

118TH CONGRESS
2D 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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Skinny Labels, Big
5 Savings Act”.

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

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

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

3 (2) by inserting after subsection (g) the fol-
4 lowing:

5 “(h)(1) The following shall not be acts of direct, in-
6 duced, or contributory infringement of a method of use
7 claim in a patent included in the list described in section
8 505(j)(7) or section 512(n)(4) of the Federal Food, Drug,
9 and Cosmetic Act (21 U.S.C. 355(j)(7), 360b(n)(4)) in an
10 action or counterclaim under this section:

11 “(A) Submitting or seeking approval of an ap-
12 plication under section 505(j) or section 512(b)(2) of
13 the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 355(j), 360b(b)(2)), or submitting or seeking
15 approval of an application described in section
16 505(b)(2) of such Act (21 U.S.C. 355(b)(2)), pro-
17 vided that such application includes a statement
18 under, as applicable, section 505(j)(2)(A)(viii), sec-
19 tion 512(n)(1)(I), or section 505(b)(2)(B) of such
20 Act (21 U.S.C. 355(j)(2)(A)(viii), 360b(n)(1)(I),
21 355(b)(2)(B)) for the method of use claims in the
22 patent with the labeling proposed in such applica-
23 tion.

1 “(B) Promoting or commercially marketing a
2 drug product with the labeling approved in an appli-
3 cation described in subparagraph (A).

4 “(C) Describing a drug product approved in an
5 application submitted under section 505(j) or section
6 512(b)(2) of such Act (21 U.S.C. 355(j),
7 360b(b)(2)) or approved in an application described
8 in section 505(b)(2) of such Act (21 U.S.C.
9 355(b)(2)) as a generic of, or therapeutically equiva-
10 lent to, the listed drug referenced in such applica-
11 tion, as applicable.

12 “(2) Subparagraphs (A) through (C) of paragraph
13 (1) shall apply only if the labeling, promotion, or commer-
14 cial marketing does not reference the condition or condi-
15 tions of use claimed in the patent that was identified by
16 the patent owner or assignee to the Secretary under sec-
17 tion 314.53 of title 21, Code of Federal Regulations (or
18 a successor regulation) and that was subject to the state-
19 ment under section 505(j)(2)(A)(viii), section
20 512(n)(1)(I), or section 505(b)(2)(B) of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)(viii),
22 360b(n)(1)(I), 355(b)(2)(B)), as applicable.

23 “(i)(1) The following shall not be acts of direct, in-
24 duced, or contributory infringement of a patent claim cov-

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

3 “(A) Submitting or seeking approval of an ap-
4 plication under section 351(k) of the Public Health
5 Service Act (42 U.S.C. 262(k)).

6 “(B) Describing a biological product approved
7 in an application described in subparagraph (A) as
8 biosimilar to, or interchangeable with, the reference
9 product, as applicable, with the labeling approved in
10 such application, when the biological product has not
11 been approved for the patented condition or condi-
12 tions of use.

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

16 “(2) Subparagraphs (A) through (C) of paragraph
17 (1) shall apply only if the labeling, promotion, or commer-
18 cial marketing does not reference the condition or condi-
19 tions of use claimed in the patent and specifically reflected
20 in the prescribing information.

21 “(j) As used in this section:

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

1 “(2) The term ‘commercial marketing’ has the
2 meaning given such term in section 314.3 of title 21,
3 Code of Federal Regulations (or a successor regula-
4 tion).

5 “(3) The term ‘labeling’ has the meaning given
6 such term in section 201(m) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 321(m)).

8 “(4) The term ‘promoting’—

9 “(A) is within the meaning of the term
10 used in section 202.1 of title 21, Code of Fed-
11 eral Regulations (or a successor regulation);
12 and

13 “(B) includes the use of promotional label-
14 ing and advertising, as described in paragraphs
15 (1) and (2) of section 202.1(l) of title 21, Code
16 of Federal Regulations (or successor regula-
17 tions).”.

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

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

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