# Senate

General Assembly

**File No. 15**

***January Session, 2021***

Senate Bill No. 269

*Senate, March 4, 2021*

The Committee on General Law reported through SEN. MARONEY of the 14th Dist., Chairperson of the Committee on the part of the Senate, that the bill ought to pass.

## *AN ACT CONCERNING THE AVAILABILITY OF GENERIC PHARMACEUTICALS.*

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2021*) For purposes of this section and section 2 of this act:

(1) "ANDA" means abbreviated new drug application.

(2) "ANDA filer" means a party that owns or controls an ANDA filed with the Food and Drug Administration or has the exclusive rights under that ANDA to distribute the ANDA product.

(3) "Agreement resolving or settling a patent infringement claim" includes any agreement that is entered into not later than thirty days after the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim. "Agreement resolving or settling a patent infringement claim" includes,

but is not limited to, the following:

(A) Any agreement required to be provided to the Federal Trade Commission or the Antitrust Division of the United States Department of Justice under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(B) Any agreement between a biosimilar or interchangeable biological product applicant and a reference drug product sponsor that resolves patent claims between the applicant and sponsor.

(4) "Biosimilar biological product application filer" means a party that owns or controls a biosimilar biological product application filed with the Food and Drug Administration under subsection (k) of section 351 of the Public Health Service Act, 42 USC 262, for licensure of a biological product as biosimilar to, or interchangeable with, a reference drug product or that has the exclusive rights under the application to distribute the biosimilar biological product.

(5) "NDA" means new drug application.

(6) "Nonreference drug filer" means (A) an ANDA filer, or (B) a biosimilar biological product application filer.

(7) "Nonreference drug product" means the product to be manufactured under an ANDA that is the subject of the patent infringement claim, a biosimilar biological product that is the product to be manufactured under the biosimilar biological product application that is the subject of the patent infringement claim, or both.

(8) "Patent infringement" means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

(9) "Patent infringement claim" means any allegation made to a nonreference drug filer, whether or not included in a complaint filed with a court of law, that its nonreference drug product or application

infringes any patent held by, or exclusively licensed to, the reference drug holder.

(10) "Reference drug holder" means:

(A) A brand holder that is any of the following:

(i) The holder of an approved NDA for a drug product application filed under subsection (b) of section 505 of the Federal Food, Drug and Cosmetic Act, 21 USC 355,

(ii) A person owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations, commonly known as the "FDA Orange Book" in connection with the NDA, or

(iii) The predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling or under common control with, any of the entities described in this subparagraph or subparagraph (B) of this subdivision, with control to be presumed by direct or indirect share ownership of fifty per cent or greater, as well as the licensees, licensors, successors and assigns of each of those entities; or

(B) A biological product license holder, which includes any of the following:

(i) The holder of an approved biological product license application for a biological drug product under subsection (a) of section 351 of the Public Health Service Act, 42 USC 262,

(ii) A person owning or controlling enforcement of any patents that claim the biological product that is the subject of the approved biological patent license application, or

(iii) The predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling or under common control with, any of the entities described in this subparagraph or subparagraph (A) of this subdivision, with control to be presumed by direct or indirect share

ownership of fifty per cent or greater, as well as the licensees, licensors, successors and assigns of each of those entities.

(11) "Reference drug product" means the product to be manufactured by the reference drug holder and includes branded drugs of the NDA holder and the biological drug product of the biological product license applicant.

(12) "Statutory exclusivity" means those prohibitions on the approval of drug applications under subsection (c) of section 505, section 527 or 505A of the Federal Food, Drug and Cosmetic Act, 21 USC 355, 360cc and 355a, or on the licensing of biological product applications under subsection (k) or (m) of section 262 of the Public Health Service Act, 42 USC 262.

Sec. 2. (NEW) (*Effective October 1, 2021*) (a) (1) Except as provided in subdivision (3) of this subsection, an agreement resolving or settling, on a final or interim basis, a patent infringement claim, 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, including, but not limited to, an exclusive license or a promise that the brand company will not launch an authorized generic version of its brand drug; and

(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.

(2) As used in subparagraph (A) of subdivision (1) of this subsection, "anything of value" does not include a settlement of a patent infringement claim in which the consideration granted by the brand or reference drug filer to the nonreference drug filer as part of the resolution or settlement consists of one or more of the following:

(A) The right to market the competing product in the United States before the expiration of either:

(i) A patent that is the basis for the patent infringement claim, or

(ii) A patent right or other statutory exclusivity that would prevent the marketing of the drug;

(B) A covenant not to sue on a claim that the nonreference drug product infringes a United States patent;

(C) Compensation for saved reasonable future litigation expenses of the reference drug holder but only if both of the following are true:

(i) The total compensation for saved litigation expenses is reflected in budgets that the reference drug holder documented and adopted at least six months before the settlement, and

(ii) The compensation does not exceed the lower of the following:

(I) Seven million five hundred thousand dollars, or

(II) Five per cent of the revenue that the nonreference drug holder projected or forecasted it would receive in the first three years of sales of its version of the reference drug documented at least twelve months before the settlement. If no projections or forecasts are available, the compensation does not exceed two hundred fifty thousand dollars;

(D) An agreement resolving or settling a patent infringement claim that permits a nonreference drug filer to begin selling, offering for sale or distributing the nonreference drug product if the reference drug holder seeks approval to launch, obtains approval to launch or launches a different dosage, strength or form of the reference drug having the same active ingredient before the date set by the agreement for entry of the nonreference drug filer. A different form of the reference drug does not include an authorized generic version of the reference drug;

(E) An agreement by the reference drug holder not to interfere with the nonreference drug filer's ability to secure and maintain regulatory approval to market the nonreference drug product or an agreement to facilitate the nonreference drug filer's ability to secure and maintain

regulatory approval to market the nonreference drug product; or

(F) An agreement resolving 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.

(3) Parties to an agreement are not in violation of subdivision (1) of this subsection if they can demonstrate by a preponderance of the evidence that either of the following are met:

(A) The value received by the nonreference drug filer described in subparagraph (A) of subdivision (1) of this subsection is a fair and reasonable compensation solely for other goods or services that the nonreference drug filer has promised to provide, or

(B) The agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

(b) In determining whether the parties to the agreement have met their burden under subdivision (3) of subsection (a) of this section, the factfinder shall not presume any of the following:

(1) That entry into the marketplace 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 the agreement is procompetitive within the meaning of subparagraph (B) of subdivision (3) of subsection (a) of this section,

(2) That any patent is enforceable and infringed by the nonreference drug filer in the absence of a final adjudication binding on the filer of those issues,

(3) That the agreement caused no delay in entry of the nonreference drug filer's drug product because of the lack of federal Food and Drug Administration approval of that or of another nonreference drug

product, or

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

This subsection shall not be construed to preclude a party from introducing evidence regarding subdivisions (1) to (4), inclusive, of this subsection and shall not be construed to preclude the factfinder from making a determination regarding said subdivisions based on the full scope of the evidence.

(c) In determining whether the parties to the agreement have met their burden under subdivision (3) of subsection (a) of this section, the factfinder shall presume that the relevant product market is that market consisting of the brand or reference drug of the company alleging patent infringement and the drug product of the nonreference company accused of infringement and any other biological product that is licensed as biosimilar or is an AB-rated generic to the reference product.

(d) (1) The provisions of this section shall not modify, impair, limit or supersede the right of any drug company applicant to assert claims or counterclaims against any person under the antitrust laws or other laws relating to unfair competition of the federal antitrust law or state law.

(2) If any provision of this section, an amendment made to this section or the application of any provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this section, the amendments made to this section and the application of the provisions of this section or amendments to any person or circumstance shall not be affected.

(e) (1) (A) Each person that violates or assists in the violation of this section shall forfeit and pay to the state a civil penalty sufficient to deter violations of this section, as follows:

(i) If the person who violated this section received any value due to that violation, 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, whichever is greater.

(ii) If the violator has not received anything of value as described in subparagraph (A)(i), an amount up to three times the value given to other parties to the agreement reasonably attributable to the violation of this section, or twenty million dollars, whichever is greater.

(iii) For purposes of this subdivision, "reasonably attributable to the violation" shall be determined by the state's share of the market for the brand drug at issue in the agreement.

(B) Any penalty described in subparagraph (A) of this subdivision shall accrue only to the state and shall be recovered in a civil action brought by the Attorney General against any party to an agreement that violates this section.

(2) Each party that violates or assists in the violation of this section shall be liable for any damages, penalties, costs, fees, injunctions, or other remedies that may be just and reasonable, as determined by the court.

(3) If the state is awarded penalties under subparagraph (A) of subdivision (1) of this subsection, it may not recover penalties pursuant to subdivision (2) of this subsection. This section shall not be construed to foreclose the state's ability to claim any relief or damages available in subdivision (2) of this subsection, other than those that are penalties.

(4) An action to enforce a cause of action for a violation of this section shall be commenced within four years after the cause of action accrued.

| This act shall take effect as follows and shall amend the following sections: | | |
|---|---|---|
| Section 1 | *October 1, 2021* | New section |
| Sec. 2 | *October 1, 2021* | New section |

***GL*** *Joint Favorable*

*The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.*

## *OFA Fiscal Note*

### *State Impact:*

| Agency Affected | Fund-Effect | FY 22 $ | FY 23 $ |
|---|---|---|---|
| Resources of the General Fund | GF - Revenue Gain | Potential | Potential |
| Attorney General | GF - Potential Cost | At least 100,585 | At least 104,105 |
| State Comptroller - Fringe Benefits[1] | GF - Potential Cost | At least 42,014 | At least 43,485 |

Note: GF=General Fund

### *Municipal Impact:* None

### *Explanation*

The bill facilitates the process for the state to bring an antitrust action for "pay-for-delay" agreements between pharmaceutical companies in which one company compensates another to delay the introduction of a generic drug into the market.

To the extent this increases the number of antitrust cases handled by the Office of the Attorney General (OAG), there may be costs to the state of at least $142,599 in FY 22 and $147,590 in FY 23, including fringe benefits, to hire an additional assistant attorney general to handle any significant caseload. The assistant attorney general would perform litigation (i.e. negotiate settlements and carry-out appeals). Additionally, external consultants such as an economist or industry expert may be retained by the Attorney General's Office to work on

[1]The fringe benefit costs for most state employees are budgeted centrally in accounts administered by the Comptroller. The estimated active employee fringe benefit cost associated with most personnel changes is 41.77% of payroll in FY 21 and FY 22.

these antitrust cases.

Please note that costs for additional staff, if incurred, may be offset by revenue generated from negotiated settlements.

### *The Out Years*

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation, the number of antitrust cases filed, and the value of negotiated settlements.

**OLR Bill Analysis**

**SB 269**

***AN ACT CONCERNING THE AVAILABILITY OF GENERIC PHARMACEUTICALS.***

## 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 provides various exceptions to the presumption, including agreements that directly generate procompetitive benefits 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, 2021

## 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, these holders are 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 that 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. (They 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.

## 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 and these benefits outweigh the agreement's anticompetitive effects.

### *Factfinder's Presumptions*

***Required 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 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.

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; or

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 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 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

General Law Committee

Joint Favorable
Yea 13 Nay 6 (02/16/2021)