

SENATE AMENDMENTS TO SENATE BILL 764

By COMMITTEE ON HEALTH CARE

April 19

1 On page 1 of the printed bill, line 3, after “drugs” insert a period and delete the rest of the line.
2 Delete lines 5 through 25 and delete pages 2 through 4 and insert:

3 **“SECTION 1. (1) As used in this section:**

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

8 **“(b) ‘Claimant’ means a person that holds a patent for a protected drug or is the bene-**
9 **ficiary of other protection for a protected drug.**

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

15 **“(d)(A) ‘Item of value’ means any tangible or intangible item including, but not limited**
16 **to:**

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

18 **“(ii) An agreement that a claimant will not manufacture, market, distribute or sell a**
19 **generic version of a protected drug in competition with the other party to the agreement.**

20 **“(B) ‘Item of value’ does not include an agreement for which there is consideration in**
21 **the form of:**

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

24 **“(I) The patent for or a right related to the patent for the protected drug; or**

25 **“(II) The period during which federal law prevents approval of an application to manu-**
26 **facture, market, distribute or sell a competing drug;**

27 **“(ii) A covenant not to sue on a claim that an alleged infringer’s competing drug in-**
28 **fringes a patent;**

29 **“(iii) A payment to the alleged infringer of a portion of the litigation and other legal ex-**
30 **penses a claimant avoided as a result of the agreement, if the claimant identified and docu-**
31 **mented the expenses at least six months before executing the agreement and the payment**
32 **does not exceed the lesser of:**

33 **“(I) \$7.5 million;**

34 **“(II) Five percent of the revenue that the alleged infringer projected receiving in the first**
35 **three years of sales of the alleged infringer’s competing drug, if the alleged infringer made**

1 and documented the projected revenue at least one year before executing the agreement; or

2 “(III) \$250,000 if the alleged infringer did not make and document the projected revenue
3 as described in sub-sub-subparagraph (II) of this sub-subparagraph;

4 “(iv) Permission for the alleged infringer to begin manufacturing, marketing, distribut-
5 ing, offering for sale or selling a competing drug if, before the expiration of the patent or
6 other protection for the protected drug, the claimant seeks or obtains approval to, or actu-
7 ally does, manufacture, market, distribute or sell a version other than a licensed generic
8 version of the protected drug that has the same active ingredient but a different dosage,
9 strength or physical form;

10 “(v) A promise from the claimant to facilitate or not to interfere with the alleged
11 infringer’s ability to obtain regulatory approval to manufacture, market, distribute and sell
12 a competing drug; or

13 “(vi) A renunciation or disclaimer of damages for an alleged infringer’s infringement of
14 the patent or other protection for the protected drug.

15 “(e) ‘Patent’ means:

16 “(A) A patent that has been issued;

17 “(B) An extension, reissue, renewal, division, continuation, continuation in part, reex-
18 amination or term restoration for a patent;

19 “(C) An application for a patent that has been filed; or

20 “(D) A patent of addition or an extension to a patent of addition.

21 “(f) ‘Protected drug’ means a pharmaceutical drug that is subject to and protected by:

22 “(A) A patent; or

23 “(B) A federal law under which approval of an application to manufacture, market, dis-
24 tribute or sell a competing drug may not occur for a specified length of time.

25 “(g) ‘Resolution agreement’ means an agreement in any form that accompanies, is part
26 of, is consideration for, is contingent upon, is substituted for, or is otherwise directly related
27 to and is entered into within 30 days before or after:

28 “(A) A settlement in lieu of a trial or a dismissal following the commencement of an
29 action;

30 “(B) A mediated compromise or other compromise;

31 “(C) A decision in an arbitration proceeding;

32 “(D) A judgment entered by a court;

33 “(E) A withdrawal, retraction or suspension of a claim or a failure to prosecute a claim
34 that leads to a dismissal; or

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

36 “(2) Except as provided in subsection (3) of this section, a court before which the Attor-
37 ney General brings an action under this section shall presume that a resolution agreement
38 that ends a dispute over an alleged infringement of a patent, or a violation of other pro-
39 tection for a protected drug, has anticompetitive effects and is a violation of this section if,
40 as part of or in connection with the resolution agreement, an alleged infringer:

41 “(a) Receives an item of value; or

42 “(b) Agrees to limit or stop researching, developing, manufacturing, marketing or selling
43 a competing drug.

44 “(3) A resolution agreement does not violate this section and a party to the resolution
45 agreement may overcome the presumption set forth in subsection (2) of this section if the

1 party by a preponderance of evidence can demonstrate that:

2 “(a) The item of value that the alleged infringer received is fair and reasonable compen-
3 sation solely for other goods or services that the claimant promised to provide to the alleged
4 infringer; or

5 “(b) The agreement has directly generated procompetitive benefits within the relevant
6 market and the procompetitive benefits of the resolution agreement favor competition to the
7 extent that the procompetitive benefits materially outweigh the anticompetitive effects of
8 the resolution agreement.

9 “(4) In determining whether a party has met the party’s burden under subsection (3) of
10 this section, the court:

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

16 “(b) May not presume that:

17 “(A) Because the alleged infringer could not have manufactured, marketed, distributed
18 or sold a competing drug before the patent or other protection for a protected drug had ex-
19 pired, or because the resolution agreement gives permission or a license to the alleged
20 infringer to manufacture, market, distribute or sell a competing drug, the benefits of the
21 resolution agreement outweigh the anticompetitive effects of the resolution agreement;

22 “(B) The patent or other protection for the protected drug was enforceable and the al-
23 leged infringer did infringe the patent or violate another available protection for the pro-
24 tected drug, unless a final adjudication on the merits of the claimant’s claim or action
25 determines that the patent or other protection was enforceable and the infringement did
26 occur;

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

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

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

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

39 “(b) \$10 million for each violation.

40 “(6) The Attorney General, within four years after a violation of this section occurs or
41 within four years after the Attorney General discovers that a violation has occurred,
42 whichever is later, may bring an action in a circuit court of this state to punish violations
43 of this section. The Attorney General shall deposit the proceeds of any civil penalty the At-
44 torney General recovers from a violator into the General Fund. Amounts the Attorney
45 General deposits into the General Fund under this subsection are available for general gov-

1 **ernmental expenses.**

2 **“(7) This section does not impair, modify, limit or supersede the applicability of ORS**
3 **646.605 to 646.652 or 646.705 to 646.805 to acts that violate this section.**

4 **“SECTION 2. Section 1 of this 2021 Act applies to resolution agreements into which a**
5 **claimant and an alleged infringer, both as defined in section 1 of this 2021 Act, enter on or**
6 **after the effective date of this 2021 Act.”.**

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