

116TH CONGRESS
1ST SESSION

H. R. 3991

To amend title 35, United States Code, to clarify and improve the process for subsection (k) applicants to resolve patent infringement claims for biological products (commonly known as the “patent dance”), and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 25, 2019

Mr. JOHNSON of Georgia (for himself and Mrs. ROBY) introduced the following bill; which was referred to the Committee on the Judiciary

A BILL

To amend title 35, United States Code, to clarify and improve the process for subsection (k) applicants to resolve patent infringement claims for biological products (commonly known as the “patent dance”), 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 Through Improvements to Patent Liti-
6 gation Act of 2019”.

1 **SEC. 2. TITLE 35 AMENDMENTS.**

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

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

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

13 “(7)(A) Subject to subparagraphs (C), (D), and (E),
14 if the sponsor of an approved application for a reference
15 product, as defined in section 351(i) of the Public Health
16 Service Act (42 U.S.C. 262(i)) (referred to in this para-
17 graph as the ‘reference product sponsor’), brings an action
18 for infringement under this section against an applicant
19 for approval of a biological product under section 351(k)
20 of such Act that references that reference product (re-
21 ferred to in this paragraph as the ‘subsection (k) appli-
22 cant’), the reference product sponsor may assert in the
23 action a total of not more than 20 patents of the type
24 described in subparagraph (B), not more than 10 of which
25 shall have issued after the date specified in section
26 351(l)(7)(A) of such Act.

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

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

9 “(ii) Patents that are included on the list of
10 patents described in section 351(l)(3)(A) of the Pub-
11 lic Health Service Act (42 U.S.C. 262(l)(3)(A)), in-
12 cluding as provided under section 351(l)(7) of such
13 Act.

14 “(iii) Patents that—

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

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

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

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

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

2 “(II) for good cause shown, which—

3 “(aa) shall be established if the subsection
4 (k) applicant fails to provide information re-
5 quired under paragraph (2)(A) that would en-
6 able the reference product sponsor to form a
7 reasonable belief with respect to whether a
8 claim of infringement under this section could
9 reasonably be asserted; and

10 “(bb) may be established—

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

16 “(BB) if, with respect to a patent on
17 the supplemental list described in section
18 351(l)(7)(A) of Public Health Service Act
19 (42 U.S.C. 262(l)(7)(A)), the patent would
20 have issued before the date specified in
21 such section 351(l)(7)(A) but for the fail-
22 ure of the Office to issue the patent or a
23 delay in the issuance of the patent, as de-
24 scribed in paragraph (1) of section 154(b)

1 and subject to the limitations under para-
2 graph (2) of such section 154(b); or

3 “(CC) for another reason that shows
4 good cause, as determined appropriate by
5 the court.

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

15 “(E) The limitation imposed under subparagraph
16 (A)—

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

22 “(ii) shall not apply with respect to any patent
23 that claims, with respect to a biological product, a
24 method for using that product in therapy, diagnosis,

1 or prophylaxis, such as an indication or method of
2 treatment or other condition of use.”.

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

○