

Requested by Senator PATTERSON

**PROPOSED AMENDMENTS TO  
SENATE BILL 764**

1 On page 1 of the printed bill, line 3, after “drugs” insert a period and  
2 delete the rest of the line.

3 Delete lines 5 through 25 and delete pages 2 through 4 and insert:

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

5 **“(a) ‘Alleged infringer’ means a person that receives or is subject**  
6 **to an allegation, complaint, demand, service of process or other com-**  
7 **munication in connection with a claim that the person’s research,**  
8 **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**  
11 **drug or is the beneficiary of other protection for a protected drug.**

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

18 **“(d)(A) ‘Item of value’ means any tangible or intangible item in-**  
19 **cluding, but not limited to:**

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

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

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

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

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

10       “(II) The period during which federal law prevents approval of an  
11 application to manufacture, market, distribute or sell a competing  
12 drug;

13       “(ii) A covenant not to sue on a claim that an alleged infringer’s  
14 competing drug infringes a patent;

15       “(iii) A payment to the alleged infringer of a portion of the liti-  
16 gation and other legal expenses a claimant avoided as a result of the  
17 agreement, if the claimant identified and documented the expenses at  
18 least six months before executing the agreement and the payment does  
19 not exceed the lesser of:

20       “(I) \$7.5 million;

21       “(II) Five percent of the revenue that the alleged infringer projected  
22 receiving in the first three years of sales of the alleged infringer’s  
23 competing drug, if the alleged infringer made and documented the  
24 projected revenue at least one year before executing the agreement;  
25 or

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

29       “(iv) Permission for the alleged infringer to begin manufacturing,  
30 marketing, distributing, offering for sale or selling a competing drug

1 if, before the expiration of the patent or other protection for the pro-  
2 tected drug, the claimant seeks or obtains approval to, or actually  
3 does, manufacture, market, distribute or sell a version other than a  
4 licensed generic version of the protected drug that has the same active  
5 ingredient but a different dosage, strength or physical form;

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

9 “(vi) A renunciation or disclaimer of damages for an alleged  
10 infringer’s infringement of the patent or other protection for the pro-  
11 tected drug.

12 “(e) ‘Patent’ means:

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

14 “(B) An extension, reissue, renewal, division, continuation, contin-  
15 uation in part, reexamination or term restoration for a patent;

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

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

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

20 “(A) A patent; or

21 “(B) A federal law under which approval of an application to man-  
22 ufacture, market, distribute or sell a competing drug may not occur  
23 for a specified length of time.

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

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

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

1       **“(C) A decision in an arbitration proceeding;**

2       **“(D) A judgment entered by a court;**

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

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

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

13       **“(a) Receives an item of value; or**

14       **“(b) Agrees to limit or stop researching, developing, manufacturing,**  
15 **marketing or selling a competing drug.**

16       **“(3) A resolution agreement does not violate this section and a**  
17 **party to the resolution agreement may overcome the presumption set**  
18 **forth in subsection (2) of this section if the party by a preponderance**  
19 **of evidence can demonstrate that:**

20       **“(a) The item of value that the alleged infringer received is fair and**  
21 **reasonable compensation solely for other goods or services that the**  
22 **claimant promised to provide to the alleged infringer; or**

23       **“(b) The agreement has directly generated procompetitive benefits**  
24 **within the relevant market and the procompetitive benefits of the re-**  
25 **solution agreement favor competition to the extent that the procom-**  
26 **petitive benefits materially outweigh the anticompetitive effects of the**  
27 **resolution agreement.**

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

30       **“(a) Shall presume that the relevant market for the purposes of**

1 **determining the effects of the resolution agreement consists of the**  
2 **market within this state for the protected drug, the competing drug**  
3 **and any other biological product that, as described in 42 U.S.C.**  
4 **262(i)(2), as in effect on the effective date of this 2021 Act, is inter-**  
5 **changeable with or biosimilar to the protected drug.**

6 **“(b) May not presume that:**

7 **“(A) Because the alleged infringer could not have manufactured,**  
8 **marketed, distributed or sold a competing drug before the patent or**  
9 **other protection for a protected drug had expired, or because the re-**  
10 **solution agreement gives permission or a license to the alleged**  
11 **infringer to manufacture, market, distribute or sell a competing drug,**  
12 **the benefits of the resolution agreement outweigh the anticompetitive**  
13 **effects of the resolution agreement;**

14 **“(B) The patent or other protection for the protected drug was en-**  
15 **forceable and the alleged infringer did infringe the patent or violate**  
16 **another available protection for the protected drug, unless a final ad-**  
17 **judication on the merits of the claimant’s claim or action determines**  
18 **that the patent or other protection was enforceable and the infringe-**  
19 **ment did occur;**

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

25 **“(D) The agreement did not delay or cause harm because the com-**  
26 **peting drug might have infringed a patent or violated a protection for**  
27 **a protected drug for which a claimant has not made a claim or for**  
28 **which a final adjudication on the merits has not occurred with respect**  
29 **to the scope, enforceability or infringement of the patent or other**  
30 **protection.**

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

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

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

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

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

19       **“SECTION 2. Section 1 of this 2021 Act applies to resolution agree-**  
20 **ments into which a claimant and an alleged infringer, both as defined**  
21 **in section 1 of this 2021 Act, enter on or after the effective date of this**  
22 **2021 Act.”.**

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