SB 764-5
(LC 2014)
4/2/21 (TSB/ps)

Requested by Senator KNOPP

PROPOSED AMENDMENTS TO
SENATE BILL 764

On page 1 of the printed bill, delete lines 5 through 25 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, manufacturing, marketing, distribution or sale of a nonreference drug product infringes a patent for a protected drug.

"(b) 'Claimant' means a person that owns or exclusively licenses a patent for a protected drug.

"(c) 'Nonreference drug product' means:

"(A) A product that will be manufactured under an abbreviated new drug approval application as described in 21 C.F.R. 314.3, as in effect on the effective date of this 2021 Act, that is the subject of a patent infringement claim; or

"(B) A biosimilar biological product that will be manufactured under a biosimilar biological product application, as defined in 21 C.F.R. 379j-51, as in effect on the effective date of this 2021 Act, that is the subject of a patent infringement claim.

"(d) '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.

"(e) 'Protected drug' means a pharmaceutical drug that is subject to and protected by a patent.

"(f) 'Resolution agreement' means an agreement that is completed in this state and that must be filed with the Federal Trade Commission under section 1112 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, P.L. 108-173, as in effect on the effective date of this 2021 Act.

"(2)(a) A resolution agreement that ends a dispute over an alleged infringement of a patent does not violate this section unless the Attorney General proves by a preponderance of evidence that:

"(A) The resolution agreement, considered as a whole, includes a large and unjustified payment or other consideration from a claimant to an alleged infringer; and

"(B) The alleged infringer has agreed to limit or stop researching, developing, manufacturing, marketing or selling a nonreference drug product.

"(b) If the Attorney General meets the burden specified in paragraph (a) of this subsection, the parties to the resolution agreement must demonstrate by a preponderance of the evidence that the resolution agreement has procompetitive benefits.

"(c) If the parties meet the burden specified in paragraph (b) of this subsection, the Attorney General must show that any anticompetitive effects of the resolution agreement outweigh the procompetitive benefits of the resolution agreement.

"(3) A resolution agreement does not violate this section if the parties to the resolution agreement can demonstrate by a preponder-

ance of the evidence that the payment described in subsection (2)(a)(A) of this section is fair and reasonable compensation solely for:

"(a) Goods or services that the claimant promised to provide to the alleged infringer;

"(b) A right or license to manufacture, market, distribute or sell within the United States a nonreference drug product before the expiration of:

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

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

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

"(d) A portion of either:

"(A) The litigation and other legal expenses a claimant avoided as a result of the resolution agreement; or

"(B) The litigation and other legal expenses the alleged infringer incurred in connection with the dispute;

"(e) Permission for the alleged infringer to begin manufacturing, marketing, distributing, offering for sale or selling a nonreference drug product once another person begins distributing, offering for sale or selling the nonreference drug product;

"(f) A promise from the claimant to facilitate or not to interfere with the alleged infringer's ability to obtain regulatory approval to manufacture, market, distribute and sell a nonreference drug product;

"(g) A renunciation or disclaimer of damages for an alleged infringer's infringement of the patent for the protected drug;

"(h) A separate agreement to settle or resolve a different litigation if the separate agreement independently complies with the provisions

of this section;

"(i) Continuation or renewal of a previous resolution agreement if:

"(A) The previous resolution agreement was entered into at least 90 days before the resolution agreement that is the subject of the alleged violation;

"(B) The terms of the continuation or renewal, including the duration of any financial terms, are substantially similar to the terms in the previous agreement; and

"(C) The continuation or renewal is not expressly contingent on an agreement to settle the patent infringement claim; or

"(j) An agreement under which the claimant provides the alleged infringer with an exclusive license.

"(4) A party that violates this section is liable for a civil penalty that is equivalent to three times the value of the payment or other consideration that an alleged infringer received from a claimant.

"(5)(a) The Attorney General may bring an action in a circuit court of this state to enforce this section not later than four years after a resolution agreement is filed with the Federal Trade Commission under section 1112 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, P.L. 108-173, as in effect on the effective date of this 2021 Act.

"(b) The Attorney General shall deposit the proceeds of any civil penalty the Attorney General recovers as a result of a violation of this section into the General Fund. Amounts the Attorney General deposits into the General Fund under this paragraph are available for general governmental expenses.

"(6) This section does not create a right of action for a person other than the Attorney General to enforce a claim against a party to a resolution agreement that is subject to this section.

"(7) 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.".
