

117TH CONGRESS
2D SESSION

S. 4918

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the use of patents, trade secrets, or other intellectual property to inhibit competition.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 22, 2022

Ms. HASSAN (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 to prohibit the use of patents, trade secrets, or other intellectual property to inhibit competition.

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 “Increasing Prescription
5 Drug Competition Act”.

1 **SEC. 2. PROHIBITING THE USE OF PATENTS, TRADE SE-**
2 **CRETS, OR OTHER INTELLECTUAL PROPERTY**
3 **ON RISK EVALUATION AND MITIGATION**
4 **STRATEGIES TO INHIBIT COMPETITION.**

5 Section 505–1 of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 355–1) is amended by adding at the
7 end the following:

8 “(n) **ADDITIONAL REQUIREMENTS.**—

9 “(1) **PATENTS CLAIMING REMS.**—If an applica-
10 tion under subsection (b)(2) or (j) of section 505 in-
11 cludes a certification under subsection (b)(2)(A) or
12 (j)(2)(A)(vii) of section 505 with respect to a patent
13 that claims an aspect of the elements to assure safe
14 use of a risk evaluation and mitigation strategy re-
15 quirements under subsection (f) for the applicable
16 listed drug, such certification shall have no effect on
17 the effective date of the approval of the application,
18 notwithstanding subparagraphs (B) and (C) of sec-
19 tion 505(c)(3) and clauses (ii) and (iii) of section
20 505(j)(5)(B). This paragraph shall apply to all ap-
21 plications submitted to the Secretary under sub-
22 section (b)(2) or (j) of section 505 before, on, or
23 after the date of enactment of the Increasing Pre-
24 scription Drug Competition Act.

25 “(2) **AGREEMENT NOT TO SEEK DAMAGES.**—In
26 the event that the sponsor of another application

1 under section 505 of this Act or section 351 of the
2 Public Health Service Act infringes a patent, trade
3 secret, or any other intellectual property held by the
4 sponsor or holder to comply with risk evaluation and
5 mitigation strategy requirements under this section,
6 the sponsor or holder of the approved application
7 shall not seek, or claim entitlement to, any remedy
8 other than damages arising from the infringement.

9 “(3) CLARIFICATIONS.—Nothing in this section
10 shall be construed as —

11 “(A) prohibiting the sponsor or holder of
12 an approved application from allowing the spon-
13 sor of another application under section 505 of
14 this Act or section 351 of the Public Health
15 Service Act to use the patent, trade secret, or
16 any other intellectual property other than as de-
17 scribed in this subsection;

18 “(B) preventing a sponsor of an applica-
19 tion under section 505 of this Act or section
20 351 of the Public Health Service Act from
21 using a different, comparable aspect of the ele-
22 ments to assure safe use as authorized under
23 this section;

24 “(C) in any way negating the applicability
25 of a risk evaluation and mitigation strategy

1 with elements to assure safe use, as otherwise
2 required under this section; or

3 “(D) limiting the application of any provi-
4 sion of the antitrust laws (as defined in sub-
5 section (a) of the first section of the Clayton
6 Act (15 U.S.C. 12(a)).”.

○