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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Increasing Prescription Drug Competition Act''.

SEC. 2. PROHIBITING THE USE OF PATENTS, TRADE SECRETS, OR OTHER INTELLECTUAL PROPERTY ON RISK EVALUATION AND MITIGATION STRATEGIES TO INHIBIT COMPETITION.

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

''(n) ADDITIONAL REQUIREMENTS.—

''(1) PATENTS CLAIMING REMS.—If an application under subsection (b)(2) or (j) of section 505 includes a certification under subsection (b)(2)(A) or (j)(2)(A)(vii) of section 505 with respect to a patent that claims an aspect of the elements to assure safe use of a risk evaluation and mitigation strategy requirements under subsection (f) for the applicable listed drug, such certification shall have no effect on the effective date of the approval of the application, notwithstanding subparagraphs (B) and (C) of section 505(c)(3) and clauses (ii) and (iii) of section 505(j)(5)(B). This paragraph shall apply to all applications submitted to the Secretary under subsection (b)(2) or (j) of section 505 before, on, or after the date of enactment of the Increasing Prescription Drug Competition Act.

''(2) AGREEMENT NOT TO SEEK DAMAGES.—In the event that the sponsor of another application

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

''(3) CLARIFICATIONS.—Nothing in this section shall be construed as —

''(A) prohibiting the sponsor or holder of an approved application from allowing the sponsor of another application under section 505 of this Act or section 351 of the Public Health Service Act to use the patent, trade secret, or any other intellectual property other than as described in this subsection;

''(B) preventing a sponsor of an application under section 505 of this Act or section 351 of the Public Health Service Act from using a different, comparable aspect of the elements to assure safe use as authorized under this section;

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

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

"(D) limiting the application of any provision of the antitrust laws (as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a))).".

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