119TH CONGRESS
1ST SESSION

S. _____

To amend title 35, United States Code, to provide for a safe harbor from infringement of a method of use patent relating to drugs or biological products.

IN THE SENATE OF THE UNITED STATES

Mr. HICKENLOOPER (for himself, Mr. WELCH, Mr. COTTON, and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend title 35, United States Code, to provide for a safe harbor from infringement of a method of use patent relating to drugs or biological products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Skinny Labels, Big Savings Act''.

SEC. 2. SAFE HARBOR FROM INFRINGEMENT OF A METHOD OF USE PATENT.

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

(1) by redesignating subsections (h) and (i) as subsections (k) and (l), respectively; and

(2) by inserting after subsection (g) the following:

''(h)(1) The following shall not be acts of direct, induced, or contributory infringement of a method of use claim in a patent included in the list described in section 505(j)(7) or section 512(n)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7), 360b(n)(4)) in an action or counterclaim under this section:

''(A) Submitting or seeking approval of an application under section 505(j) or section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j), 360b(b)(2)), or submitting or seeking approval of an application described in section 505(b)(2) of such Act (21 U.S.C. 355(b)(2)), provided that such application includes a statement under, as applicable, section 505(j)(2)(A)(viii), section 512(n)(1)(I), or section 505(b)(2)(B) of such Act (21 U.S.C. 355(j)(2)(A)(viii), 360b(n)(1)(I), 355(b)(2)(B)) for the method of use claims in the patent with the labeling proposed in such application.

"(B) Promoting or commercially marketing a drug product with the labeling approved in an application described in subparagraph (A).

"(C) Describing a drug product approved in an application submitted under section 505(j) or section 512(b)(2) of such Act (21 U.S.C. 355(j), 360b(b)(2)) or approved in an application described in section 505(b)(2) of such Act (21 U.S.C. 355(b)(2)) as a generic of, or therapeutically equivalent to, the listed drug referenced in such application, as applicable.

"(2) Subparagraphs (A) through (C) of paragraph (1) shall apply only if the labeling, promotion, or commercial marketing does not reference the condition or conditions of use claimed in the patent that was identified by the patent owner or assignee to the Secretary under section 314.53 of title 21, Code of Federal Regulations (or a successor regulation) and that was subject to the statement under section 505(j)(2)(A)(viii), section 512(n)(1)(I), or section 505(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)(viii), 360b(n)(1)(I), 355(b)(2)(B)), as applicable.

"(i)(1) The following shall not be acts of direct, induced, or contributory infringement of a patent claim cov-

ering a method of using the reference product in an action or counterclaim under this section:

''(A) Submitting or seeking approval of an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

''(B) Describing a biological product approved in an application described in subparagraph (A) as biosimilar to, or interchangeable with, the reference product, as applicable, with the labeling approved in such application, when the biological product has not been approved for the patented condition or conditions of use.

''(C) Promoting or commercially marketing a biological product with the labeling approved in an application described in subparagraph (A).

''(2) Subparagraphs (A) through (C) of paragraph (1) shall apply only if the labeling, promotion, or commercial marketing does not reference the condition or conditions of use claimed in the patent and specifically reflected in the prescribing information.

''(j) As used in this section:

''(1) The terms 'biological product', 'biosimilar', 'interchangeable', and 'reference product' have the meanings given such terms in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

"(2) The term 'commercial marketing' has the meaning given such term in section 314.3 of title 21, Code of Federal Regulations (or a successor regulation).

"(3) The term 'labeling' has the meaning given such term in section 201(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(m)).

"(4) The term 'promoting'—

"(A) is within the meaning of the term used in section 202.1 of title 21, Code of Federal Regulations (or a successor regulation); and

"(B) includes the use of promotional labeling and advertising, as described in paragraphs (1) and (2) of section 202.1(l) of title 21, Code of Federal Regulations (or successor regulations).".

(b) APPLICATION.—This Act and the amendments made by this Act shall apply to—

(1) conduct that occurs before, on, or after the date of enactment of this Act; and

(2) all judicial or other proceedings pending as of such date of enactment.