

118TH CONGRESS
1ST SESSION

H. R. 6436

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

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 15, 2023

Mr. RYAN introduced the following bill; which was referred to the Committee
on the Judiciary

A BILL

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

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 “Stopping Pharma’s
5 Ripoffs and Drug Savings For All Act”.

6 **SEC. 2. PREVENTION OF DOUBLE PATENTING.**

7 (a) IN GENERAL.—Section 253 of title 35, United
8 States Code, is amended by adding at the end the fol-
9 lowing:

10 “(c) DISCLAIMERS OF DRUG PATENT TERM.—

1 “(1) IN GENERAL.—Except as provided in para-
2 graph (2), in a proceeding challenging the validity of
3 patents under section 505(c) of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 355(c)) with re-
5 spect to a drug, under section 351(l) of the Public
6 Health Service Act (42 U.S.C. 262(l)) with respect
7 to a biological product, or a Federal district court
8 proceeding involving patents that are the subject of
9 an action under section 271(e)(2), the patentee shall
10 be presumed to have disclaimed the patent term for
11 each of the listed patents after the date on which the
12 term of the first patent expires, subject to the excep-
13 tions provided for in subsection (2).

14 “(2) DEMONSTRATION OF DISTINCT INVEN-
15 TIONS.—If a patentee demonstrates by a preponder-
16 ance of the evidence that certain patents described
17 in paragraph (1) cover patentably distinct inventions
18 from the invention claimed in the first such patent
19 to expire, no part of the term of any such patent
20 shall be presumed to have been disclaimed, and all
21 patent term extensions granted by the United States
22 Patent and Trademark Office shall be respected, un-
23 less and to the extent the patentee expressly dis-
24 claims, in writing, the patent term for each such
25 patent.”.

1 (b) USPTO REVIEW.—

2 (1) DEFINITIONS.—In this subsection—

3 (A) the term “Office” means the United
4 States Patent and Trademark Office; and

5 (B) the term “Director” means the Under
6 Secretary of Commerce for Intellectual Property
7 and Director of the Office.

8 (2) REVIEW.—The Director shall conduct a
9 comprehensive review of the patent examination pro-
10 cedures of the Office to determine whether the Of-
11 fice—

12 (A) is using best examination practices,
13 guidance, and procedures to avoid the issuance
14 of patents relating to the same drug, or biologi-
15 cal product, that are not patentably distinct
16 from one another, and not subject to an appro-
17 priate disclaimer of patent term; and

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

20 (i) improve examination of patent ap-
21 plications relating to the same drug or bio-
22 logical product; and

23 (ii) reduce the improper issuance of
24 patents that improperly extend the term of

1 exclusivity afforded a new drug or biologi-
2 cal product.

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

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

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

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