

113<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4287

To advance the public health by encouraging independent innovators to pursue drug repurposing research and develop new treatments and cures by providing appropriate intellectual property protections for those innovations, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 24, 2014

Mr. CASTRO of Texas (for himself and Mr. FORBES) introduced the following bill; which was referred to the Committee on the Judiciary

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## A BILL

To advance the public health by encouraging independent innovators to pursue drug repurposing research and develop new treatments and cures by providing appropriate intellectual property protections for those innovations, 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 “Independent Innovator  
5        and Repurposing Act”.

1 **SEC. 2. EXTENSION OF PATENT TERM FOR METHOD OF**  
2 **USING BIOLOGICAL PRODUCT.**

3 (a) **EXTENSION FOR REGULATORY DELAY.**—The  
4 term of a patent claiming a method of using a biological  
5 product shall be extended for 5 years from the original  
6 expiration date of the patent, which shall include any pat-  
7 ent term adjustment granted under section 154(b) of title  
8 35, United States Code, if—

9 (1) an application for an extension is submitted  
10 by the owner of record of the patent or its agent in  
11 accordance with the requirements of subsection (b);  
12 and

13 (2) the term of the patent—

14 (A) has not expired before the application  
15 is so submitted; and

16 (B) has not been extended under sub-  
17 section (c) of this section or section 156 of title  
18 35, United States Code.

19 (b) **APPLICATION FOR EXTENSION.**—To obtain an  
20 extension of the term of a patent under this section, the  
21 owner of record of the patent or its agent shall submit  
22 an application to the Director. The application shall con-  
23 tain—

24 (1) the identity of the biological product;

25 (2) the identity of the patent for which an ex-  
26 tension is being sought and the identity of each

1 claim of such patent that claims the method of using  
2 the biological product;

3 (3) information demonstrating to the Director  
4 that—

5 (A) the patent was issued to an inde-  
6 pendent innovator;

7 (B) the owner of record is—

8 (i) the independent innovator; or

9 (ii) a qualified small business in which  
10 the independent innovator has an owner-  
11 ship interest;

12 (C) an application under section 351(a) of  
13 the Public Health Service Act (42 U.S.C.  
14 262(a)) for commercial marketing of the bio-  
15 logical product for a method of use claimed in  
16 the patent has been filed; and

17 (D) a period of not less than 10 years  
18 elapsed between the original date of submission  
19 of an application for an exemption under sec-  
20 tion 505(i) of the Federal Food, Drug, and  
21 Cosmetic Act (21 U.S.C. 355(i)) for inves-  
22 tigating such method of use and the date on  
23 which the Food and Drug Administration ap-  
24 proved the application described in subpara-  
25 graph (C); and

1           (4) a brief description of the activities under-  
2 taken by the owner of record of the patent, or the  
3 agent of such owner, during such period with respect  
4 to the biological product and the significant dates  
5 applicable to such activities to the extent such infor-  
6 mation is possessed by such owner.

7           (c) DETERMINATION OF EXTENSION.—

8           (1) IN GENERAL.—A determination that a pat-  
9 ent is eligible for extension shall be made by the Di-  
10 rector solely on the basis of the representations con-  
11 tained in the application for the extension. If the Di-  
12 rector determines that a patent is eligible for exten-  
13 sion under subsection (a) and that the requirements  
14 of subsection (b) have been complied with, the Direc-  
15 tor shall issue to the applicant for the extension of  
16 the term of the patent a certificate of extension,  
17 under seal, for 5 years. Such certificate shall be re-  
18 corded in the official file of the patent and shall be  
19 considered as part of the original patent.

20           (2) INTERIM EXTENSION.—If the term of a pat-  
21 ent for which an application has been submitted  
22 under subsection (b) would expire before a certifi-  
23 cate of extension is issued or denied under para-  
24 graph (1) respecting the application, the Director  
25 shall extend, until such determination is made, the

1 term of the patent for periods of up to one year if  
2 the Director determines that the patent is eligible  
3 for extension.

4 (d) DEFINITIONS.—In this section:

5 (1) BIOLOGICAL PRODUCT.—The term “biologi-  
6 cal product” has the meaning given to such term in  
7 section 351(i)(1) of the Public Health Service Act  
8 (42 U.S.C. 262(i)(1)).

9 (2) DIRECTOR.—The term “Director” means  
10 the Under Secretary of Commerce for Intellectual  
11 Property and Director of the United States Patent  
12 and Trademark Office.

13 (3) INDEPENDENT INNOVATOR.—

14 (A) The term “independent innovator”  
15 means any person or entity that—

16 (i) obtains a method of use patent for  
17 a biological product; and

18 (ii) is not, at the time of invention or  
19 patent filing, affiliated with the holder of a  
20 marketing application approved under sec-  
21 tion 351(a) of the Public Health Service  
22 Act (42 U.S.C. 262(a)) for the commercial  
23 marketing of such biological product.

24 (B) For purposes of subparagraph (A) and  
25 paragraph (4), the term “affiliated” refers to

1           any relationship of employment, control, or  
2           common ownership, whether direct or indirect,  
3           including through one or more intermediaries.

4           (4) QUALIFIED SMALL BUSINESS.—The term  
5           “qualified small business” means any entity with  
6           fewer than 500 employees, including employees of  
7           affiliates, and which is not affiliated with the holder  
8           of the marketing application approved under section  
9           351(a) of the Public Health Service Act (42 U.S.C.  
10          sec. 262(a)) for the commercial marketing of such  
11          biological product.

12          (e) EFFECTIVE DATE.—This section shall take effect  
13          on the date of the enactment of this Act and shall apply  
14          to any unexpired patent issued before, on, or after that  
15          effective date.

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