

118TH CONGRESS  
2D SESSION

# S. 4878

To amend the Federal Food, Drug, and Cosmetic Act with respect to approval of abbreviated new drug applications.

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## IN THE SENATE OF THE UNITED STATES

JULY 31, 2024

Mr. DURBIN (for himself and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to approval of abbreviated new drug applications.

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 “Reforming  
5       Evergreening and Manipulation that Extends Drug Years  
6       Act” or the “REMEDY Act”.

7       **SEC. 2. AMENDMENTS TO ANDA APPROVAL PROVISIONS.**

8       Section 505 of the Federal Food, Drug, and Cosmetic  
9       Act (21 U.S.C. 355) is amended—

(1) in subsection (c)(2) by adding at the end the following: “With respect to a drug approved on or after the date of enactment of the Reforming Evergreening and Manipulation that Extends Drug Years Act, when a holder of an approved application first files information under this paragraph with respect to one or more patents described in subsection (b)(1)(A)(viii), the holder shall select one such patent with respect to which the owner or licensee may receive the 30-month stay under paragraph (3)(C), as applicable; for purposes of paragraphs (3)(C) and (3)(E) and subsections (j)(5)(D)(iii) and (j)(5)(F)(ii), such patent shall be referred to as the ‘covered patent’. The selection of such covered patent may not be changed or amended.”;

(2) in subsection (c)(3)(C)—

(A) in the matter preceding clause (i)—

(i) by striking “an action is brought for infringement” and all that follows through the period at the end of the first sentence and inserting “with respect to a drug approved under this subsection before the date of enactment of the Reforming Evergreening and Manipulation that Extends Drug Years Act, an action is

1 brought for infringement of any patent  
2 that is the subject of the certification and  
3 for which information was submitted to the  
4 Secretary under paragraph (2) or sub-  
5 section (b)(1) before the date on which the  
6 application (excluding an amendment or  
7 supplement to the application) was sub-  
8 mitted, or, with respect to a drug approved  
9 under this subsection on or after the date  
10 of enactment of the Reforming  
11 Evergreening and Manipulation that Ex-  
12 tends Drug Years Act, an action is  
13 brought for infringement of the covered  
14 patent (as described in paragraph (2)), be-  
15 fore the date on which the application (ex-  
16 cluding an amendment or supplement to  
17 the application) was submitted.”; and

18 (ii) by striking “an action is brought  
19 before” and inserting “an action with re-  
20 spect to a patent or a covered patent, as  
21 applicable, is brought before”; and

22 (B) in clause (i), by striking “decides that  
23 the patent” and inserting “decides that the pat-  
24 ent or the covered patent, as applicable”;

(3) in the second sentence of subsection (c)(3)(E)(ii), by inserting “with respect to any patent that claims a drug that was approved under this subsection before the date of enactment of the Reforming Evergreening and Manipulation that Extends Drug Years Act, or, with respect to a covered patent (as described in paragraph (2)) that claims a drug approved under this subsection on or after the date of enactment of such Act,” after “action for patent infringement”;

(4) in subsection (j)(5)(B)(iii)—

(A) in the matter preceding subclause

(I)—

(i) by striking “an action is brought for infringement” and all that follows through the period at the end of the first sentence and inserting “with respect to a drug approved under subsection (c) before the date of enactment of the Reforming Evergreening and Manipulation that Extends Drug Years Act, an action is brought for infringement of any patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2)

1 before the date on which the application  
2 (excluding an amendment or supplement to  
3 the application), which the Secretary later  
4 determines to be substantially complete,  
5 was submitted, or, with respect to a drug  
6 approved under subsection (c) on or after  
7 the date of enactment of the Reforming  
8 Evergreening and Manipulation that Ex-  
9 tends Drug Years Act, an action is  
10 brought for infringement of the covered  
11 patent (as described in subsection (c)(2))  
12 before the date on which the application  
13 (excluding an amendment or supplement to  
14 the application), which the Secretary later  
15 determines to be substantially complete,  
16 was submitted.”; and

17 (ii) by striking “an action is brought  
18 before” and inserting “an action with re-  
19 spect to a patent or a covered patent, as  
20 applicable, is brought before”; and

21 (B) in subclause (I), by striking “decides  
22 that the patent” and inserting “decides that the  
23 patent or covered patent, as applicable,”; and

24 (5) in the second sentence of subsection  
25 (j)(5)(F)(ii), by inserting “with respect to any pat-

1       ent that claims a drug that was approved under sub-  
2       section (c) before the date of enactment of the Re-  
3       forming Evergreening and Manipulation that Ex-  
4       tends Drug Years Act, or, with respect to a covered  
5       patent (as described in subsection (c)(2)) that claims  
6       a drug approved under subsection (c) on or after the  
7       date of enactment of such Act,” after “action for  
8       patent infringement”.

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