

CALIFORNIA LEGISLATION INCREASES ANTITRUST SCRUTINY OF PATENT SETTLEMENTS BETWEEN BRANDED AND GENERIC PHARMACEUTICAL MANUFACTURERS

To Our Clients and Friends:

On October 7, 2019, California enacted Assembly Bill 824 (AB 824)^[1] in an effort to increase antitrust scrutiny of patent settlement agreements between branded and generic pharmaceutical manufacturers. The focus of the legislation is on settlements of patent infringement litigation brought under the Hatch-Waxman Act^[2] that include a so-called “reverse payment,” i.e., where the generic manufacturer receives a cash payment or some other form of consideration from the branded manufacturer. AB 824 also, however, expressly covers settlements of patent litigation brought under the Biologics Price Competition and Innovation Act (BPCIA). The California legislation threatens to greatly complicate the settlement of these actions and we recommend that any branded or generic manufacturer involved in such matters carefully consider and take account of such legislation.

Increased Burdens on Defense. AB 824 seeks to make it more difficult for parties to defend patent settlements with “reverse payments” by shifting the burdens of proof. Under the U.S. Supreme Court’s opinion in *FTC v. Actavis*, the plaintiff bears the burden of demonstrating that the settlement contains a “large and unjustified” reverse payment and an overall “anticompetitive effect.”^[3] Only upon such a showing would the burden shift to the settling parties to demonstrate the agreement’s pro-competitive merit. Under AB 824, however, once an antitrust plaintiff or enforcement body shows that the generic manufacturer agrees to limit or delay its market entry and receives “anything of value” in the patent settlement, anticompetitive effects are presumed and the burden is shifted to the settling parties to show the settlement agreement in question is procompetitive.^[4] The settling parties may seek to rebut the presumption of anticompetitive effects by demonstrating that the procompetitive effects of the settlement outweigh any anticompetitive effects, or that the value received by the generic manufacturer was “fair and reasonable compensation solely for other goods and services” that the generic has agreed to provide the branded manufacturer.^[5] The legislation also contains several other presumptions that are designed to make it more difficult for the settling parties to argue that their agreement was innocuous and/or had no material effect on competition.

“Anything of Value.” AB 824 defines “anything of value” broadly to include exclusive licenses and so-called “no authorized generic” provisions wherein the branded manufacturer agrees not to market or license an authorized generic during a negotiated period of time.^[6] But it expressly excludes several categories of payments or agreements including licenses to market a generic version of a drug before expiration of a listed patent, acceleration clauses based on the NDA holder marketing a different dosage strength or form, waiver of damages accrued from an at-risk launch of the generic drug, and, “reasonable future litigation expenses” that have been previously documented.^[7] These exceptions could prove useful

in litigation and parties negotiating such settlements will likely want to carefully consider whether their proposed settlements fit within these apparent safe harbors

Civil Penalties and Potential for Individual Liability. AB 824 purports to increase parties’ existing exposure under California antitrust and unfair competition law by providing for civil penalties of \$20 million or more. Of perhaps greatest concern is that AB 824 could potentially be read to permit those civil penalties to be applied to individuals at the involved companies who “participate” or “assist” in its violation.[8]

Retroactivity. A question might be raised as to whether AB 824 could be applied to settlement agreements reached before its enactment. Statutes (especially those that include penalties), are generally presumed to be prospective only, and AB 824 has an effective date of January 1, 2020. There is therefore good reason to believe that AB 824 should not be interpreted to apply retroactively, although the statute is silent on this point.

Constitutional? The legislation’s broad sweep—and its departure from the standards set forth by the Supreme Court under federal law—raises serious questions as to whether the statute violates the U.S. Constitution. Although the legislation has provisions that purport to limit its application to agreements within California’s jurisdictional reach, in practice the standards and penalties it provides are likely to effectively regulate the content of almost any patent settlement in the U.S. between a branded and generic manufacturer given that such settlements typically apply nationally and cannot practically be limited to a particular section of the country. For this reason, the legislation appears to be vulnerable to a challenge based on the Dormant Commerce Clause of the U.S. Constitution. In a recent development, a lawsuit was filed by a consortium of generic drug manufacturers challenging AB 824 on that and a variety of other constitutional grounds.[9]

[1] To be codified at Cal. Health & Safety Code § 134000.

[2] Drug Price Competition and Patent Term Restoration Act (codified at 21 U.S.C. §§ 355 & 360cc).

[3] See *FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013); see also *In re Cipro Cases I & II*, 61 Cal. 4th 116, 348 P. 3d 845 (Cal. 2015).

[4] AB 824 § 134002(a)(1)(A) and (B).

[5] *Id.* at § 134002(a)(3)(A).

[6] *Id.*

[7] AB 824 § 134002(a)(2)(A)–(F). “Reasonable future litigation expenses” must be documented in budgets by the Abbreviated New Drug Application (ANDA) holder at least six months prior to the settlement, and cannot exceed the greater of \$7,500,000 or 5% of the ANDA holder’s projected revenue

for the first three years of sales of its generic, with documentation predating the settlement by at least 12 months. *Id.* at § 134002 (a)(2)(C)(ii)(I-II).

[8] *Id.* at § 134002(e)(1)(A)(i) (“Each *person* that violates or assists in the violation of this section shall forfeit and pay to the State of California a civil penalty sufficient to deter violations of this section . . . an amount up to three times the value received by the party that is reasonably attributable to the violation of this section, or twenty million dollars (\$20,000,000), whichever is greater.”) (emphasis added).

[9] *See Association for Accessible Medicines v. Becerra*, No. 19-CV-2281 (E.D. Cal. Nov. 12, 2019).



Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding these developments. To learn more about these issues, please contact the Gibson Dunn lawyer with whom you usually work, any member of the firm's Antitrust and Competition practice group, or any of the following authors:

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