



102ND GENERAL ASSEMBLY

State of Illinois

2021 and 2022

HB3729

Introduced 2/22/2021, by Rep. Tom Demmer

SYNOPSIS AS INTRODUCED:

New Act

Creates the Preserving Access to Affordable Drugs Act. Provides that an agreement resolving or settling, on a final or interim basis, a patent infringement claim in connection with the sale of a pharmaceutical product is presumed to have anticompetitive effects and is a violation of the Act if certain circumstances apply. Provides other requirements for patent infringement claims in connection with the sale of a pharmaceutical product. Contains provisions regarding presumptions in an action under the Act. Provides civil penalties for violating the Act. Provides that any penalty shall accrue only to the State of Illinois and shall be recovered in a civil action brought by the Attorney General against any party to an agreement that violates this Act. Requires an action to enforce a cause of action for a violation of the Act to be commenced within 4 years after the cause of action accrued. Contains other provisions.

LRB102 13949 CPF 19301 b

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

1 AN ACT concerning health.

2 **Be it enacted by the People of the State of Illinois,**
3 **represented in the General Assembly:**

4 Section 1. Short title. This Act may be cited as the
5 Preserving Access to Affordable Drugs Act.

6 Section 5. Definitions. In this Act:

7 "ANDA" means abbreviated new drug application.

8 "ANDA filer" means a party that owns or controls an ANDA
9 filed with the Food and Drug Administration or has the
10 exclusive rights under that ANDA to distribute the ANDA
11 product.

12 "Agreement" means anything that would constitute an
13 agreement or a trust under Illinois law.

14 "Agreement resolving or settling a patent infringement
15 claim" includes any agreement that is entered into within 30
16 days of the resolution or the settlement of the claim or any
17 other agreement that is contingent upon, provides a contingent
18 condition for, or is otherwise related to the resolution or
19 settlement of the claim. "Agreement resolving or settling a
20 patent infringement claim" includes, but is not limited to,
21 the following:

22 (1) Any agreement required to be provided to the
23 Federal Trade Commission or the Antitrust Division of the

1 United States Department of Justice under the federal
2 Medicare Prescription Drug, Improvement, and Modernization
3 Act of 2003 (Public Law 108-173).

4 (2) Any agreement between a biosimilar or
5 interchangeable product applicant and a reference product
6 sponsor that resolves patent claims between the applicant
7 and sponsor.

8 "Biosimilar biological product application filer" means a
9 party that owns or controls a biosimilar biological product
10 application filed with the Food and Drug Administration under
11 Section 351(k) of the federal Public Health Service Act (42
12 U.S.C. 262(k)) for licensure of a biological product as
13 biosimilar to, or interchangeable with, a reference product,
14 or that has the exclusive rights under the application to
15 distribute the biosimilar biological product.

16 "NDA" means new drug application.

17 "Nonreference drug filer" means either:

18 (1) an ANDA filer; or

19 (2) a biosimilar biological product application filer.

20 "Nonreference drug product" means the product to be
21 manufactured under an ANDA that is the subject of the patent
22 infringement claim, a biosimilar biological product that is
23 the product to be manufactured under the biosimilar biological
24 product application that is the subject of the patent
25 infringement claim, or both.

26 "Patent infringement" means infringement of any patent or

1 of any filed patent application, extension, reissue, renewal,
2 division, continuation, continuation in part, reexamination,
3 patent term restoration, patent of addition, and any extension
4 thereof.

5 "Patent infringement claim" means any allegation made
6 against a nonreference drug filer, whether or not included in
7 a complaint filed with a court of law, that its nonreference
8 drug product or application infringes any patent held by, or
9 exclusively licensed to, the reference drug holder.

10 "Reference drug holder" means either:

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

12 (A) The holder of an approved NDA for a drug
13 product application filed under Section 505(b) of the
14 federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 355(b)).

16 (B) A person owning or controlling enforcement of
17 the patent listed in the Approved Drug Products With
18 Therapeutic Equivalence Evaluations (commonly known as
19 the "FDA Orange Book") in connection with the NDA.

20 (C) The predecessors, subsidiaries, divisions,
21 groups, and affiliates controlled by, controlling, or
22 under common control with, any of the entities
23 described in subparagraph (A) or (B), with control to
24 be presumed by direct or indirect share ownership of
25 50% or greater, as well as the licensees, licensors,
26 successors, and assigns of each of those entities.

1 (2) A biological product license holder, which means
2 any of the following:

3 (A) The holder of an approved biological product
4 license application for a biological drug product
5 under Section 351(a) of the federal Public Health
6 Service Act (42 U.S.C. 262(a)).

7 (B) A person owning or controlling enforcement of
8 any patents that claim the biological product that is
9 the subject of the approved biological patent license
10 application.

11 (C) The predecessors, subsidiaries, divisions,
12 groups, and affiliates controlled by, controlling, or
13 under common control with, any of the entities
14 described in subparagraph (A) or (B), with control to
15 be presumed by direct or indirect share ownership of
16 50% or greater, as well as the licensees, licensors,
17 successors, and assigns of each of those entities.

18 "Reference drug product" means the product to be
19 manufactured by the reference drug holder and includes both
20 branded drugs of the NDA holder and the biologic drug product
21 of the biologic product license applicant.

22 "Statutory exclusivity" means those prohibitions on the
23 approval of drug applications under clauses (ii) through (iv),
24 inclusive, of Section 505(c)(3)(E) (5-year and 3-year data
25 exclusivity), Section 527 (orphan drug exclusivity), or
26 Section 505A (pediatric exclusivity) of the federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E), 360cc, and
2 355a, respectively) or on the licensing of biological product
3 applications under Section 262(k)(7) of Title 42 of the United
4 States Code (12-year exclusivity) or Section 262(m)(2) or (3)
5 of Title 42 of the United States Code (pediatric exclusivity).

6 Section 10. Patent infringement claim.

7 (a) Except as provided in subsection (b), an agreement
8 resolving or settling, on a final or interim basis, a patent
9 infringement claim, in connection with the sale of a
10 pharmaceutical product, is presumed to have anticompetitive
11 effects and is a violation of this Act if both of the following
12 apply:

13 (1) A nonreference drug filer receives anything of
14 value from another company asserting patent infringement,
15 including, but not limited to, an exclusive license or a
16 promise that the brand company will not launch an
17 authorized generic version of its brand drug.

18 (2) The nonreference drug filer agrees to limit or
19 forgo research, development, manufacturing, marketing, or
20 sales of the nonreference drug filer's product for any
21 period of time.

22 As used in this subsection, "anything of value" does not
23 include a settlement of a patent infringement claim in which
24 the consideration granted by the brand or reference drug filer
25 to the nonreference drug filer as part of the resolution or

1 settlement consists of only one or more of the following:

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

4 (A) a patent that is the basis for the patent
5 infringement claim; or

6 (B) a patent right or other statutory exclusivity
7 that would prevent the marketing of the drug.

8 (2) A covenant not to sue on a claim that the
9 nonreference drug product infringes a United States
10 patent.

11 (3) Compensation for saved reasonable future
12 litigation expenses of the reference drug holder, but only
13 if both of the following are true:

14 (A) The total compensation for saved litigation
15 expenses is reflected in budgets that the reference
16 drug holder documented and adopted at least 6 months
17 before the settlement.

18 (B) The compensation does not exceed the lower of
19 the following:

20 (i) \$7,500,000.

21 (ii) 5% of the revenue that the nonreference
22 drug holder projected or forecasted it would
23 receive in the first 3 years of sales of its
24 version of the reference drug documented at least
25 12 months before the settlement. If no projections
26 or forecasts are available, the compensation does

1 not exceed \$250,000.

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

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

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

25 (b) Parties to an agreement are not in violation of
26 subsection (a) if they can demonstrate by a preponderance of

1 the evidence that either of the following are met:

2 (1) The value received by the nonreference drug filer
3 described in paragraph (1) of subsection (a) is a fair and
4 reasonable compensation solely for other goods or services
5 that the nonreference drug filer has promised to provide.

6 (2) The agreement has directly generated
7 procompetitive benefits and the procompetitive benefits of
8 the agreement outweigh the anticompetitive effects of the
9 agreement.

10 Section 15. Presumptions.

11 (a) In determining whether the parties to the agreement
12 have met their burden under subsection (b) of Section 10, the
13 fact-finder shall not presume any of the following:

14 (1) That entry into the marketplace could not have
15 occurred until the expiration of the relevant patent
16 exclusivity or that the agreement's provision for entry of
17 the nonreference drug product before the expiration of any
18 patent exclusivity means that the agreement is
19 procompetitive within the meaning of paragraph (2) of
20 subsection (b) of Section 10.

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

24 (3) That the agreement caused no delay in entry of the
25 nonreference drug filer's drug product because of the lack

1 of United States Food and Drug Administration approval of
2 that or of another nonreference drug product.

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

10 This subsection shall not be construed to preclude a party
11 from introducing evidence regarding paragraphs (1) through
12 (4), inclusive, and shall not be construed to preclude the
13 fact-finder from making a determination regarding paragraphs
14 (1) through (4), based on the full scope of the evidence.

15 (b) In determining whether the parties to the agreement
16 have met their burden under subsection (b) of Section 10, the
17 fact-finder shall presume that the relevant product market is
18 that market consisting of the brand or reference drug of the
19 company alleging patent infringement and the drug product of
20 the nonreference company accused of infringement and any other
21 biological product that is licensed as biosimilar or is an
22 AB-rated generic to the reference product.

23 (c) This Act does not modify, impair, limit, or supersede
24 the right of any drug company applicant to assert claims or
25 counterclaims against any person under the antitrust laws or
26 other laws relating to unfair competition of the federal

1 antitrust law or State law.

2 Section 20. Violations; commencing an action.

3 (a) Each person that violates or assists in the violation
4 of this Act shall forfeit and pay to the State of Illinois a
5 civil penalty sufficient to deter violations of this Act, as
6 follows:

7 (1) If the person who violated this Section received
8 any value due to that violation, an amount up to 3 times
9 the value received by the party that is reasonably
10 attributable to the violation of this Section, or
11 \$20,000,000, whichever is greater.

12 (2) If the violator has not received anything of value
13 due to that violation, an amount up to 3 times the value
14 given to other parties to the agreement reasonably
15 attributable to the violation of this Act, or \$20,000,000,
16 whichever is greater.

17 For purposes of this subsection, "reasonably attributable
18 to the violation" shall be determined by Illinois' share of
19 the market for the brand drug at issue in the agreement.

20 (b) Any penalty described in subsection (a) shall accrue
21 only to the State of Illinois and shall be recovered in a civil
22 action brought by the Attorney General in his or her own name,
23 or by any of his or her attorneys designated by him or her for
24 that purpose, against any party to an agreement that violates
25 this Act.

1 (c) An action to enforce a cause of action for a violation
2 of this Act shall be commenced within 4 years after the cause
3 of action accrued.