Client Alert | Antitrust/Competition

California's New Reverse Payment Law Departs from Supreme Court Standard in *FTC v. Actavis*

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On October 7, 2019, California became the first state to enact legislation—Assembly Bill 824 ("AB 824")—rendering certain pharmaceutical patent litigation settlement agreements presumptively anticompetitive.[1] This alert provides a brief summary of some of the key provisions as written; the final implications of this statute await judicial review.

Reverse Payment Settlements Including "Anything of Value" Presumed Illegal

The settlement agreements subject to the new law, sometimes referred to pejoratively as "reverse payment" or "pay for delay" agreements, typically resolve Hatch-Waxman patent litigation[2] in which a generic pharmaceutical manufacturer has challenged a patent covering a brand pharmaceutical manufacturer's drug product, and in which a plaintiff or government enforcer alleges that the generic manufacturer obtains any form of "value" as part of the settlement agreement.

The California law marks a stark (and apparently intended[3]) departure from the Rule of Reason framework for analyzing patent settlements established by the US Supreme Court in *FTC v. Actavis*.[4] In *Actavis*, the Supreme Court rejected the FTC's proposal to adopt a "quick look" standard, which would have made "reverse payment" agreements presumptively anticompetitive, and instead held that an antitrust plaintiff "must prove its case as in other rule-of-reason cases."[5]

By contrast, California's new law presumes an anticompetitive effect; under AB 824, "reverse payment" settlements are rendered presumptively unlawful if (1) the generic manufacturer obtains "anything of value" out of the deal (which may include exclusive licenses of the brand's patent rights[6]), and (2) the generic

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1 To be codified at Cal. Health & Safety Code § 134000 (Deering 2019).

2 Under the Hatch-Waxman Act, prior to obtaining FDA approval to sell its generic drug, a generic manufacturer may challenge a brand manufacturer's patent on the grounds that the patent is not valid or would not be infringed by the generic's product. The generic manufacturer's challenge, referred to as a Paragraph IV certification, triggers the brand manufacturer's right to sue the generic manufacturer for patent infringement. The resulting litigation is sometimes referred to as Hatch-Waxman Litigation. *See FTC v. Actavis, Inc.*, 570 US 136, 142-43 (2013).

3 *See* Assembly Committee on Health, *Hearing on AB 824* at 7 (Cal. Mar. 26, 2019), https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201920200AB824# ("This bill establishes a different standard of review for pay-for-delay agreement than what was decided in the *FTC v. Actavis* case.").

4 *Actavis*, 570 US at 156.

5 570 US at 159-60.

6 AB 824 § 134002(a)(1)(A).

manufacturer does not immediately attempt to sell its infringing product.[7] For purposes of this statute, "anything of value" does not include agreements to allow early generic entry or compensation for saved litigation costs (subject to limitations, and which costs must be reflected in estimates that pre-date the settlement agreement), among other things.[8] In addition, contrary to the prevailing case law, AB 824 presumes that the settlement agreement was anticompetitive and shifts the burden from the plaintiffs to the defendant pharmaceutical manufacturer(s) to rebut that presumption by demonstrating that any value received by the generic manufacturer was fair compensation for goods or services, or that the settlement agreement generated procompetitive benefits.[9]

AB 824 identifies certain presumptions that the court shall (or shall not) make in evaluating whether the manufacturer met its burden to demonstrate that procompetitive benefits outweigh anticompetitive effects. The most notable example—which is a stark departure from decisional law in *Brown Shoe*[10] and in *Doryx*[11]—is a presumption that the relevant product market includes *only* the branded drug product and its AB-rated generic substitutes; in other words, every brand is a monopoly, and therapeutic classes of drugs are full of competing "monopolies."[12] This one-tiny-sized-market-fits-all approach is divorced from the fact that in many instances drugs are competing in the therapeutic class against other brands and generics.

Penalties and Damages

The new law purports to allow the State of California—and only the State of California—to obtain civil penalties from each of the brand and generic manufacturer of **up to three times the value of the alleged payment** based on California's share of sales in the drug, **or $20 million**, whichever is greater.[13] While AB 824 prohibits the California Attorney General from receiving civil penalties under both AB 824 and California's antitrust and unfair competition laws, it apparently does not prohibit the Attorney General from seeking damages under those state antitrust and consumer protection laws.[14]

Effective Date and Retroactivity

AB 824 is set to be effective as of January 1, 2020.[15] Given that the California legislature has indicated that it does not believe the statute creates a new cause of action, but rather merely codifies a particular *burden of proof* for these claims, there remains an open question as to whether AB 824's legal structure applies to settlement agreements reached before the law was enacted.

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7 AB 824 §134002(a)(1) ("Except as provided in paragraph (3), an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, *shall be presumed to have anticompetitive effects* and shall be a violation of this section if both of the following apply: (A) A nonreference drug filer *receives anything of value* from another company asserting patent infringement . . . (B) the nonreference drug filer *agrees to limit or forego research, development, manufacturing, marketing, or sales* of the nonreference drug filer's product *for any period of time*.") (emphasis added).

8 AB 824 § 134002(a)(2).

9 AB 824 § 134002(a)(3).

10 *Brown Shoe Co. v. United States*, 370 US 294, 325 (1962).

11 *Mylan Pharm. Inc. v. Warner Chilcott plc*, 838 F.3d 421, 433-38 (3d Cir. 2016).

12 AB 824 § 134002(c). The statute purports to forbid the finder of fact from presuming that (1) generic entry "could not have occurred until the expiration of the relevant patent exclusivity or that the agreement's provision for entry of the nonreference drug product before the expiration of any patent exclusivity means that agreement is procompetitive," (2) the patent at issue is enforceable and infringed, (3) "the agreement caused no delay in entry of" the generic manufacturer's product because of the lack of FDA approval, or (4) that the settlement caused no harm because of "the possibility that the [generic manufacturer's] drug product might infringe some patent" that had not been asserted against the generic manufacturer. *See* AB 824 § 134002(b).

13 AB 824 § 134002(e)(1)(A).

14 AB 824 § 134002(e)(2)-(3).

15 Press Release, Attorney General Becerra & Assembly member Wood, California Enacts First-in-the-Nation Law to Combat Pay-for-Delay Agreements that Inflate Drug Prices (Oct. 7, 2019), https://oag.ca.gov/news/press-releases/attorney-general-becerra-assemblymember-wood-california-enacts-first-nation-law ("The new law, set to go into effect on January 1, 2020 . . . .").

To the extent anyone were to take the position that AB 824 could be applied retroactively, a secondary question remains whether existing cases alleging violations of the Cartwright Act or other unfair competition laws can take advantage of California's new legal standard.

Effect on Private Actions Under California law

The new law further provides that parties in violation of AB 824 shall be liable for damages and other remedies available under California state antitrust and consumer protection laws.[16] This creates uncertainty as to the relationship between the new law and California's pre-existing antitrust and consumer protection laws. Commentators already have voiced concern that the law may create a new private right of action, although proponents of the law have taken the position that it does not create a new private cause of action but simply "codif[ies] a particular burden of proof" for analyzing reverse payment settlements under existing state law.[17]

While it remains to be seen how AB 824 will be employed in future litigation or construed by the courts, due to its apparent departure from more rigorous federal requirements, plaintiffs may choose to bring antitrust challenges to settlement agreements under the California law at an increased rate. As the law does not alter the "reverse payment" framework under federal antitrust law (or other state antitrust laws following federal antitrust law), plaintiffs may attempt to pursue duplicative "reverse payment" actions on behalf of California consumers separately from proposed nationwide class actions of the type that have long been prevalent in federal court. In addition, whether the act is substantive or procedural under *Erie* is one of the many unanswered questions.

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16 AB 824 § 134002(e)(2).

17 Assembly Committee on Judiciary, *Hearing on AB 824* at 13, 15 (Cal. Apr. 9, 2019), https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201920200AB824#.