

116TH CONGRESS
1ST SESSION

S. 3092

To amend the Federal Food, Drug, and Cosmetic Act with respect to the 180-day exclusivity period, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 18, 2019

Ms. SMITH (for herself and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the 180-day exclusivity period, 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 “Expanding Access to
5 Low-Cost Generics Act of 2019”.

6 **SEC. 2. 180-DAY EXCLUSIVITY PERIOD.**

7 (a) IN GENERAL.—Section 505(j)(5)(B)(iv) of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 355(j)(5)(B)(iv)) is amended—

1 (1) in subclause (I), by striking “effective on
2 the date that is 180 days after” and all that follows
3 through the period at the end and inserting the fol-
4 lowing: “effective—

5 “(aa) except as provided in item (bb),
6 on the date that is 180 days after the date
7 of the first commercial marketing of the
8 drug (including the commercial marketing
9 of the listed drug) by any first applicant;
10 or

11 “(bb) if, in an infringement action
12 brought in a district court solely against
13 the applicant for the application described
14 in this subclause (or any affiliate of the
15 applicant), or an action in a district court
16 for a declaratory judgment brought by that
17 applicant, with respect to each patent to
18 which a first applicant had submitted and
19 lawfully maintained a certification under
20 paragraph (2)(A)(vii)(IV), the district
21 court decides that each patent is invalid or
22 not infringed (including any substantive
23 determination that there is no cause of ac-
24 tion for patent infringement or invalidity),
25 and the applicant for the application de-

1 scribed in this subclause meets the require-
2 ments under subclause (III), immediately
3 upon the district court entering such deci-
4 sion for such applicant.”; and

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

6 “(III) APPLICANT REQUIREMENTS.—The
7 requirements under this subclause are that the
8 applicant for the application described in sub-
9 clause (I)—

10 “(aa) does not stay the action de-
11 scribed in item (bb) of such subclause;

12 “(bb) does not agree to be bound by
13 a judgment as to another applicant; and

14 “(cc) does not request joinder under
15 section 42.122 of title 37, Code of Federal
16 Regulations (or any corresponding similar
17 regulation or ruling), for any petition that
18 the applicant may have filed with respect
19 to the application.”.

20 (b) APPLICABILITY.—The amendments made by sub-
21 section (a) shall apply only with respect to an application
22 filed under section 505(j) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 355(j)) after the date of enact-
24 ment of this Act that identifies a listed drug for which

- 1 no certification under paragraph (2)(A)(vii)(IV) of such
- 2 section was made before such date of enactment.

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