

119TH CONGRESS
2D SESSION

S. 1041

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Affordable Prescrip-
3 tions for Patients Act”.

4 **SEC. 2. PATENT INFRINGEMENT.**

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

7 (1) in paragraph (2), in the flush text following
8 subparagraph (C)(ii), by adding at the end the fol-
9 lowing: “With respect to a submission described in
10 subparagraph (C)(ii), the act of infringement shall
11 extend to any patent that claims the biological prod-
12 uct, a method of using the biological product, or a
13 method or product used to manufacture the biologi-
14 cal product.”; and

15 (2) by adding at the end the following:

16 “(7)(A) Subject to subparagraphs (C), (D), and (E),
17 if the sponsor of an approved application for a reference
18 product, as defined in section 351(i) of the Public Health
19 Service Act (42 U.S.C. 262(i)) (referred to in this para-
20 graph as the ‘reference product sponsor’), brings an action
21 for infringement under this section against an applicant
22 for approval of a biological product under section 351(k)
23 of such Act that references that reference product (re-
24 ferred to in this paragraph as the ‘subsection (k) appli-
25 cant’), the reference product sponsor may assert in the
26 action a total of not more than 20 patents of the type

1 described in subparagraph (B), not more than 10 of which
2 shall have issued after the date specified in section
3 351(l)(7)(A) of such Act.

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

6 “(i) Patents that claim the biological product
7 that is the subject of an application under section
8 351(k) of the Public Health Service Act (42 U.S.C.
9 262(k)) (or a use of that product) or a method or
10 product used in the manufacture of such biological
11 product.

12 “(ii) Patents that are included on the list of
13 patents described in paragraph (3)(A) of section
14 351(l) of the Public Health Service Act (42 U.S.C.
15 262(l)), including as provided under paragraph (7)
16 of such section 351(l).

17 “(iii) Patents that—

18 “(I) have an actual filing date of more
19 than 4 years after the date on which the ref-
20 erence product is approved; or

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

1 “(C) The court in which an action described in sub-
 2 paragraph (A) is brought may increase the number of pat-
 3 ents limited under that subparagraph—

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

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

7 “(II) for good cause shown, which—

8 “(aa) shall be established if the subsection
 9 (k) applicant fails to provide information re-
 10 quired by section 351(k)(2)(A) of the Public
 11 Health Service Act (42. U.S.C. 262(k)(2)(A))
 12 that would enable the reference product sponsor
 13 to form a reasonable belief with respect to
 14 whether a claim of infringement under this sec-
 15 tion could reasonably be asserted; and

16 “(bb) may be established—

17 “(AA) if there is a material change to
 18 the biological product (or process with re-
 19 spect to the biological product) of the sub-
 20 section (k) applicant that is the subject of
 21 the application;

22 “(BB) if, with respect to a patent on
 23 the supplemental list described in section
 24 351(l)(7) of the Public Health Service Act
 25 (42 U.S.C. 262(l)(7)), the patent would

1 have issued before the date specified in
2 section 351(l)(7)(A) of such Act but for
3 the failure of the Office to issue the patent
4 or a delay in the issuance of the patent, as
5 described in paragraph (1) of section
6 154(b) and subject to the limitations under
7 paragraph (2) of such section 154(b); or

8 “(CC) for another reason that shows
9 good cause, as determined appropriate by
10 the court.

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

20 “(E) The limitation imposed under subparagraph
21 (A)—

22 “(i) shall apply only if the subsection (k) appli-
23 cant completes all actions required under paragraphs
24 (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of

1 section 351(l) of the Public Health Service Act (42
2 U.S.C. 262(l)); and

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

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

Passed the Senate July 21, 2026.

Attest:

Secretary.

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