

STATE OF NEW YORK

4370--A

2021-2022 Regular Sessions

IN SENATE

February 3, 2021

Introduced by Sens. BIAGGI, BROOKS, BROUK, COMRIE, GAUGHRAN, HOYLMAN, LIU, MANNION, MAY, MYRIE, RAMOS -- read twice and ordered printed, and when printed to be committed to the Committee on Health -- recommitted to the Committee on Health in accordance with Senate Rule 6, sec. 8 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the public health law, in relation to preserving access to affordable drugs

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. Article 2-A of the public health law is amended by adding a
2 new title IV to read as follows:

TITLE IV

PRESERVING ACCESS TO AFFORDABLE DRUGS

Section 282. Definitions.

283. Preserving access to affordable drugs.

3 § 282. Definitions. For the purposes of this title, the following
4 terms shall have the following meanings:

5 1. "ANDA" shall mean abbreviated new drug application as described by
6 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 335(j).

7 2. "ANDA filer" shall mean a party that owns or controls an ANDA filed
8 with the federal food and drug administration or has the exclusive
9 rights under that ANDA to distribute the ANDA product.

10 3. "Agreement" shall mean anything that would constitute an agreement
11 under state law.

12 4. "Agreement resolving or settling a patent infringement claim"
13 includes any agreement that is entered into within thirty days of the
14 resolution or the settlement of the claim, or any other agreement that
15 is contingent upon, provides a contingent condition for, or is otherwise
16 related to the resolution or settlement of the claim. This shall
17 include, but is not limited to, the following:

18 EXPLANATION--Matter in italics (underscored) is new; matter in brackets
19 [-] is old law to be omitted.

LBD04644-02-2

(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, Pub. L. No. 108-173;

(b) Any agreement between a biosimilar or interchangeable product applicant and a reference product sponsor under the Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, that resolves patent claims between the applicant and sponsor.

5. "Biosimilar biological product application filer" shall mean a party that owns or controls a biosimilar biological product application filed with the federal food and drug administration pursuant to section 351(k) of the Public Health Service Act, 42 U.S.C. 262(k), for licensure of a biological product as biosimilar to, or interchangeable with, a reference product, or that has the exclusive rights under the application to distribute the biosimilar biological product.

6. "NDA" shall mean a new drug application.

7. "Nonreference drug filer" shall mean either:

(a) An ANDA filer;

(b) A company that seeks an abbreviated approval pathway for its drug product under 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(b)(2); or

(c) A biosimilar biological product application filer, or company seeking FDA approval for a biosimilar under 42 U.S.C. 262.

8. "Nonreference drug product" shall mean 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.

9. "Patent infringement" shall mean 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.

10. "Patent infringement claim" shall mean 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.

11. "Reference drug holder" shall mean either:

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

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

(ii) A person owning or controlling enforcement of the patent listed in the approved drug products with therapeutic equivalence evaluations 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 subparagraph (i) or (ii) of this paragraph, with control to be presumed by direct or indirect share ownership of fifty percent or greater, as well as the licensees, licensors, successors, and assigns of each of those entities; or

(b) A biological product license holder, which shall mean any of the following:

(i) The holder of an approved biological product license application for a biological drug product under section 351(a) of the Public Health Service Act, 42 U.S.C. 262(a);

(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 subparagraph (i) or (ii) of this paragraph, with control to be presumed by direct or indirect share ownership of fifty percent or greater, as well as the licensees, licensors, successors, and assigns of each of those entities.

12. "Reference drug product" shall mean the product to be manufactured by the reference drug holder and includes both branded drugs of the NDA holder and the biologic drug product of the biologic product license applicant.

13. "Statutory exclusivity" shall mean those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E), section 527 or section 505A of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c)(3)(E), on the licensing of biological product applications under section 262(k)(7) of Title 42 of the United States Code or section 262(m)(2) or (3) of Title 42 of the United States Code.

§ 283. Preserving access to affordable drugs. 1. (a) Except as provided in paragraph (c) of this subdivision, 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:

(i) 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

(ii) 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.

(b) As used in subparagraph (i) of paragraph (a) of this subdivision, "anything of value" shall be interpreted broadly to include any type of consideration, value or benefit a reference drug holder or nonreference drug filer could possibly obtain from the agreement. "Anything of value" shall not include a settlement of a patent infringement claim in which the consideration granted by the brand or reference drug holder to the nonreference drug filer as part of the resolution or settlement consists of only one or more of the following:

(i) 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 patent infringement claim; or

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

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

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

(A) 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

(B) The compensation shall not exceed the lower of the following:

(1) Seven million five hundred thousand dollars; or

1 (2) Five percent of the revenue that the nonreference drug filer
2 projected or forecasted it would receive in the first three years of
3 sales of its version of the reference drug documented at least twelve
4 months before the settlement. If no projections or forecasts are avail-
5 able, the compensation shall not exceed two hundred fifty thousand
6 dollars;

7 (iv) An agreement resolving or settling a patent infringement claim
8 that permits a nonreference drug filer to begin selling, offering for
9 sale, or distributing the nonreference drug product if the reference
10 drug holder seeks approval to launch, obtains approval to launch, or
11 launches a different dosage, strength, or form of the reference drug
12 having the same active ingredient before the date set by the agreement
13 for entry of the nonreference drug filer. A different form of the refer-
14 ence drug shall not include an authorized generic version of the refer-
15 ence drug;

16 (v) An agreement by the reference drug holder not to interfere with
17 the nonreference drug filer's ability to secure and maintain regulatory
18 approval to market the nonreference drug product or an agreement to
19 facilitate the nonreference drug filer's ability to secure and maintain
20 regulatory approval to market the nonreference drug product; or

21 (vi) An agreement resolving a patent infringement claim in which the
22 reference drug holder forgives the potential damages accrued by a
23 nonreference drug filer for an at-risk launch of the nonreference drug
24 product that is the subject of that claim.

25 (c) Parties to an agreement are not in violation of paragraph (a) of
26 this subdivision if they can demonstrate by clear and convincing
27 evidence that either of the following are met:

28 (i) The value received by the nonreference drug filer described in
29 subparagraph (i) of paragraph (a) of this subdivision is a fair and
30 reasonable compensation solely for other goods or services that the
31 nonreference drug filer has promised to provide; or

32 (ii) The agreement has directly generated procompetitive benefits and
33 the procompetitive benefits of the agreement outweigh the anticompet-
34 itive effects of the agreement.

35 2. In determining whether the parties to the agreement have met their
36 burden under paragraph (c) of subdivision one of this section, a court
37 of competent jurisdiction shall not consider any of the following:

38 (a) That entry into the marketplace could not have occurred until the
39 expiration of the relevant patent exclusivity or that the agreement's
40 provision for entry of the nonreference drug product before the expira-
41 tion of any patent exclusivity means that the agreement is procompet-
42 itive within the meaning of subparagraph (ii) of paragraph (c) of subdi-
43 vision one of this section;

44 (b) That any patent is enforceable and infringed by the nonreference
45 drug filer in the absence of a final adjudication binding on the filer
46 of those issues;

47 (c) That the agreement caused no delay in entry of the nonreference
48 drug filer's drug product because of the lack of Federal Food and Drug
49 Administration (FDA) approval of that or of another nonreference drug
50 product; or

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

1 3. In determining whether the parties to the agreement have met their
2 burden under paragraph (c) of subdivision one of this section, a court
3 of competent jurisdiction shall presume that the relevant product market
4 is that market consisting of the brand or reference drug of the company
5 alleging patent infringement and the drug product of the nonreference
6 drug filer accused of infringement and any other biological product that
7 is licensed as biosimilar or is an AB-rated generic to the reference
8 product.

9 4. (a) This section shall not modify, impair, limit, or supersede the
10 applicability of the antitrust laws of the state pursuant to article
11 twenty-two of the general business law, unfair competition laws of the
12 state pursuant to article twenty-two-A of the general business law or
13 the availability of damages or remedies provided therein. This section
14 shall not modify, impair, limit, or supersede the right of any drug
15 company applicant to assert claims or counterclaims against any person,
16 under the antitrust laws or other laws relating to unfair competition of
17 the federal antitrust law or state law.

18 (b) If any provision of this subdivision, an amendment made to this
19 subdivision, or the application of any provision or amendment to any
20 person or circumstance is held to be unconstitutional, the remainder of
21 this subdivision, the amendments made to this subdivision, and the
22 application of the provisions of this subdivision or amendments to any
23 person or circumstance shall not be affected.

24 5. (a)(i) Each person that violates or assists in the violation of
25 this section shall forfeit and pay to the state a civil penalty suffi-
26 cient to deter violations of this section, as follows:

27 (A) If the person who violated this section received any value due to
28 that violation, an amount up to three times the value received by the
29 party that is reasonably attributable to the violation of this section,
30 or twenty million dollars, whichever is greater; or

31 (B) If the violator has not received anything of value as described in
32 this subparagraph, an amount up to three times the value given to other
33 parties to the agreement reasonably attributable to the violation of
34 this section, or twenty million dollars.

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

38 (ii) Any penalty described in subparagraph (i) of this paragraph shall
39 accrue only to the state and shall be recovered in a civil action
40 brought by the attorney general in its own name, or by any of its attor-
41 neys designated by it for that purpose, against any party to an agree-
42 ment that violates this section.

43 (b) Each party that violates or assists in the violation of this
44 section shall be liable for any damages, penalties, costs, fees, injunc-
45 tions, or other equitable or legal remedies, including, but not limited
46 to, restitution and disgorgement, that may be just and reasonable. Such
47 remedies shall include, but not be limited to, any remedy available
48 under articles twenty-two or twenty-two-A of the general business law
49 and section sixty-three of the executive law.

50 (c) If the state is awarded penalties under subparagraph (i) of para-
51 graph (a) of this subdivision, it shall not recover penalties pursuant
52 to another law identified in paragraph (b) of this subdivision. This
53 section shall not be construed to foreclose the state's ability to claim
54 any equitable or legal remedy available in paragraph (b) of this subdi-
55 vision.

1 (d) An action to enforce a cause of action for a violation of this
2 section shall be commenced within six years after the cause of action
3 accrued.

4 § 2. Severability clause. If any clause, sentence, paragraph, subdivi-
5 sion, section or part of this act shall be adjudged by any court of
6 competent jurisdiction to be invalid or unenforceable, such judgment
7 shall not affect, impair, or invalidate the remainder thereof, but shall
8 be confined in its operation to the clause, sentence, paragraph, subdivi-
9 sion, section or part thereof directly involved in the controversy in
10 which such judgment shall have been rendered. It is hereby declared to
11 be the intent of the legislature that this act would have been enacted
12 even if such invalid provisions had not been included herein.

13 § 3. This act shall take effect on the sixtieth day after it shall
14 have become a law.