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California's landmark ban on reverse payments: Legal concerns and practical implications

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California recently became the first U.S. state to enact legislation to curb reverse payment, or "pay for delay," litigation settlements in the pharmaceutical and biologics industries. Because of the importance of California as a market, the statute, referred to as Assembly Bill 824, has the potential to significantly deter settlements of patent infringement lawsuits across the country in cases involving pharmaceutical and biologic inventions.

To the extent the law survives constitutional challenges, parties must plan at the outset of litigation and at the point of settlement to avoid an enforcement action by the California attorney general or private litigants who might seek to rely on an alleged violation as a predicate for antitrust or consumer rights actions.

BACKGROUND

Reverse payment settlements provide a practical means to settle patent litigation regarding a proposed generic pharmaceutical or biosimilar. Typically, the patent holder pays the alleged infringer money (although other incentives are often used) to delay market entry until a specified date, avoiding further costs and risks of litigation.

California AB 824[1] took effect Jan. 1. It provides that a settlement where the accused infringing generic or biosimilar applicant "receives anything of value" in exchange for delayed market entry is presumptively anti-competitive, subject to limited exemptions and exceptions. Penalties for violating the law can exceed $20 million.

Under the Hatch-Waxman Act, 21 U.S.C.A. § 355, an applicant seeking Food and Drug Administration approval of a generic pharmaceutical commonly certifies that it does not infringe any valid patent listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, known as the Orange Book.

The brand company holding the new drug application for the reference-listed drug must sue for patent infringement within 45 days of being notified of the generic application in order to stay the FDA's approval.

The Biologics Price Competition and Innovation Act, 42 U.S.C.A. § 262, similarly provides a mechanism for a reference product sponsor to file suit for infringement against the biosimilar applicant filing an abbreviated biologic license application.

Since a lawsuit is generally filed before FDA approval, the generic or biosimilar applicant has no competing product on the market and the brand has suffered no actual monetary damages at the time of suit.

By encouraging premarketing suits, these mechanisms minimize the financial risk to both the generic or biosimilar applicant and the brand manufacturer because, irrespective of the outcome of any patent litigation, the parties can litigate the patents before the generic or biosimilar becomes liable for substantial monetary damages or the brand irretrievably loses market share or pricing power.

> Only a small fraction of potential products achieve FDA approval, and companies regularly spend well over a decade and billions of dollars to develop an FDA-approved product.

Regardless of the outcome of any patent litigation, generics and biosimilars encounter little risk when they challenge patents — and they have an economic incentive to do so.

On the other hand, brands face high risk and have an economic incentive to enforce patents. The U.S. market for prescription drugs in 2018 was approximately $344 billion.[2] Only a small fraction of potential products achieve FDA approval, and companies regularly spend well over a decade and billions of dollars to develop an FDA-approved product.[3]

Patents are critical to protect that investment by allowing the patent holder a lawful monopoly to exclude generic and biosimilar competitors beyond the relatively short periods of exclusivity granted by the FDA.

A brand's sales decline precipitously upon introduction of a competitor to the market. The prices of medicines plunge by about

50% in the first year after generic entry and up to about 80% within five years.[4] A generic is preferentially dispensed to patients 97% of the time when available.[5]

It is therefore unsurprising that, even where the brand views its patent portfolio as strong, settlement agreements in this industry can result in payments by the brand because they buy the brand peace for a shortened period of time before the expiration of the patent, and the generic or biosimilar still gains otherwise early entry to the market.

CALIFORNIA AB 824

California AB 824 is intended to disrupt this dynamic and discourage reverse payment settlements. The settlement of a patent infringement claim is deemed presumptively anti-competitive if a generic or biosimilar applicant receives anything of value in exchange for agreeing to delay research, development, manufacturing, marketing or sale of the product for any period of time.

> Consideration of patent validity may inform the inquiry of causation when analyzing an antitrust claim and the expected competition that would have arisen in the absence of a settlement agreement.

The California attorney general may enforce the law against any party that violates it or assists in the violation. Violators may be liable for three times the value of the consideration based on California's share of sales for the drug, or $20 million, whichever is greater.

An enforcement action must be brought within four years after the cause of action accrues, which one assumes is on the date of execution or effective date of the settlement agreement.

By identifying reverse payment settlement agreements as violative of California law, the new law also appears to open litigants up to private actions under other state statutes, including the Cartwright Act, Cal. Bus. & Prof. Code § 16700; the Unfair Practices Act, Cal. Bus. & Prof. Code § 17000; or the unfair-competition law, Cal. Bus. & Prof. Code § 17200.

AB 824 defines "anything of value" broadly to mean not just monetary payments (above certain caps), but also to include an exclusive license or a promise that the brand company will not launch an authorized generic version of its own brand drug.

It also provides narrow but important exemptions and exceptions that litigants will need to adhere to if they want to enter into a reverse payment settlement without violating the statute.

Exemptions

The law exempts from "anything of value" certain types of consideration paid by the brand reference drug holder.

One notable exemption is if the accused infringer is compensated only for "saved reasonable future litigation expenses" of the reference drug holder, but only if:

- The amount of saved litigation expenses is reflected in budgets the reference drug holder adopted at least six months before the settlement.
- The compensation does not exceed the lower of $7.5 million[6] or 5% of the revenue that the nonreference drug holder projected it would receive in the first three years of sales of the brand version of the drug documented at least 12 months before the settlement, or $250,000, if no projections are available.

This exemption is important to the current landscape of reverse payment settlements, where the majority of agreements contain payment in the form of litigation fees that often range between $250,000 and $7 million.[7]

To qualify for this exemption, it will be important for the reference drug holder to maintain reasonable budgets throughout litigation. Further, while it is already common practice, the nonreference drug holder should prepare reasonable three-year revenue projections, ideally before litigation commences. Importantly, this provision favors earlier settlement as litigation cost savings decrease over time.

Additional exemptions from "anything of value" under the statute are:

- Market entry before the expiration of patent or statutory exclusivity (e.g., without monetary payment to the accused infringer).[8]
- A covenant not to sue.
- Permitting a nonreference drug filer to launch its product if the reference drug holder seeks approval or launches a different dosage, strength or form of the reference drug, other than an authorized generic, with the same active ingredient before the date set by the agreement for entry of the nonreference drug filer.
- An agreement to either facilitate or not interfere with the nonreference drug filer's ability to obtain approval.
- Forgiving damages accrued by a nonreference drug holder for an at-risk launch of the generic drug product at issue.

Exceptions

AB 824 also provides that a reverse payment settlement agreement does not violate the statute if the parties can demonstrate by a preponderance of the evidence that either of the following exceptions is met:

- The value received by the generic drug application filer is a "fair and reasonable compensation" for other goods or services that the nonreference drug filer has agreed to provide.
- The agreement has directly yielded procompetitive benefits, and the agreement's procompetitive benefits outweigh its anti-competitive effects.

This latter exception may provide room for parties to continue entering into more creative settlements, such as manufacturing, supply, distribution, marketing or packaging agreements. Further, the parties may continue to argue that a particular reverse payment settlement agreement has greater procompetitive benefits. In either event, California's law shifts the burden to the settling parties to justify the agreement.

CONSTITUTIONAL AND FEDERAL PREEMPTION ISSUES

Several aspects of AB 824 appear subject to challenge on constitutional and federal preemption grounds, particularly as private parties attempt to use the new law as a basis for private suits under other California statutes.

One apparent argument is that the law violates the extraterritoriality principle as it relates to the dormant commerce clause of the U.S. Constitution.[9]

"When a state statute directly regulates or discriminates against interstate commerce, ... [the Supreme Court has] generally struck down the statute without further inquiry."[10]

On its face, AB 824 directly regulates interstate commerce in drugs by dictating permissible terms of settlement of out-of-state litigation based on potential delays in out-of-state sales of products covered by federally issued patents. To the extent private litigants attempt to rely on AB 824, defendants are even more likely to raise challenges to the validity of AB 824.

Likewise, retroactive application of the statute would arguably violate the contracts clause of the U.S. Constitution.

Typically, the question of whether a state statute violates the contracts clause is evaluated using a three-part test: whether there is a preexisting contractual obligation; whether the legislation imposes a "substantial impairment"[11]; and if there is an impairment, whether the legislation is "reasonable and necessary to serve an important public purpose."[12]

Even if controlling drug pricing constitutes an important public purpose, it is unclear whether this legislation — which impairs the ability of parties to contractually settle litigation claims — is reasonable and necessary to serve that purpose.

The statute also appears to directly contradict federal patent law by requiring that the fact-finder "shall not presume" that "any patent is enforceable and infringed ... in the absence of a final adjudication binding on the filer of those issues."

While an antitrust fact-finder generally need not consider patent validity,[13] that is not universally the case, and it is unclear whether precluding the fact-finder from presuming patent validity runs afoul of the U.S. Constitution's patent and copyright clause, U.S. Const. art. I, § 8, cl. 8, and the presumption of validity for duly issued patents under Section 282 of the Patent Act, 35 U.S.C.A. § 282.

Consideration of patent validity may inform the inquiry of causation when analyzing an antitrust claim and the expected competition that would have arisen in the absence of a settlement agreement. Further, at least some courts have observed that patent validity issues are appropriately considered under certain circumstances within the antitrust context.[14]

Rather than a bright-line rule banning the fact-finder from ever presuming validity, the U.S. Supreme Court could require a more nuanced approach that allows the presumption to be considered under proper circumstances.

The California law also imposes other presumptions that appear to contradict federal case law. For example, the law requires that the fact-finder "shall presume" the relevant product market includes only the branded drug product and its AB-rated generic substitutes.

This potentially contradicts federal antitrust law in the pharmaceutical arena.[15] However, because the law only imposes a rebuttable evidentiary presumption and does not directly contradict a federal statute, it is arguably not preempted by federal antitrust laws.

KEY TAKEAWAYS

California AB 824 will increase scrutiny over reverse payment settlement agreements and may lead to an increase in related antitrust and consumer rights litigation in California.

Depending on how it is enforced, the statute has the potential to upset the carefully balanced frameworks under Hatch-Waxman and the Biologics Price Competition and Innovation Act, causing litigation to revert to post-entry litigation and potentially large damages awards that previously dissuaded generic drugmakers from challenging patents on blockbuster drugs.

The legislation is likely to be challenged on constitutional and federal preemption grounds. Indeed, at least one association representing generic drug manufacturers has already sued the state over the constitutionality of AB 824 and sought (unsuccessfully, for now) to preliminarily enjoin its enforcement. *Ass'n for Accessible Meds. v. Becerra*, No. 19-cv-2281, *complaint filed*, 2019 WL 6001779 (E.D. Cal. Nov. 12, 2019).

The court denied a preliminary injunction primarily on the grounds that it was premature to determine whether the law would be enforced in an unconstitutional manner. However, it also indicated the plaintiff could "seek[] another preliminary injunction should certain facts develop and/or certain claims become ripe." *Ass'n for Accessible Meds. v. Becerra*, No. 19-cv-2281, 2019 WL 7370421 (E.D. Cal. Dec. 31, 2019).

The court's reasoning suggests that the constitutionality of the new law in light of the dormant commerce clause may only be properly considered in the context of "a currently pending reverse payment settlement negotiation in which the parties would not settle as a result of AB 824 or feared prosecution under AB 824."

But in rejecting that argument for the time being, the court also warned that "if the attorney general were to enforce the terms of AB 824 against two out-of-state parties that entered into a settlement agreement outside of California, having nothing to do with California, such conduct would likely violate the dormant commerce clause."

The court also rejected the association's preemption arguments as "too speculative for the court to find one way or another that AB 824 will frustrate or further the aims of the Hatch-Waxman Act."

Notably though, the court's ruling rests largely on the plaintiff's failure to identify a specific provision of AB 824 that ostensibly contradicts federal patent law. In addition, the plaintiff did not squarely raise the law's prohibition on the presumption that an issued patent is enforceable.

Finally, the court held that AB 824 did not appear to violate due process, because like federal antitrust laws, it provides settling companies meaningful opportunities to rebut the presumption that a particular reverse payment settlement has procompetitive effects.

The court's decision leaves open whether AB 824 will be enforceable when faced with more developed facts surrounding an actual attempt by the California attorney general to enforce it.

In the meantime, reference and nonreference drug manufacturers should consider ways to structure reverse payment settlement agreements to avoid the prohibitions of the statute.

For example, a reverse payment settlement that does not explicitly delay generic or biologic entry, but instead attaches a high royalty reflective of the brand's anticipated losses to pre-expiration sales, may arguably not violate the statute even though it may have the same ultimate market effect.

At the very least, reference drug holders considering patent litigation should plan to document and adopt litigation budgets and nonreference drug holders should prepare three-year revenue projections well in advance of any potential settlement to take advantage of the litigation savings exemption.

Parties should continue to consider settlements where the nonreference drug filer is compensated "solely for other goods or services."

Parties should approach internal and external communications and analysis regarding litigation that may be settled with a focus on procompetitive considerations.

NOTES

[1] Cal. Health & Safety Code, Div. 114.01 (Preserving Access to Affordable Drugs), § 134000.

[2] IQVIA Inst. for Human Data Sci., "Medicine Use and Spending in the U.S." (May 2019, summary available at https://bit.ly/34yQIAd)

[3] Joe Kennedy, "The Link Between Drug Prices and Research on the Next Generation of Cures," Info. Tech. & Innovation Found. (Sept. 9, 2019) at https://bit.ly/36YBAOB.

[4] IMS Inst. for Healthcare Informatics, "Price Declines after Branded Medicines Lose Exclusivity in the U.S." (Jan. 2016) at https://bit.ly/2Ey9gGl). Biosimilars are trending upward on market share when accessible, being dispensed 31% of the time when accessible in Q4 2018. IQVIA Inst. for Human Data Sci., "Medicine Use and Spending in the U.S." (May 2019, summary available at https://bit.ly/34yQIAd).

[5] *Id.*

[6] This amount is consistent with the Federal Trade Commission's recent statement that its "consent settlements often include an exception for avoided litigation fee payments under $7 million." "Then, now, and down the road: Trends in pharmaceutical patent settlements after FTC v. Actavis" (May 28, 2019), https://bit.ly/2NmE6Xv.

[7] "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://bit.ly/34zqPkq.

[8] Brands settle without "any compensation" to the generic approximately 80% of the time. *See id*.

[9] *See, e.g., Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 666 (4th Cir. 2018) (holding Maryland statute on sale of prescription drugs violated dormant commerce clause).

[10] *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986).

[11] *Energy Reserves Grp. v. Kan. Power & Light Co.*, 459 U.S. 400, 411-12 (1983); *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 244-45 (1978).

[12] *U.S. Trust Co. v. New Jersey*, 431 U.S. 1, 22-27 (1977).

[13] *Fed. Trade Comm'n v. Actavis Inc.*, 570 U.S. 136, 157 (2013) ("it is normally not necessary to litigate patent validity to answer the antitrust question").

[14] *See, e.g., In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 63 (1st Cir. 2016) ("The district court thus did not err by requiring some evidence of the patents' invalidity or noninfringement before allowing the plaintiffs to pursue an at-risk launch theory.").

[15] *See, e.g., Mylan Pharm. Inc. v. Warner Chilcott PLC*, 838 F.3d 421, 437 (3d Cir. 2016) ("given the high degree of interchangeability and cross-elasticity demonstrated in the record, we agree with the district court that the relevant market consisted of Doryx and other oral tetracyclines prescribed to treat acne").

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