AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 2884

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act''.

SEC. 2. TITLE 35 AMENDMENTS.

(a) IN GENERAL.—Section 271(e) of title 35, United States Code, is amended—

(1) in paragraph (2)(C), in the flush text following clause (ii), by adding at the end the following: ''With respect to a submission described in clause (ii), the act of infringement shall extend to any patent that claims the biological product, a method of using the biological product, or a method or product used to manufacture the biological product.''; and

(2) by adding at the end the following:

''(7)(A) Subject to subparagraphs (C), (D), and (E), if the sponsor of an approved application for a reference

product, as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) (referred to in this paragraph as the 'reference product sponsor'), brings an action for infringement under this section against an applicant for approval of a biological product under section 351(k) of such Act that references that reference product (referred to in this paragraph as the 'subsection (k) applicant'), the reference product sponsor may assert in the action a total of not more than 20 patents of the type described in subparagraph (B), not more than 10 of which shall have issued after the date specified in section 351(l)(7)(A) of such Act.

''(B) The patents described in this subparagraph are patents that satisfy each of the following requirements:

''(i) Patents that claim the biological product that is the subject of an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) (or a use of that product) or a method or product used in the manufacture of such biological product.

''(ii) Patents that are included on the list of patents described in section 351(l)(3)(A) of the Public Health Service Act (42 U.S.C. 262(l)(3)(A)), including as provided under section 351(l)(7) of such Act.

''(iii) Patents that—

''(I) have an actual filing date of more than 4 years after the date on which the reference product is approved; or

''(II) include a claim to a method in a manufacturing process that is not used by the reference product sponsor.

''(C) The court in which an action described in subparagraph (A) is brought may increase the number of patents limited under that subparagraph—

''(i) if the request to increase that number is made without undue delay; and

''(ii)(I) if the interest of justice so requires; or

''(II) for good cause shown, which—

''(aa) shall be established if the subsection (k) applicant fails to provide information required under section 351(k)(2)(A) of the Public Health Service Act (42 U.S.C. 262(k)(2)(A)) that would enable the reference product sponsor to form a reasonable belief with respect to whether a claim of infringement under this section could reasonably be asserted; and

''(bb) may be established—

''(AA) if there is a material change to the biological product (or process with re-

spect to the biological product) of the subsection (k) applicant that is the subject of the application;

''(BB) if, with respect to a patent on the supplemental list described in section 351(l)(7)(A) of Public Health Service Act (42 U.S.C. 262(l)(7)(A)), the patent would have issued before the date specified in such section 351(l)(7)(A) but for the failure of the Office to issue the patent or a delay in the issuance of the patent, as described in paragraph (1) of section 154(b) and subject to the limitations under paragraph (2) of such section 154(b); or

''(CC) for another reason that shows good cause, as determined appropriate by the court.

''(D) In determining whether good cause has been shown for the purposes of subparagraph (C)(ii)(II), a court may consider whether the reference product sponsor has provided a reasonable description of the identity and relevance of any information beyond the subsection (k) application that the court believes is necessary to enable the court to form a belief with respect to whether a claim of

infringement under this section could reasonably be asserted.

''(E) The limitation imposed under subparagraph (A)—

''(i) shall apply only if the subsection (k) applicant completes all actions required under paragraphs (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of section 351(l) of the Public Health Service Act (42 U.S.C. 262(l)); and

''(ii) shall not apply with respect to any patent that claims, with respect to a biological product, a method for using that product in therapy, diagnosis, or prophylaxis, such as an indication or method of treatment or other condition of use.''.

(b) APPLICABILITY.—The amendments made by subsection (a) shall apply with respect to an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) on or after the date of the enactment of this Act.

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