

# Calendar No. 44

119<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 1041

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

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## 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

APRIL 10, 2025

Reported by Mr. GRASSLEY, with amendments

[Omit the parts struck through and insert the parts printed in italic]

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## 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”.

1 **SEC. 2. PATENT INFRINGEMENT; MEDICARE IMPROVEMENT**  
2 **FUND.**

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

5 (1) in paragraph (2) ~~(C)~~, in the flush text fol-  
6 lowing ~~clause subparagraph (C)(ii)~~, by adding at the  
7 end the following: “With respect to a submission de-  
8 scribed in ~~clause subparagraph (C)(ii)~~, the act of in-  
9 fringement shall extend to any patent that claims  
10 the biological product, a method of using the biologi-  
11 cal product, or a method or product used to manu-  
12 facture the biological product.”; and

13 (2) by adding at the end the following:  
14 “(7)(A) Subject to subparagraphs (C), (D), and (E),  
15 if the sponsor of an approved application for a reference  
16 product, as defined in section 351(i) of the Public Health  
17 Service Act (42 U.S.C. 262(i)) (referred to in this para-  
18 graph as the ‘reference product sponsor’), brings an action  
19 for infringement under this section against an applicant  
20 for approval of a biological product under section 351(k)  
21 of such Act that references that reference product (re-  
22 ferred to in this paragraph as the ‘subsection (k) appli-  
23 cant’), the reference product sponsor may assert in the  
24 action a total of not more than 20 patents of the type  
25 described in subparagraph (B), not more than 10 of which

1 shall have issued after the date specified in section  
2 351(l)(7)(A) of such Act.

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

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

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

16 “(iii) Patents that—

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

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

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

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

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

4 “(II) for good cause shown, which—

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

13 “(bb) may be established—

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

19 “(BB) if, with respect to a patent on  
20 the supplemental list described in section  
21 351(l)(7) ~~(A)~~ of *the* Public Health Service  
22 Act (42 U.S.C. 262(l)(7) ~~(A)~~), the patent  
23 would have issued before the date specified  
24 in ~~such~~ section 351(l)(7)(A) of *such Act*  
25 but for the failure of the Office to issue

1 the patent or a delay in the issuance of the  
2 patent, as described in paragraph (1) of  
3 section 154(b) and subject to the limita-  
4 tions under paragraph (2) of such section  
5 154(b); or

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

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

18 “(E) The limitation imposed under subparagraph  
19 (A)—

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

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

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



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