

119TH CONGRESS
1ST SESSION

S. 1041

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

MARCH 13, 2025

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

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; MEDICARE IMPROVEMENT**

7 **FUND.**

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

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

9 (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 para-
14 graph as the ‘reference product sponsor’), brings an action
15 for infringement under this section against an applicant
16 for approval of a biological product under section 351(k)
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 are
25 patents that satisfy each of the following requirements:

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—

1 “(aa) shall be established if the subsection
2 (k) applicant fails to provide information re-
3 quired by 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(l)(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

1 “(CC) for another reason that shows
2 good cause, as determined appropriate by
3 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 subparagraph
14 (A)—

15 “(i) shall apply only if the subsection (k) appli-
16 cant completes all actions required under paragraphs
17 (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of
18 section 351(l) of the Public Health Service Act (42
19 U.S.C. 262(l)); and

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

1 (b) APPLICABILITY.—The amendments made by sub-
2 section (a) shall apply with respect to an application sub-
3 mitted under section 351(k) of the Public Health Service
4 Act (42 U.S.C. 262(k)) on or after the date of enactment
5 of this Act.

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