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.

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

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.

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 “Independent Innovator and Repurposing Act”.

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

(a) Extension for Regulatory Delay.—The term of a patent claiming a method of using a biological product shall be extended for 5 years from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b) of title 35, United States Code, if—

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

(2) the term of the patent—

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

(B) has not been extended under subsection (c) of this section or section 156 of title 35, United States Code.

(b) Application for Extension.—To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. The application shall contain—

(1) the identity of the biological product;

(2) the identity of the patent for which an extension is being sought and the identity of each
claim of such patent that claims the method of using
the biological product;

(3) information demonstrating to the Director
that—

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

(B) the owner of record is—

(i) the independent innovator; or

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

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

(D) a period of not less than 10 years
elapsed between the original date of submission
of an application for an exemption under sec-
tion 505(i) of the Federal Food, Drug, and
Cosmetic Act (21 U.S.C. 355(i)) for inves-
tigating such method of use and the date on
which the Food and Drug Administration ap-
proved the application described in subpara-
graph (C); and
(4) a brief description of the activities undertaken by the owner of record of the patent, or the agent of such owner, during such period with respect to the biological product and the significant dates applicable to such activities to the extent such information is possessed by such owner.

(c) DETERMINATION OF EXTENSION.—

(1) IN GENERAL.—A determination that a patent is eligible for extension shall be made by the Director solely on the basis of the representations contained in the application for the extension. If the Director determines that a patent is eligible for extension under subsection (a) and that the requirements of subsection (b) have been complied with, the Director shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for 5 years. Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

(2) INTERIM EXTENSION.—If the term of a patent for which an application has been submitted under subsection (b) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the
term of the patent for periods of up to one year if
the Director determines that the patent is eligible
for extension.
(d) Definitions.—In this section:
(1) Biological Product.—The term “biological
product” has the meaning given to such term in
section 351(i)(1) of the Public Health Service Act
(42 U.S.C. 262(i)(1)).
(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) Independent Innovator.—
(A) The term “independent innovator”
means any person or entity that—
(i) obtains a method of use patent for
a biological product; and
(ii) is not, at the time of invention or
patent filing, affiliated with the holder of a
marketing application approved under sec-
tion 351(a) of the Public Health Service
Act (42 U.S.C. 262(a)) for the commercial
marketing of such biological product.
(B) For purposes of subparagraph (A) and
paragraph (4), the term “affiliated” refers to
any relationship of employment, control, or common ownership, whether direct or indirect, including through one or more intermediaries.

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

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