

STATE OF NEW YORK

7245

2021-2022 Regular Sessions

IN ASSEMBLY

April 29, 2021

Introduced by M. of A. GOTTFRIED -- read once and referred to the
Committee on Health

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 Assem-
bly, 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.

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

9 1. "ANDA" shall mean abbreviated new drug application.

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

13 3. "Agreement" shall mean anything that would constitute an agreement
14 under state law.

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

21 (a) Any agreement required to be provided to the federal trade commis-
22 sion or the antitrust division of the United States Department of
23 Justice under the Medicare Prescription Drug, Improvement, and Modern-
24 ization Act of 2003, Pub. L. No. 108-173;

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

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

5 5. "Biosimilar biological product application filer" shall mean a
6 party that owns or controls a biosimilar biological product application
7 filed with the federal food and drug administration pursuant to section
8 351(k) of the Public Health Service Act, 42 U.S.C. 262(k), for licensure
9 of a biological product as biosimilar to, or interchangeable with, a
10 reference product, or that has the exclusive rights under the applica-
11 tion to distribute the biosimilar biological product.

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

13 7. "Nonreference drug filer" shall mean either:

14 (a) An ANDA filer; or

15 (b) A biosimilar biological product application filer.

16 8. "Nonreference drug product" shall mean the product to be manufac-
17 tured under an ANDA that is the subject of the patent infringement
18 claim, a biosimilar biological product that is the product to be manu-
19 factured under the biosimilar biological product application that is the
20 subject of the patent infringement claim, or both.

21 9. "Patent infringement" shall mean infringement of any patent or of
22 any filed patent application, extension, reissue, renewal, division,
23 continuation, continuation in part, reexamination, patent term restora-
24 tion, patents of addition, and extensions thereof.

25 10. "Patent infringement claim" shall mean any allegation made to a
26 nonreference drug filer, whether or not included in a complaint filed
27 with a court of law, that its nonreference drug product or application
28 infringes any patent held by, or exclusively licensed to, the reference
29 drug holder.

30 11. "Reference drug holder" shall mean either:

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

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

35 (ii) A person owning or controlling enforcement of the patent listed
36 in the approved drug products with therapeutic equivalence evaluations
37 in connection with the NDA; or

38 (iii) The predecessors, subsidiaries, divisions, groups, and affil-
39 iates controlled by, controlling, or under common control with, any of
40 the entities described in subparagraph (i) or (ii) of this paragraph,
41 with control to be presumed by direct or indirect share ownership of
42 fifty percent or greater, as well as the licensees, licensors, succes-
43 sors, and assigns of each of those entities; or

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

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

49 (ii) A person owning or controlling enforcement of any patents that
50 claim the biological product that is the subject of the approved biolog-
51 ical patent license application; or

52 (iii) The predecessors, subsidiaries, divisions, groups, and affil-
53 iates controlled by, controlling, or under common control with, any of
54 the entities described in subparagraph (i) or (ii) of this paragraph,
55 with control to be presumed by direct or indirect share ownership of

1 fifty percent or greater, as well as the licensees, licensors, succes-
2 sors, and assigns of each of those entities.

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

7 13. "Statutory exclusivity" shall mean those prohibitions on the
8 approval of drug applications under clauses (ii) through (iv) of section
9 505(c)(3)(E), section 527 or section 505A of the Federal Food, Drug, and
10 Cosmetic Act, 21 U.S.C. 355(c)(3)(E), on the licensing of biological
11 product applications under section 262(k)(7) of Title 42 of the United
12 States Code or section 262(m)(2) or (3) of Title 42 of the United States
13 Code.

14 § 283. Preserving access to affordable drugs. 1. (a) Except as
15 provided in paragraph (c) of this subdivision, an agreement resolving or
16 settling, on a final or interim basis, a patent infringement claim, in
17 connection with the sale of a pharmaceutical product, shall be presumed
18 to have anticompetitive effects and shall be a violation of this section
19 if both of the following apply:

20 (i) A nonreference drug filer receives anything of value from another
21 company asserting patent infringement, including, but not limited to, an
22 exclusive license or a promise that the brand company will not launch an
23 authorized generic version of its brand drug; and

24 (ii) The nonreference drug filer agrees to limit or forego research,
25 development, manufacturing, marketing, or sales of the nonreference drug
26 filer's product for any period of time.

27 (b) As used in subparagraph (i) of paragraph (a) of this subdivision,
28 "anything of value" shall not include a settlement of a patent infringe-
29 ment claim in which the consideration granted by the brand or reference
30 drug filer to the nonreference drug filer as part of the resolution or
31 settlement consists of only one or more of the following:

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

34 (A) A patent that is the basis for the patent infringement claim; or

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

37 (ii) A covenant not to sue on a claim that the nonreference drug prod-
38 uct infringes a United States patent;

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

41 (A) The total compensation for saved litigation expenses is reflected
42 in budgets that the reference drug holder documented and adopted at
43 least six months before the settlement; and

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

45 (1) Seven million five hundred thousand dollars; or

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

52 (iv) An agreement resolving or settling a patent infringement claim
53 that permits a nonreference drug filer to begin selling, offering for
54 sale, or distributing the nonreference drug product if the reference
55 drug holder seeks approval to launch, obtains approval to launch, or
56 launches a different dosage, strength, or form of the reference drug

1 having the same active ingredient before the date set by the agreement
2 for entry of the nonreference drug filer. A different form of the refer-
3 ence drug shall not include an authorized generic version of the refer-
4 ence drug;

5 (v) An agreement by the reference drug holder not to interfere with
6 the nonreference drug filer's ability to secure and maintain regulatory
7 approval to market the nonreference drug product or an agreement to
8 facilitate the nonreference drug filer's ability to secure and maintain
9 regulatory approval to market the nonreference drug product; or

10 (vi) An agreement resolving a patent infringement claim in which the
11 reference drug holder forgives the potential damages accrued by a
12 nonreference drug holder for an at-risk launch of the nonreference drug
13 product that is the subject of that claim.

14 (c) Parties to an agreement are not in violation of paragraph (a) of
15 this subdivision if they can demonstrate by a preponderance of the
16 evidence that either of the following are met:

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

21 (ii) The agreement has directly generated procompetitive benefits and
22 the procompetitive benefits of the agreement outweigh the anticompet-
23 itive effects of the agreement.

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

27 (a) That entry into the marketplace could not have occurred until the
28 expiration of the relevant patent exclusivity or that the agreement's
29 provision for entry of the nonreference drug product before the expira-
30 tion of any patent exclusivity means that the agreement is procompet-
31 itive within the meaning of subparagraph (ii) of paragraph (c) of subdivi-
32 vision one of this section;

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

36 (c) That the agreement caused no delay in entry of the nonreference
37 drug filer's drug product because of the lack of Federal Food and Drug
38 Administration (FDA) approval of that or of another nonreference drug
39 product;

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

45 (e) This subdivision shall not be construed to preclude a party from
46 introducing evidence regarding paragraphs (a), (b), (c) and (d) of this
47 subdivision, inclusive, and shall not be construed to preclude a court
48 of competent jurisdiction from making a determination regarding para-
49 graphs (a), (b), (c) and (d) of this subdivision, inclusive, based on
50 the full scope of the evidence.

51 3. In determining whether the parties to the agreement have met their
52 burden under paragraph (c) of subdivision one of this section, a court
53 of competent jurisdiction shall presume that the relevant product market
54 is that market consisting of the brand or reference drug of the company
55 alleging patent infringement and the drug product of the nonreference
56 company accused of infringement and any other biological product that is

1 licensed as biosimilar or is an AB-rated generic to the reference prod-
2 uct.

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

12 (b) If any provision of this subdivision, an amendment made to this
13 subdivision, or the application of any provision or amendment to any
14 person or circumstance is held to be unconstitutional, the remainder of
15 this subdivision, the amendments made to this subdivision, and the
16 application of the provisions of this subdivision or amendments to any
17 person or circumstance shall not be affected.

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

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

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

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

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

37 (b) Each party that violates or assists in the violation of this
38 section shall be liable for any damages, penalties, costs, fees, injunc-
39 tions, or other remedies that may be just and reasonable and available
40 under articles twenty-two or twenty-two-A of the general business law.

41 (c) If the state is awarded penalties under subparagraph (i) of para-
42 graph (a) of this subdivision, it shall not recover penalties pursuant
43 to another law identified in paragraph (b) of this subdivision. This
44 section shall not be construed to foreclose the state's ability to claim
45 any relief or damages available in paragraph (b) of this subdivision,
46 other than those that are penalties.

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

50 § 2. Severability clause. If any clause, sentence, paragraph, subdivi-
51 sion, section or part of this act shall be adjudged by any court of
52 competent jurisdiction to be invalid, such judgment shall not affect,
53 impair, or invalidate the remainder thereof, but shall be confined in
54 its operation to the clause, sentence, paragraph, subdivision, section
55 or part thereof directly involved in the controversy in which such judg-
56 ment shall have been rendered. It is hereby declared to be the intent of

1 the legislature that this act would have been enacted even if such
2 invalid provisions had not been included herein.
3 § 3. This act shall take effect on the one hundred eightieth day after
4 it shall have become a law.