New Calif. Pay-For-Delay Law May Hurt Those It Aims To Help

By **Chad Landmon and Chantelle Ankerman** (November 5, 2019)

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In the continuing effort to reduce the costs of pharmaceuticals, a new California law governing patent settlement agreements was signed into law on Oct. 7. The statute attempts to prevent so-called "pay-for-delay" or "reverse-payment" settlements in which a branded drug company pays a generic pharmaceutical company purportedly to delay the generic coming to market.

Specifically, the statute states that such agreements "shall be presumed to have anticompetitive effects" if the generic company receives "anything of value" from the company asserting patent infringement. Because this new law goes further than courts or legislation have gone in the past, pharmaceutical companies litigating patent cases need to keep this in mind when approaching settlements given that some traditional means of settling such cases may be implicated.

Although well-intentioned, this legislation may have the unintended consequence of precluding pro-competitive settlement agreements that allow for generic drug entry significantly earlier than patent expiration. If this legislation survives potential court challenges, it may lead to fewer settlements and more patent cases being fully litigated through trial and appeal. This will, in turn create uncertainty for pharmaceutical companies and require that greater resources be dedicated to litigation instead of research and development, potentially resulting in less generic competition and higher overall drug prices.

The Actavis Decision

In 2013, the U.S. Supreme Court ruled in Federal Trade Commission v. Actavis Inc. that patent settlement agreements that involve reverse payments can violate the antitrust laws under a rule-of-reason analysis but are not presumptively anti-competitive. The court ruled that "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, and not against procompetitive antitrust policies as well."[1]

The Actavis decision gave the FTC and the courts authority to review settlements on a case-by-case basis considering factors including "[the payment's] size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."

The court rejected the "quick look" approach under which any payment from a patent holder to a generic patent challenger who agrees to delay market entry would be considered prima facie evidence of an antitrust violation. Under the "quick look" approach, all reverse payment settlements would be presumed illegal absent convincing evidence from defendants of procompetitive benefits.

California A.B. 824

California A.B. 824 appears to go beyond the Actavis decision by creating a statutory

presumption that settlement agreements are illegal if the generic company receives "anything of value" from the patent holder. This broad term includes nonmonetary consideration, such as a brand company's agreeing not to launch an authorized generic version of its branded drug.[2]

A.B. 824 also shifts the burden from the government to demonstrate that a settlement is anti-competitive to the parties to show that it is not anti-competitive, making it easier for the government to challenge settlements. Parties to a settlement agreement can only overcome the anti-competitive presumption of A.B. 824 if they demonstrate by a preponderance of the evidence that the value exchanged "is a fair and reasonable compensation" or that the agreement has "directly generated procompetitive benefits that outweigh the anticompetitive effects of the agreement."

Many commentators — including those in favor of increasing consumer access to generics and biosimilars — are opposed to the law, stating that it will have the opposite of its intended effect. In a press release following the bill's signing, Chip Davis, president and CEO of the Association for Accessible Medicines[3], stated that "recent patent litigation settlements have overwhelmingly accelerated the launch of more affordable generic and biosimilar medicines prior to the branded drug's patent expiration date ... AB 824 will harm patients in California by denying them earlier access to affordable generic and biosimilar prescriptions drugs."

Eve Bukowski, vice president of patient advocacy, outreach and education at the California Life Sciences Association similarly opined that "[p]roponents of AB 824 say they want to prevent any settlement agreement that would lengthen patent protections for a given medication ... But their proposed solution would also disrupt legitimate patent settlements between pharmaceutical manufacturers. That approach is nonsensical and counterproductive, as it would result in reduced access to needed medicines and increased costs to consumers."[4]

Some also question the need for California's law given the steep decline of settlement agreements involving reverse payments in recent years. According to an FTC report on Hatch-Waxman patent settlements, only one of the 232 agreements between generic and brand drug companies in 2016 were reverse payment settlements — the lowest number of such agreements since 2004.[5] FTC Chairman Joe Simons said of the report that "[t]he data are clear: the Supreme Court's Actavis decision [from 2013] has significantly reduced the kinds of reverse payment agreements that are most likely to impede generic entry and harm consumers."[6]

Increased Litigation Costs

A.B. 824 may have the perverse effect of slowing the process of bringing cost-saving generic drugs to market because it will have a chilling effect on patent settlements. Those who run afoul of A.B. 824 must pay the greater of up to three times the value received that is "reasonably attributable to the violation," or $20 million.

According to Jeff Francer, AAM's senior vice-president and general counsel, "most [settlements] include an acceleration clause whereby if another generic manufacturer launches its product, the party to the settlement can market its generic at the same time. This has value to the generic or biosimilar company and would trigger the 'anything of value' provision." It is thus clear that California's new law could have a broad impact upon future settlements.

The likelihood of incurring steep civil penalties in California may force pharmaceutical companies to litigate patent disputes through trial and appeal, driving up costs for both brand and generic companies — costs which will eventually be passed on to consumers. Without the efficient and often pro-competitive alternative to litigation that settlement agreements provide, consumers will literally pay the price for brand and generic companies to resolve their patent disputes.

Possible Constitutional Challenges

Some contend that A.B. 824 violates the U.S. Constitution by attempting to regulate federal patents and transactions that occur wholly in other states. A.B. 824 runs the risk of being preempted by the federal patent system, which contemplates giving exclusive licenses to use inventions.

A Maryland law that sought to lower prescription drug prices by prohibiting manufacturers or wholesale distributors from engaging in "price gouging" for generic drugs was successfully challenged on such grounds last year. The U.S. Court of Appeals for the Fourth Circuit ruled that the law was unconstitutional because it directly regulated the price of transactions that occur outside Maryland.[7] This past February, the U.S. Supreme Court denied Maryland's petition for a writ of certiorari seeking to appeal the Fourth Circuit's decision. This outcome could very well impact a similar constitutional challenge to A.B. 824.

Takeaways

The pharmaceutical industry should take notice of A.B. 824 and be mindful of its provisions in approaching the settlement of any patent case. Despite the good intentions of those who were behind it, A.B. 824 may unfortunately jeopardize patient access to affordable medicine.

Patent settlements serve a vital function in encouraging generic competition, resulting in billions of dollars in consumer savings. Given the complexity of the pharmaceutical market and regulatory framework, any future legislation addressing settlement agreements should be handled carefully to avoid upsetting the critical role played by such settlements in promoting generic competition and lower drug costs.

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[1] 570 U.S. 136, 148.

[2] Under AB 824, "anything of value" does not include compensation for saved reasonable future litigation expenses of the reference drug holder if those expenses are reflected in budgets documented and adopted at least six months before the settlement. This compensation is capped at $7.5 million or five percent of the revenue the nonreference drug holder projected it would receive in the first three years of sales of its product at least 12 months before the settlement, whichever is lower. 2019-2020 Assemb., Reg. Sess. (Cal.

2019).

[3] Association for Accessible Medicines is an industry group focused on improving access to generic and biosimilar medicines. See Association for Accessible Medicines, About the Association, https://accessiblemeds.org/about (last accessed Oct. 15, 2019).

[4] Why legislation that promises patient protection is bad medicine, Cal Matters (Sept. 2, 2019), https://calmatters.org/commentary/access-to-medication/.

[5] Fed.Trade Comm'n., Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed In Fiscal Year 2016: A Report By the Bureau of Competition, (May 2019), https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf.

[6] FTC Staff Issues FY 2016 Report on Branded Drug Firms' Patent Settlements with Generic Competitors, Fed. Trade Comm'n, (May 23, 2019), https://www.ftc.gov/news-events/press-releases/2019/05/ftc-staff-issues-fy-2016-report-branded-drug-firms-patent.

[7] Ass'n for Accessible Medicines v. Frosh, 887 F.3d 664, 666 (4th Cir. 2018), cert. denied, 139 S. Ct. 1168 (2019).