on even those settlements occurring wholly outside of California.

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