

Senate Bill 764

Sponsored by Senator PATTERSON, Representative WALLAN, Senator LINTHICUM, Representative HUDSON; Senators GORSEK, LIEBER, Representatives CAMPOS, GRAYBER, LEVY, NERON, NOSSE, PRUSAK, SALINAS, SANCHEZ, SCHOUTEN, WITT

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced**.

Provides that Attorney General and court must presume that resolution agreement that ends dispute over alleged infringement of patent or violation of other protection for protected drug has anticompetitive effects if alleged infringer receives item of value as part of or in connection with resolution agreement or if alleged infringer agrees to limit or stop researching, developing, manufacturing, marketing or selling competing drug.

Specifies basis on which party to resolution agreement may overcome presumption.

Provides that Attorney General may bring action to recover civil penalty for violations of Act in amount that is equivalent to three times value of item of value that alleged infringer received or \$10 million, whichever is greater.

Takes effect on 91st day following adjournment sine die.

A BILL FOR AN ACT

1
2 Relating to agreements that lead to anticompetitive behavior in the market for pharmaceutical
3 drugs; and prescribing an effective date.

4 **Be It Enacted by the People of the State of Oregon:**

SECTION 1. (1) As used in this section:

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6 (a) **"Alleged infringer" means a person that receives or is subject to an allegation, com-**
7 **plaint, demand, service of process or other communication in connection with a claim that**
8 **the person's research, development, manufacture, marketing, distribution or sale of a com-**
9 **peting drug infringes a patent or other protection for a protected drug.**

10 (b) **"Claimant" means a person that holds a patent for a protected drug or is the benefi-**
11 **ciary of other protection for a protected drug.**

12 (c) **"Competing drug" means a drug that has properties that are similar enough to the**
13 **properties of a protected drug to offer market competition to the protected drug or that**
14 **serve as a basis for a claimant's claim that an alleged infringer that manufactures, markets,**
15 **distributes or sells the drug has infringed the patent or other protection for the protected**
16 **drug.**

17 (d)(A) **"Item of value" means any tangible or intangible item including, but not limited**
18 **to:**

19 (i) **An exclusive license to manufacture, market, distribute or sell a protected drug; or**

20 (ii) **A promise that a claimant will not manufacture, market, distribute or sell a generic**
21 **version of a protected drug in competition with the recipient of the promise.**

22 (B) **"Item of value" does not include an agreement for which there is consideration in the**
23 **form of:**

24 (i) **A right or license to manufacture, market, distribute or sell in the United States a**
25 **competing drug before the expiration of:**

NOTE: Matter in **boldfaced** type in an amended section is new; matter *[italic and bracketed]* is existing law to be omitted. New sections are in **boldfaced** type.

- 1 **(I) The patent for or a right related to the patent for the protected drug; or**
2 **(II) The period during which federal law prevents approval of an application to manufac-**
3 **ture, market, distribute or sell a competing drug;**
4 **(ii) A covenant not to sue on a claim that an alleged infringer’s competing drug infringes**
5 **a patent;**
6 **(iii) A payment to the alleged infringer of a portion of the litigation and other legal ex-**
7 **penditures a claimant avoided as a result of the agreement, if the claimant identified and docu-**
8 **mented the expenses at least six months before executing the agreement and the payment**
9 **does not exceed the lesser of:**
10 **(I) \$7.5 million;**
11 **(II) Five percent of the revenue that the alleged infringer projected receiving in the first**
12 **three years of sales of the alleged infringer’s competing drug, if the alleged infringer made**
13 **and documented the projected revenue at least one year before executing the agreement; or**
14 **(III) \$250,000 if the alleged infringer did not make and document the projected revenue**
15 **as described in sub-sub-subparagraph (II) of this sub-subparagraph;**
16 **(iv) Permission for the alleged infringer to begin manufacturing, marketing, distributing,**
17 **offering for sale or selling a competing drug if before the expiration of the patent or other**
18 **protection for the protected drug the claimant seeks or obtains approval to, or actually does,**
19 **manufacture, market, distribute or sell a version other than a licensed generic version of the**
20 **protected drug that has the same active ingredient but a different dosage, strength or**
21 **physical form;**
22 **(v) A promise from the claimant to facilitate or not to interfere with the alleged**
23 **infringer’s ability to obtain regulatory approval to manufacture, market, distribute and sell**
24 **a competing drug; or**
25 **(vi) A renunciation or disclaimer of damages for an alleged infringer’s infringement of**
26 **the patent or other protection for the protected drug.**
27 **(e) “Patent” means:**
28 **(A) A patent that has been issued;**
29 **(B) An extension, reissue, renewal, division, continuation, continuation in part, reexam-**
30 **ination or term restoration for a patent;**
31 **(C) An application for a patent that has been filed; or**
32 **(D) A patent of addition or an extension to a patent of addition.**
33 **(f) “Protected drug” means a pharmaceutical drug that is subject to and protected by:**
34 **(A) A patent; or**
35 **(B) A federal law under which approval of an application to manufacture, market, dis-**
36 **tribute or sell a competing drug may not occur for a specified length of time.**
37 **(g) “Resolution agreement” means an agreement in any form that accompanies, is part**
38 **of, is consideration for, is contingent upon, is substituted for, or is otherwise directly related**
39 **to and is entered into within 30 days before or after:**
40 **(A) A settlement in lieu of a trial or a dismissal following the commencement of an**
41 **action;**
42 **(B) A mediated compromise or other compromise;**
43 **(C) A decision in an arbitration proceeding;**
44 **(D) A judgment entered by a court;**
45 **(E) A withdrawal, retraction or suspension of a claim or a failure to prosecute a claim**

1 that leads to a dismissal; or

2 (F) Any other formal or informal resolution that ends a dispute.

3 (2) Except as provided in subsection (3) of this section, the Attorney General and any
4 court before which the Attorney General brings an action under this section shall presume
5 that a resolution agreement that ends a dispute over an alleged infringement of a patent,
6 or a violation of other protection for a protected drug, has anticompetitive effects and is a
7 violation of this section if, as part of or in connection with the resolution agreement, an al-
8 leged infringer:

9 (a) Receives an item of value; or

10 (b) Agrees to limit or stop researching, developing, manufacturing, marketing or selling
11 a competing drug.

12 (3) A resolution agreement does not violate this section and a party to the resolution
13 agreement may overcome the presumption set forth in subsection (2) of this section if the
14 party by a preponderance of evidence can demonstrate that:

15 (a) The item of value that the alleged infringer received is fair and reasonable compen-
16 sation solely for goods or services that the claimant promised to provide to the alleged
17 infringer; or

18 (b) The agreement has directly fostered competition within the relevant market and the
19 benefits of the resolution agreement favor competition to the extent that the benefits out-
20 weigh the anticompetitive effects of the resolution agreement.

21 (4) In determining whether a party has met the party's burden under subsection (3) of
22 this section, the Attorney General or the court:

23 (a) Shall presume that the relevant market for the purposes of determining the effects
24 of the resolution agreement consists of the market within this state for the protected drug,
25 the competing drug and any other biological product that, as described in 42 U.S.C. 262(i)(2),
26 as in effect on the effective date of this 2021 Act, is interchangeable with or biosimilar to the
27 protected drug.

28 (b) May not presume that:

29 (A) Because the alleged infringer could not have manufactured, marketed, distributed or
30 sold a competing drug before the patent or other protection for a protected drug had expired,
31 or because the resolution agreement gives permission or a license to the alleged infringer
32 to manufacture, market, distribute or sell a competing drug, the benefits of the resolution
33 agreement outweigh the anticompetitive effects of the resolution agreement;

34 (B) The patent or other protection for the protected drug was enforceable and the alleged
35 infringer did infringe the patent or violate another available protection for the protected
36 drug, unless a final adjudication on the merits of the claimant's claim or action determines
37 that the patent or other protection was enforceable and the infringement did occur;

38 (C) The agreement did not delay the manufacturing, marketing, distribution or sale of a
39 competing drug because the alleged infringer lacked approval from the federal Food and Drug
40 Administration and the lack of approval meant that the alleged infringer could not have
41 manufactured, marketed, distributed or sold the competing drug; or

42 (D) The agreement did not delay or cause harm because the competing drug might have
43 infringed a patent or violated a protection for a protected drug for which a claimant has not
44 made a claim or for which a final adjudication on the merits has not occurred with respect
45 to the scope, enforceability or infringement of the patent or other protection.

1 (5) The presumptions set forth in subsections (2) and (3) of this section do not preclude
2 a party from introducing evidence with respect to the presumptions and do not preclude the
3 Attorney General or the court from making a determination, based on the full scope of the
4 evidence, as to whether the presumptions are warranted.

5 (6) A person that violates or assists in violating this section, in addition to and not in lieu
6 of other remedies available under other law, is liable for a civil penalty in an amount that
7 is equivalent to the greater of:

8 (a) Three times the value of the item of value that the alleged infringer received; or

9 (b) \$10 million.

10 (7) The Attorney General, within four years after a violation of this section occurs or
11 within four years after the Attorney General discovers that a violation has occurred,
12 whichever is later, may bring an action in a circuit court of this state to punish violations
13 of this section. The Attorney General shall deposit the proceeds of any civil penalty the At-
14 torney General recovers from a violator into the General Fund. Amounts the Attorney
15 General deposits into the General Fund under this subsection are available for general gov-
16 ernmental expenses.

17 (8) This section does not impair, modify, limit or supersede the applicability of ORS
18 646.605 to 646.652 or 646.705 to 646.805 to acts that violate this section, except that to the
19 extent the Attorney General recovers a civil penalty under this section, an agency of this
20 state may not recover a civil penalty or other monetary amount under ORS 646.605 to 646.652
21 or 646.705 to 646.805 for the same act.

22 SECTION 2. Section 1 of this 2021 Act applies to resolution agreements into which a
23 claimant and an alleged infringer, both as defined in section 1 of this 2021 Act, enter on or
24 after the effective date of this 2021 Act.

25 SECTION 3. This 2021 Act takes effect on the 91st day after the date on which the 2021
26 regular session of the Eighty-first Legislative Assembly adjourns sine die.
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