

116TH CONGRESS
1ST SESSION

S. 659

To provide for certain additional requirements with respect to patent disclosures.

IN THE SENATE OF THE UNITED STATES

MARCH 5, 2019

Ms. COLLINS (for herself, Mr. KAINE, Mr. PORTMAN, Mrs. SHAHEEN, Mr. BRAUN, and Ms. STABENOW) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for certain additional requirements with respect to patent disclosures.

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 “Biologic Patent Trans-
5 parency Act”.

6 **SEC. 2. PATENT DISCLOSURE REQUIREMENTS.**

7 (a) IN GENERAL.—Section 351 of the Public Health
8 Service Act (42 U.S.C. 262) is amended by adding at the
9 end the following:

1 “(o) ADDITIONAL REQUIREMENTS WITH RESPECT
2 TO PATENTS.—

3 “(1) APPROVED APPLICATION HOLDER LISTING
4 REQUIREMENTS.—

5 “(A) IN GENERAL.—Beginning on the date
6 of enactment of the Biologic Patent Trans-
7 parency Act, within 30 days of approval of an
8 application under subsection (a) or (k), the
9 holder of such approved application shall sub-
10 mit to the Secretary a list of each patent re-
11 quired to be disclosed (as described in para-
12 graph (3)).

13 “(B) PREVIOUSLY APPROVED OR LI-
14 CENSED BIOLOGICAL PRODUCTS.—

15 “(i) PRODUCTS APPROVED UNDER
16 SECTION 351 OF THE PHSA.—Not later
17 than 30 days after the date of enactment
18 of the Biologic Patent Transparency Act,
19 the holder of a biological product license
20 that was approved under subsection (a) or
21 (k) before the date of enactment of such
22 Act shall submit to the Secretary a list of
23 each patent required to be disclosed (as de-
24 scribed in paragraph (3)).

1 “(ii) PRODUCTS APPROVED UNDER
2 SECTION 505 OF THE FFDCA.—Not later
3 than 30 days after March 23, 2020, the
4 holder of an approved application for a bio-
5 logical product under section 505 of the
6 Federal Food, Drug, and Cosmetic Act
7 that is deemed to be a license for the bio-
8 logical product under this section on
9 March 23, 2020, shall submit a list of each
10 patent required to be disclosed (as de-
11 scribed in paragraph (3)).

12 “(C) UPDATES.—The holder of a biological
13 product license approved under subsection (a)
14 or (k) shall submit to the Secretary a list that
15 includes—

16 “(i) any patent first required to be
17 disclosed (as described in paragraph (3))
18 after the submission under subparagraph
19 (A) or (B), as applicable, within 30 days of
20 the earlier of—

21 “(I) the date of issuance of such
22 patent by the United States Patent
23 and Trademark Office; or

1 “(II) the date of approval of a
2 supplemental application for the bio-
3 logical product; and

4 “(ii) any patent, or any claim with re-
5 spect to a patent, included on the list pur-
6 suant to this paragraph with respect to the
7 biological product subsequently determined
8 to be invalid or unenforceable, within 30
9 days of a determination of patent inva-
10 lidity.

11 “(2) PUBLICATION OF INFORMATION.—

12 “(A) IN GENERAL.—Within 1 year of the
13 date of enactment of the Biologic Patent Trans-
14 parency Act, the Secretary shall publish and
15 make available to the public a single, easily
16 searchable, list that includes—

17 “(i) the official and proprietary name
18 of each biological product licensed under
19 subsection (a) or (k), and of each biological
20 product application approved under section
21 505 of the Federal Food, Drug, and Cos-
22 metic Act and deemed to be a license for
23 the biological product under this section on
24 March 23, 2020;

1 “(ii) with respect to each biological
2 product described in clause (i), each patent
3 submitted in accordance with paragraph
4 (1);

5 “(iii) the date of licensure and appli-
6 cation number for each such biological
7 product;

8 “(iv) the marketing status, dosage
9 form, route of administration, strength,
10 and, if applicable, reference product, for
11 each such biological product;

12 “(v) the licensure status for each such
13 biological product, including whether the li-
14 cense at the time of listing is approved,
15 withdrawn, or revoked;

16 “(vi) any period of any exclusivity
17 under subsection (k)(7)(A) or subsection
18 (k)(7)(B) of this section or section 527 of
19 the Federal Food, Drug, and Cosmetic
20 Act, and any extension of such period in
21 accordance with subsection (m) of this sec-
22 tion with respect to each such biological
23 product, and the date on which such exclu-
24 sivity expires;

1 “(vii) information regarding any de-
 2 termination related to biosimilarity or
 3 interchangeability for each such biological
 4 product; and

5 “(viii) information regarding approved
 6 indications for each such biological prod-
 7 uct, in such manner as the Secretary de-
 8 termines appropriate.

9 “(B) UPDATES.—Every 30 days after the
 10 publication of the first list under subparagraph
 11 (A), the Secretary shall revise the list to in-
 12 clude—

13 “(i)(I) each biological product licensed
 14 under subsection (a) or (k) during the 30-
 15 day period; and

16 “(II) with respect to each biological
 17 product described in subclause (I), the in-
 18 formation described in clauses (i) through
 19 (viii) of subparagraph (A); and

20 “(ii) any updates to information pre-
 21 viously published in accordance with sub-
 22 paragraph (A).

23 “(3) PATENTS REQUIRED TO BE DISCLOSED.—
 24 In this section, a ‘patent required to be disclosed’ is
 25 any patent for which the holder of a biological prod-

1 uct license approved under subsection (a) or (k), or
 2 a biological product application approved under sec-
 3 tion 505 of the Federal Food, Drug, and Cosmetic
 4 Act and deemed to be a license for a biological prod-
 5 uct under this section on March 23, 2020, believes
 6 a claim of patent infringement could reasonably be
 7 asserted by the holder, or by a patent owner that
 8 has granted an exclusive license to the holder with
 9 respect to the biological product that is the subject
 10 of such license, if a person not licensed by the holder
 11 engaged in the making, using, offering to sell, sell-
 12 ing, or importing into the United States of the bio-
 13 logical product that is the subject of such license.”.

14 (b) DISCLOSURE OF PATENTS.—Section
 15 351(l)(3)(A)(i) of the Public Health Service Act (42
 16 U.S.C. 262(l)(3)(A)(i)) is amended by inserting “included
 17 in the list provided by the reference product sponsor under
 18 subsection (o)(1)” after “a list of patents”.

19 (c) RESTRICTION ON CLAIMS OF PATENT INFRINGE-
 20 MENT.—Section 271(e) of title 35, United States Code,
 21 is amended by adding at the end the following:

22 “(7) The owner of a patent that should have
 23 been included in the list described in section
 24 351(o)(1) of the Public Health Service Act (42
 25 U.S.C. 262(o)(1)), including any updates required

1 under subparagraph (C) of that section, but was not
2 timely included in such list, may not bring an action
3 under this section for infringement of the patent.”.

4 (d) REGULATIONS.—The Secretary of Health and
5 Human Services may promulgate regulations to carry out
6 subsection (o) of section 351 of the Public Health Service
7 Act (42 U.S.C. 262), as added by subsection (a).

8 (e) RULE OF CONSTRUCTION.—Nothing in this Act,
9 including an amendment made by this Act, shall be con-
10 strued to require or allow the Secretary of Health and
11 Human Services to delay the licensing of a biological prod-
12 uct under section 351 of the Public Health Service Act
13 (42 U.S.C. 262).

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