119th CONGRESS 1st Session

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To amend title 35, United States Code, to address the infringement of patents that claim biological products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. CORNYN (for himself, Mr. BLUMENTHAL, Mr. GRASSLEY, and Mr. DUR-BIN) introduced the following bill; which was read twice and referred to the Committee on ______

A BILL

- To amend title 35, United States Code, to address the infringement of patents that claim biological products, and for other purposes.
 - 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 "Affordable Prescrip-

5 tions for Patients Act".

6 SEC. 2. PATENT INFRINGEMENT.

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

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1 (1) in paragraph (2)(C), in the flush text fol-2 lowing clause (ii), by adding at the end the fol-3 lowing: "With respect to a submission described in 4 clause (ii), the act of infringement shall extend to 5 any patent that claims the biological product, a 6 method of using the biological product, or a method 7 or product used to manufacture the biological prod-8 uct."; and

(2) by adding at the end the following:

10 "(7)(A) Subject to subparagraphs (C), (D), and (E), 11 if the sponsor of an approved application for a reference 12 product, as defined in section 351(i) of the Public Health 13 Service Act (42 U.S.C. 262(i)) (referred to in this paragraph as the 'reference product sponsor'), brings an action 14 15 for infringement under this section against an applicant for approval of a biological product under section 351(k) 16 17 of such Act that references that reference product (re-18 ferred to in this paragraph as the 'subsection (k) appli-19 cant'), the reference product sponsor may assert in the 20 action a total of not more than 20 patents of the type 21 described in subparagraph (B), not more than 10 of which 22 shall have issued after the date specified in section 23 351(l)(7)(A) of such Act.

24 "(B) The patents described in this subparagraph are25 patents that satisfy each of the following requirements:

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1	"(i) Patents that claim the biological product
2	that is the subject of an application under section
3	351(k) of the Public Health Service Act (42 U.S.C.
4	262(k)) (or a use of that product) or a method or
5	product used in the manufacture of such biological
6	product.
7	"(ii) Patents that are included on the list of
8	patents described in paragraph $(3)(A)$ of section
9	351(l) of the Public Health Service Act (42 U.S.C.
10	262(l), including as provided under paragraph (7)
11	of such section 351(l).
12	"(iii) Patents that—
13	"(I) have an actual filing date of more
14	than 4 years after the date on which the ref-
15	erence product is approved; or
16	"(II) include a claim to a method in a
17	manufacturing process that is not used by the
18	reference product sponsor.
19	"(C) The court in which an action described in sub-
20	paragraph (A) is brought may increase the number of pat-
21	ents limited under that subparagraph—
22	"(i) if the request to increase that number is
23	made without undue delay; and
24	"(ii)(I) if the interest of justice so requires; or
25	"(II) for good cause shown, which—

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1	"(aa) shall be established if the subsection
2	(k) applicant fails to provide information re-
3	quired section $351(k)(2)(A)$ of the Public
4	Health Service Act (42 U.S.C. $262(k)(2)(A)$)
5	that would enable the reference product sponsor
6	to form a reasonable belief with respect to
7	whether a claim of infringement under this sec-
8	tion could reasonably be asserted; and
9	"(bb) may be established—
10	"(AA) if there is a material change to
11	the biological product (or process with re-
12	spect to the biological product) of the sub-
13	section (k) applicant that is the subject of
14	the application;
15	"(BB) if, with respect to a patent on
16	the supplemental list described in section
17	351(l)(7)(A) of Public Health Service Act
18	(42 U.S.C. $262(1)(7)(A))$, the patent would
19	have issued before the date specified in
20	such section $351(l)(7)(A)$ but for the fail-
21	ure of the Office to issue the patent or a
22	delay in the issuance of the patent, as de-
23	scribed in paragraph (1) of section $154(b)$
24	and subject to the limitations under para-
25	graph (2) of such section $154(b)$; or

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

4 "(D) In determining whether good cause has been 5 shown for the purposes of subparagraph (C)(ii)(II), a 6 court may consider whether the reference product sponsor 7 has provided a reasonable description of the identity and 8 relevance of any information beyond the subsection (k) ap-9 plication that the court believes is necessary to enable the 10 court to form a belief with respect to whether a claim of 11 infringement under this section could reasonably be as-12 serted.

13 "(E) The limitation imposed under subparagraph14 (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 sub section (a) shall apply with respect to an application sub mitted under section 351(k) of the Public Health Service
 Act (42 U.S.C. 262(k)) on or after the date of enactment
 of this Act.