116TH CONGRESS
1ST SESSION

S. _____

To amend title 35, United States Code, to provide that changes to dosing regimens or delivery mechanisms with respect to drugs or biological products shall be presumed to be obvious changes that are not patentable, and for other purposes.

IN THE SENATE OF THE UNITED STATES

_____

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend title 35, United States Code, to provide that changes to dosing regimens or delivery mechanisms with respect to drugs or biological products shall be presumed to be obvious changes that are not patentable, and for other purposes.

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 ''No Combination Drug Patents Act''.

SEC. 2. DEFINITIONS.

In this Act:

(1) BIOLOGICAL PRODUCT.—The term ''biological product'' has the meaning given the term in section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) DIRECTOR.—The term ''Director'' means the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

(3) DRUG.—The term ''drug'' has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

SEC. 3. FINDINGS.

Congress finds the following:

(1) Article I, section 8, clause 8 of the Constitution of the United States (referred to in this section as the ''Constitution'') recognizes the importance of intellectual property to the foundation of the United States.

(2) The Leahy-Smith America Invents Act (Public Law 112–29; 125 Stat. 284) provided necessary updates to the patent system of the United States.

(3) A series of 7 unanimous decisions by the Supreme Court of the United States during the 13-year period preceding the date of enactment of this

Act strengthened the patent system of the United States to meet the requirements imposed on the patent system of the United States system by the Constitution.

(4) Recent increases in the prices of drugs have far outpaced increases in inflation and in spending on research and development with respect to those drugs.

(5) Numerous combination patents on the same underlying drug and biological product substances, with varying methods of delivery or dosing regimens, or in combination with generic drugs or biological products, have created dense patent thickets that deter competition from generic versions of those drugs or biological products.

(6) The repeated combination patents described in paragraph (5) contain obvious product developments that manufacturers of drugs and biological products routinely investigate.

(7) In Neptune Generics, LLC v. Eli Lilly & Co., 921 F.3d 1372 (Fed. Cir. 2019), the United States Court of Appeals for the Federal Circuit correctly determined the limited occasions in which a combination patent would not be considered unpatentable as obvious.

(8) Absent findings similar to those identified in Neptune Generics, as described in paragraph (7), awarding additional patents for the modifications described in paragraph (6)—

(A) extend patent terms and create patent thickets; and

(B) do not promote the progress of science and the useful arts.

(9) A modification of the standard under section 103 of title 35, United States Code, with accompanying guidance, is necessary to address the patent thickets described in paragraph (8)(A).

SEC. 4. PATENTABILITY.

(a) IN GENERAL.—Section 103 of title 35, United States Code, is amended—

(1) in the first sentence, by striking ''A patent'' and inserting the following:

''(a) IN GENERAL.—A patent''; and

(2) by adding at the end the following:

''(b) PRESUMPTION WITH RESPECT TO CERTAIN CHANGES TO DRUGS AND BIOLOGICAL PRODUCTS.—

''(1) DEFINITIONS.—In this subsection:

''(A) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given the

term in section 351 of the Public Health Service Act (42 U.S.C. 262).

"(B) COVERED CLAIMED INVENTION.—The term 'covered claimed invention' means a claimed invention that—

"(i) contains or uses a drug or biological product that is prior art; and

"(ii) is different from the prior art only with respect to—

"(I) a dosing regimen for the drug or biological product described in clause (i);

"(II) a method of administration or delivery for the drug or biological product described in clause (i);

"(III) a method of treatment using the drug or biological product described in clause (i); or

"(IV) a pharmaceutical formulation including the drug or biological product described in clause (i).

"(C) DRUG.—The term 'drug' has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

''(2) PRESUMPTION.—For the purposes of subsection (a), with respect to a covered claimed invention, there shall be a presumption, which the applicant with respect to the covered claimed invention may rebut, that the differences between the covered claimed invention and the prior art are such that the covered claimed invention as a whole would have been obvious before the effective filing date of the covered claimed invention, as described in that subsection.

''(3) RULE OF CONSTRUCTION.—Nothing in this subsection may be construed to affect the conditions for patentability with respect to any claimed invention that is a drug, a biological product, a dosing regimen or method of administration for a drug or biological product, a method of treatment using a drug or biological product, or a pharmaceutical formulation including a drug or biological product if the patent application with respect to the claimed invention claims only that drug, biological product, regimen or method of administration, method of treatment, or formulation, as applicable.''.

(b) GUIDANCE.—

(1) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Director shall

issue guidance to patent examiners at the United States Patent and Trademark Office with respect to carrying out the amendments made by subsection (a).

(2) CONTENTS.—The Director shall—

(A) ensure that the guidance issued under paragraph (1) is consistent with final precedential opinions issued by—

(i) the United States Court of Appeals for the Federal Circuit; and

(ii) the Supreme Court of the United States; and

(B) update the guidance issued under paragraph (1) as necessary to remain consistent with the final precedential opinions of the courts described in subparagraph (A).