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116TH CONGRESS
1ST SESSION

H. R. 3199

To amend title 35, United States Code, to prevent double patenting, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 11, 2019

Mr. JEFFRIES (for himself, Mr. COLLINS of Georgia, Ms. MUCARSEL-POWELL, and Mr. CLINE) introduced the following bill; which was referred to the Committee on the Judiciary

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A BILL

To amend title 35, United States Code, to prevent double patenting, 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 ''Terminating the Extension of Rights Misappropriated Act of 2019'' or the ''Term Act of 2019''.

SEC. 2. PREVENTION OF DOUBLE PATENTING.

(a) IN GENERAL.—Section 253 of title 35, United States Code, is amended by adding at the end the following:

''(c) DISCLAIMERS OF DRUG PATENT TERM.—

''(1) IN GENERAL.—Except as provided in paragraph (2), in a proceeding challenging the validity of patents under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) with respect to a drug, under section 351(l) of the Public Health Service Act (42 U.S.C. 262(l)) with respect to a biological product, or a Federal district court proceeding involving patents that are the subject of an action under section 271(e)(2), the patentee shall be presumed to have disclaimed the patent term for each of the listed patents after the date on which the term of the first patent expires, subject to the exceptions provided for in subsection (2).

''(2) DEMONSTRATION OF DISTINCT INVENTIONS.—If a patentee demonstrates by a preponderance of the evidence that certain patents described in paragraph (1) cover patentably distinct inventions from the invention claimed in the first such patent to expire, no part of the term of any such patent shall be presumed to have been disclaimed, and all patent term extensions granted by the United States Patent and Trademark Office shall be respected, unless and to the extent the patentee expressly dis-

claims, in writing, the patent term for each such patent.''.

(b) USPTO REVIEW.—

(1) DEFINITIONS.—In this subsection—

(A) the term ''Office'' means the United States Patent and Trademark Office; and

(B) the term ''Director'' means the Under Secretary of Commerce for Intellectual Property and Director of the Office.

(2) REVIEW.—The Director shall conduct a comprehensive review of the patent examination procedures of the Office to determine whether the Office—

(A) is using best examination practices, guidance, and procedures to avoid the issuance of patents relating to the same drug, or biological product, that are not patentably distinct from one another, and not subject to an appropriate disclaimer of patent term; and

(B) should develop and implement new practices, guidance, or procedures to—

(i) improve examination of patent applications relating to the same drug or biological product; and

(ii) reduce the improper issuance of patents that improperly extend the term of exclusivity afforded a new drug or biological product.

(3) REPORT.—Not later than 1 year after the date of enactment of this Act, the Director shall submit to the Committee on the Judiciary of the House of Representatives a report that contains—

(A) the findings from the review conducted under paragraph (2); and

(B) any recommendations of the Director with respect to the review conducted under paragraph (2).

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