SB 764-A6
(LC 2014)
4/26/21 (TSB/ps)

Requested by Representative HAYDEN

PROPOSED AMENDMENTS TO
A-ENGROSSED SENATE BILL 764

On page 1 of the printed A-engrossed bill, line 3, after "drugs" insert "; and prescribing an effective date".

Delete lines 5 through 22 and delete pages 2 through 4 and insert:

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

"(a) 'Alleged infringer' means a person that receives or is subject to an allegation, complaint, demand, service of process or other communication in connection with a claim that the person's research, development, manufacture, marketing, distribution or sale of a competing drug infringes a patent or other protection for a protected drug.

"(b) 'Claimant' means a person that holds a patent for a protected drug or is the beneficiary of other protection for a protected drug.

"(c) 'Competing drug' means a product to be manufactured under an abbreviated new drug application that is the subject of a patent infringement claim or a biosimilar biological product that is a product to be manufactured under a biosimilar biological product application that is the subject of a patent infringement claim.

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

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

"(ii) A promise that a claimant will not manufacture, market, dis-

tribute or sell a generic version of a protected drug in competition with the recipient of the promise.

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

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

"(I) The patent for or a right related to the patent for the protected drug; or

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

"(ii) A covenant not to sue on a claim that an alleged infringer's competing drug infringes a patent;

"(iii) A payment to the alleged infringer of the litigation and other legal expenses a claimant avoided as a result of the agreement, if the claimant identified and documented the expenses at least six months before executing the agreement, or of the alleged infringer's actual litigation and other legal expenses in the matter that is subject to the resolution agreement, and the payment does not exceed the lesser of:

"(I) $7.5 million;

"(II) Five percent of the revenue that the alleged infringer projected receiving in the first three years of sales of the alleged infringer's competing drug, if the alleged infringer made and documented the projected revenue at least one year before executing the agreement; or

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

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

if:

"(I) Before the expiration of the patent or other protection for the protected drug the claimant seeks or obtains approval to, or actually does, manufacture, market, distribute or sell a version other than a licensed generic version of the protected drug that has the same active ingredient but a different dosage, strength or physical form;

"(II) Before the date on which the alleged infringer may begin manufacturing, marketing, distributing or selling a competing drug in accordance with the agreement, a person that is not a party to the agreement sells a competing drug in this state under a license from the claimant or an authorization that has the same effect as a license; or

"(III) A court determines that the competing drug that is the subject of litigation does not infringe the patent for the protected drug or that the patent claims for the protected drug are invalid or unenforceable; or

"(vi) A renunciation or disclaimer of damages for an alleged infringer's infringement of the patent or other protection for the protected drug.

"(e) 'Patent' means:

"(A) A patent that has been issued;

"(B) An extension, reissue, renewal, division, continuation, continuation in part, reexamination or term restoration for a patent;

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

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

"(f) 'Protected drug' means a pharmaceutical drug that is subject to and protected by:

"(A) A patent; or

"(B) A federal law under which approval of an application to manufacture, market, distribute or sell a competing drug may not occur

for a specified length of time.

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

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

"(B) A mediated compromise or other compromise;

"(C) A decision in an arbitration proceeding;

"(D) A judgment entered by a court;

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

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

"(2) Except as provided in subsection (3) of this section, the Attorney General and any court before which the Attorney General brings an action under this section shall presume that a resolution agreement that ends a dispute over an alleged infringement of a patent has anticompetitive effects and is a violation of this section if, as part of or in connection with the resolution agreement, an alleged infringer:

"(a) Receives an item of value; and

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

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

"(a) The item of value that the alleged infringer received is fair and reasonable compensation solely for goods or services that the claimant promised to provide to the alleged infringer; or

"(b) The procompetitive benefits of the resolution agreement out-

weigh the anticompetitive effects of the resolution agreement.

"(4) In determining whether a party has met the party's burden under subsection (3) of this section, the Attorney General or the court may not presume that:

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

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

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

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

"(5) The presumptions set forth in subsections (2) and (3) of this section:

"(a) Do not preclude a party from introducing evidence with respect to the presumptions;

"(b) Do not preclude the Attorney General or the court from making a determination, based on the full scope of the evidence, as to whether the presumptions are warranted; and

"(c) Apply only in an action described in subsection (7) of this section.

"(6) An alleged infringer or claimant that violates or assists in violating this section, in addition to and not in lieu of other remedies available under other law, is liable for a civil penalty in an amount that is equivalent to the greater of:

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

"(b) $10 million.

"(7) The Attorney General, within four years after the date of an agreement that is subject to a challenge as a violation of this section, may bring an action in a circuit court of this state to punish violations of this section. The Attorney General shall deposit the proceeds of any civil penalty the Attorney General recovers from a violator into the General Fund. Amounts the Attorney General deposits into the General Fund under this subsection are available for general governmental expenses.

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

"SECTION 2. Section 1 of this 2021 Act applies to resolution agreements into which a claimant and an alleged infringer, both as defined

in section 1 of this 2021 Act, enter on or after the effective date of this 2021 Act.

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