**OLR Bill Analysis**

**sHB 6619**

***AN ACT CONCERNING PROHIBITING PAY FOR DELAY.***

## SUMMARY

This bill makes it easier for the state to bring an antitrust action for "pay-for-delay" agreements between pharmaceutical companies in which one company (the "reference drug holder") compensates another (the "nonreference drug filer") to delay the introduction of a generic or biosimilar drug into the market. The U.S. Supreme Court has held that these agreements can violate antitrust laws (see BACKGROUND).

The bill establishes a presumption that the transfer of value from a reference drug holder to a nonreference drug filer to settle patent infringement litigation, combined with a delay of entry into the market, has an anti-competitive effect. A patent infringement claim is an allegation that a nonreference drug filer's nonreference drug product or associated application infringes a patent held by, or exclusively licensed to, the reference drug holder.

The bill has various exceptions to the presumption, including agreements that directly generate procompetitive benefits (i.e., favorable competitive consequences from resolving the agreement or settling a patent infringement claim) that outweigh the agreement's anticompetitive effects.

Generally, a violation of the bill's provisions (i.e., entering into an anticompetitive pay-for-delay agreement) is punishable by a civil penalty paid to the state. For parties to the agreement, the penalty is the greater of up to three times the amount of compensation provided for delayed market entry or $20 million.

The bill specifies that it does not modify, impair, limit, or supersede a drug company applicant's right to assert antitrust claims or

counterclaims. It also has a severability clause specifying that if part of the bill is held unconstitutional, the rest remains enforceable.

EFFECTIVE DATE: October 1, 2023

## SCOPE OF THE BILL

### *Covered Agreements*

The bill applies to agreements resolving or settling a patent infringement claim on either a final or interim basis. These include agreements that are (1) entered into within 30 days after a claim's resolution or settlement, or (2) contingent upon, provide a contingent condition for, or are otherwise related to the claim's resolution or settlement. They also include those that are:

1. given to the Federal Trade Commission or Department of Justice's Antitrust Division under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which allows for a review and challenge of anticompetitive settlements, or

2. between a biosimilar or interchangeable biological product applicant and a reference drug product sponsor to resolve patent claims.

### *Parties to an Agreement*

The bill applies to agreements between "reference drug holders" and "nonreference drug filers."

"Reference drug holders" are certain brand holders and biological product license holders. Specifically, the:

1. holder of an approved (a) new drug application (NDA) for a drug product application or (b) biological product license application for a biological drug product, as filed under federal law, or

2. person owning or controlling enforcement of (a) the patent listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" ("FDA Orange Book"), in connection with the

NDA, or (b) any patent that claims the biological product is the subject of the approved biological patent license application.

A "reference drug holder" includes the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the above-described brand or biological product license holders, as well as these entities' licensees, licensors, successors, and assigns. Control is presumed by directly or indirectly owning at least 50% of shares.

Under the bill, "nonreference drug filers" are filers of abbreviated new drug applications (ANDA) or biosimilar biological product applications (BBPA) with the federal Food and Drug Administration (FDA). Specifically, "ANDA filers" are those that own or control an ANDA or have exclusive rights under that ANDA to distribute the ANDA product. (In practice, these filers seek approval of generic drugs.) "BBPA filers" are those that own or control a BBPA or have the exclusive rights under the BBPA to distribute the biosimilar biological product.

### *Drug Products*

Under the bill, a "reference drug product" is the product manufactured by the reference drug holder and includes a (1) holder's branded drug and (2) biological product license applicant's biological drug product.

A "nonreference drug product" is the (1) product to be manufactured under an ANDA that is the subject of the patent infringement claim or (2) biosimilar biological product to be manufactured under a BBPA that is the subject of the patent infringement claim, or both.

## PRESUMPTION OF ANTICOMPETITIVE EFFECTS

Under the bill, an agreement resolving or settling a patent infringement claim is presumed to have anticompetitive effects if the nonreference drug filer:

1. receives "anything of value" from the company claiming patent infringement, such as an exclusive license or a promise that the

brand company will not launch an authorized generic of its brand drug, and

2. agrees to limit or forego research, development, manufacturing, marketing, or sales of their product for any period of time.

The bill excludes several items from "anything of value," as described below.

## REBUTTING THE PRESUMPTION

Parties can rebut the presumption of anticompetitive effects by showing, by a preponderance of the evidence, that either the:

1. value received by the nonreference drug filer is fair and reasonable compensation solely for other goods or services that it promised to provide, or

2. agreement directly generated procompetitive benefits that outweigh the agreement's anticompetitive effects.

### *Factfinder's Presumptions*

Under the bill, when determining if the parties have met their burden, the factfinder must presume that the relevant product market is the market for:

1. the brand or reference drug of the company alleging patent infringement;

2. the drug product of the nonreference company accused of infringement; and

3. any other biological product that is licensed as biosimilar or has a therapeutic equivalency rating of AB-rated generic (i.e., a pharmaceutically and therapeutically bioequivalent) to the reference product.

***Prohibited Presumptions.*** The bill lists several conditions that the factfinder cannot presume when determining if the parties met their burden. But it allows parties to introduce evidence on these conditions

and the factfinder to decide based on the full scope of the evidence.

Under the bill, the conditions that cannot be presumed are:

1. entry into the marketplace could not have occurred until the relevant patent exclusivity expired or that the agreement's allowance for the nonreference drug product's entry before expiration means the agreement is "procompetitive," as required to rebut the presumption;

2. a patent is enforceable and infringed by the nonreference drug filer absent a final judgement binding on the filer of those issues;

3. the agreement did not delay the entry of the nonreference drug filer's drug product because of the lack of FDA approval of that or of another nonreference drug product; and

4. the agreement caused no harm or delay from the possibility that the nonreference drug filer's drug product might infringe a patent that (a) has not been asserted against the nonreference drug filer or (b) is not subject to a judgement on that filer as to the patent's scope, enforceability, and infringement.

## "ANYTHING OF VALUE" EXCLUSIONS

Under the bill, "anything of value" does not include an agreement to:

1. resolve or settle a patent infringement claim that permits a nonreference drug filer, before the agreement's date for entry of the nonreference drug filer, to begin selling, offering for sale, or distributing their product, if the reference drug holder seeks or obtains approval to launch, or launches a different dosage, strength, or form of the reference drug having the same active ingredient, but a different form does not include an authorized generic version;

2. not interfere with or facilitate the nonreference drug filer's ability to secure and maintain regulatory approval to market their product; or

3. resolve a patent infringement claim in which the reference drug holder forgives the potential damages accrued by a nonreference drug holder for an at-risk launch of the nonreference drug product that is the subject of that claim. (An "at-risk launch" is a launch of a nonreference drug before a nonappealable court decision is resolved or a patent expires.)

The bill also excludes from "anything of value":

1. the right to market the competing product in the United States before the expiration of either (a) a patent that is the basis for the infringement claim or (b) a patent right or other federal statutory exclusivity that would prevent marketing the drug;

2. a covenant not to sue on a claim that the product infringes a United States patent; and

3. compensation for the reference drug holder's saved reasonable future litigation expenses, subject to certain parameters.

To qualify as excluded consideration, compensation for saved litigation expenses must be:

1. documented and adopted in the reference drug holder's budgets at least six months before the settlement; and

2. capped at the lesser of (a) $7,500,000 or (b) 5% of the nonreference drug holder's projected revenue for the first three years of sales that is documented at least 12 months before the settlement (but if no projections are available, then the compensation does not exceed $250,000).

## LIABILITY

The bill's ban on anticompetitive agreements to resolve or settle a patent infringement claim is enforceable against any party to the agreement and those who assist in the violation. Under the bill, the statute of limitations for bringing a claim is four years.

A violation is punishable by a civil penalty, paid to the state. The bill's

penalty amount, which is "sufficient to deter violations," is the greater of (1) up to three times the value received or given as a party to the agreement that is reasonably attributable to the violation, based on the state's market share for the brand drug at issue, or (2) $20 million. This penalty is recoverable only in an action brought by the Connecticut attorney general against a party to an agreement.

Violators and those who help them are also generally liable for damages, penalties, costs, fees, injunctions, or other remedies that the court determines are just and reasonable. The state cannot recover these penalties if it is awarded the bill's primary penalty, described above.

## BACKGROUND

### *Related Case*

In a case concerning pay-for-delay agreements between name brand manufacturers and prospective generic manufacturers, the U.S. Supreme Court held that while these agreements are not presumptively illegal, they could have anticompetitive effects and a brand manufacturer's reverse payment settlements may violate antitrust laws (*FTC* v. *Actavis, Inc.*, 570 U.S. 136 (2013)).

## COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable
Yea 12 Nay 0 (03/14/2023)