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113TH CONGRESS
2D SESSION

S. 3004

To promote the development of meaningful treatments for patients.

IN THE SENATE OF THE UNITED STATES

DECEMBER 11, 2014

Mr. HATCH (for himself and Mr. BENNET) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To promote the development of meaningful treatments for patients.

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 ''Dormant Therapies Act of 2014''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. DEFINITIONS.

In this Act:

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

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

(3) The term ''dormant therapy'' means a medicine designated as a dormant therapy under section 4(a).

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

(5) The term ''medicine'' means a biological product or a drug.

(6) The term ''protection period'', with respect to a dormant therapy, means the period that—

(A) begins on the date on which the Secretary first approves an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for the dormant therapy for any indication; and

(B) ends on the date that is 15 years after the date of such approval.

(7) The term ''Secretary'' means the Secretary of Health and Human Services.

(8) The term ''sponsor'', with respect to a dormant therapy, is the person who takes responsibility for the designation and development of the dormant therapy. The sponsor may be a single entity or an entity collaborating with one or more other entities.

SEC. 4. CAPTURING LOST OPPORTUNITIES AND CREATING NEW CURES FOR PATIENTS.

(a) DESIGNATION AS A DORMANT THERAPY.—The Secretary shall designate a medicine as a dormant therapy if—

(1) the sponsor of the medicine submits a request for such designation meeting the requirements under subsection (b), and the request has not been withdrawn under subsection (d)(1); and

(2) the Secretary determines that—

(A) the medicine is being investigated or is intended to be investigated for an indication to address one or more unmet medical needs;

(B) a suitable clinical plan for such investigations of the medicine has been developed by the sponsor;

(C) the sponsor intends to file an application pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for approval or licensing of the medicine for an indication described in subparagraph (A); and

(D) at the time the request for designation is made, the medicine for which designation is being requested contains, in the case of a drug an active moiety that is not the same as, and in the case of a biological product an active moiety that is not highly similar to, an active moiety in a medicine for which an application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) has been submitted.

(b) REQUIREMENTS FOR REQUEST FOR DESIGNATION AS DORMANT THERAPY.—A request under subsection (a)(1) with respect to a medicine may be made only by the sponsor of the medicine and shall contain each of the following:

(1) A listing of all United States patents and applications for patents under which the sponsor has

rights and that may be reasonably construed to provide protection for the medicine.

(2) A waiver of patent rights to the extent required under subsection (c) to take effect, if at all, as provided under subsection (c)(3).

(3) Such additional information as the Secretary may require by regulation in order to determine eligibility for designation under subsection (a).

(c) WAIVER OF PATENT RIGHTS EXPIRING AFTER THE PROTECTION PERIOD ENDS.—

(1) PATENT WAIVER.—

(A) IN GENERAL.—Subject to subparagraph (B), the request under this subsection shall include a waiver of the right to enforce or otherwise assert any patent described in subsection (b)(1) (or any patent issued on the basis of an application described in subsection (b)(1)), which may expire after the end of the protection period for the dormant therapy, against any applicable product described in paragraph (2). The waiver shall be made by the owner of the patent or application for patent, as the case may be.

(B) LIMITATIONS ON PATENT WAIVER.—Any patent waiver provided pursuant to this section, should it become effective—

(i) shall have no effect during the protection period for the medicine to which the waiver relates; and

(ii) shall have no effect with respect to the subject matter of a claimed invention in a patent that does not provide any protection for such medicine with respect to an applicable product described in paragraph (2).

(2) APPLICABLE PRODUCTS DESCRIBED.—An applicable product is described in this paragraph only if—

(A) it is approved or licensed pursuant to an application that—

(i) is filed under section 505(b)(2) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2), (j)) or section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(ii) references or otherwise relies upon the approval or licensure of the dormant therapy to which the waiver relates; and

(B) the approval or licensure of the product occurs after the expiration of the protection period applicable to the medicine to which the request under subsection (a)(1) relates.

(3) EFFECTIVE DATE OF WAIVER.—A waiver under subsection (b)(2) with respect to a patent shall take effect, if at all, on the date the Director publishes the notice required under subsection (e)(2)(F) relating to the patent.

(d) WITHDRAWAL OF REQUEST FOR DESIGNATION, REVOCATION BY THE SECRETARY.—

(1) IN GENERAL.—The sponsor of a medicine may withdraw a request for designation under subsection (a)(1) with respect to a medicine unless the medicine has been approved or licensed under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262). The Secretary shall deny a designation request or revoke any designation granted if at any time the Secretary finds that the sponsor is not in compliance with subsection (c)(1) or (g)(1).

(2) EFFECTS OF WITHDRAWAL OF REQUEST OR REVOCATION OF DESIGNATION.—If the sponsor of a medicine withdraws a request under subsection (b)

or the Secretary denies a designation request or revokes a designation with respect to the medicine—

(A) any patent waiver submitted under this section with respect to the medicine, but not yet effective, is canceled and deemed a nullity;

(B) any patent waiver that has taken effect under this section with respect to the medicine shall remain in effect;

(C) any patent term extension granted by the Director under subsection (e)(2) with respect to the medicine shall be canceled, except that the Director shall maintain the patent term extension for one patent, to be selected by the sponsor of the medicine, for the period of extension that would have been applicable under section 156 of title 35, United States Code; and

(D) the designation, if made, otherwise shall be treated as never having been requested or made or having effect.

(3) BASIS FOR REVOCATION.—The Secretary may revoke a designation made under subsection (a), but only based upon a finding by the Secretary under paragraph (1).

(e) GUARANTEED PROTECTIONS FOR DORMANT THERAPIES.—

(1) APPLICATIONS FILED DURING THE PROTECTION PERIOD.—During the protection period for a dormant therapy, notwithstanding any other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.)—

(A) absent a right of reference from the holder of such approved application for the dormant therapy, the Secretary shall not approve an application filed pursuant to section 505(b)(2) or section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2), (j)) or section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) referencing or otherwise relying on the approval of the dormant therapy;

(B) the Secretary shall not approve—

(i) an application filed pursuant to such section 505(b)(2) or 505(j) that references or otherwise relies on the approval of a medicine that is not the dormant therapy, was approved subsequent to the approval of the dormant therapy, and con-

tains the same active moiety as the active moiety in the dormant therapy (or if the dormant therapy contains more than one active moiety, all of the active moieties are the same); or

(ii) an application filed pursuant to such section 351(k) that references or otherwise relies on the licensure of a medicine that is not the dormant therapy, was licensed subsequent to the licensure of the dormant therapy, and contains an active moiety that is highly similar to the active moiety in the dormant therapy (or if the dormant therapy contains more than one active moiety, all of the active moieties are highly similar); and

(C) the Secretary shall not approve an application filed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) for a drug that contains the same active moiety as the active moiety in the qualifying medicine (or if the qualifying medicine contains more than one active moiety, all of the active moieties are the same), or an application filed pursuant to section 351(a) of the

Public Health Service Act (42 U.S.C. 262(a)) for a biological product that contains an active moiety that is highly similar to the active moiety in the qualifying medicine (or if the qualifying medicine contains more than one active moiety, all of the active moieties are highly similar), unless the information provided to support approval of such application is comparable in scope and extent, including with respect to design and extent of preclinical and clinical testing, to the information provided to support approval of the application for the qualifying medicine under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(2) PATENT TERM ALIGNMENT WITH DATA PACKAGE PROTECTION PERIOD.—

(A) IN GENERAL.—Notwithstanding any provision of title 35, United States Code, a sponsor of a medicine designated as a dormant therapy under subsection (a)(1), upon the approval or licensure thereof under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health

Service Act (42 U.S.C. 262), and in lieu of filing a patent term extension application under section 156(d) of such title 35, shall be entitled to patent term extensions in accordance with this paragraph.

(B) SUBMISSION OF FINAL LISTING OF PATENTS AND APPLICATIONS FOR PATENTS FOLLOWING APPROVAL OR LICENSURE.—

(i) SUBMISSION.—The sponsor of the dormant therapy, within a period to be set by the Director of not less than 2 months beginning on the date the Secretary approves or licenses the dormant therapy, shall submit to the Director—

(I) the listing of patents and applications for patents provided to the Secretary under subsection (b)(1);

(II) any revisions to such listing as may be required for compliance with subsection (b)(1); and

(III) any documentation the Director may require from the patentee or patent applicant (as the case may be) of the waiver of patent rights required under subsection (b)(2).

(ii) FAILURE TO PROVIDE SUFFICIENT DOCUMENTATION OF WAIVER.—If the Director determines that the sponsor has not complied with the waiver requirements under subsection (c), after providing the sponsor the opportunity to remedy any insufficiency, the Director shall so notify the Secretary that the patent waiver requirements for designation have not been satisfied.

(C) EXTENSION OF PATENTS.—

(i) IN GENERAL.—Unless the Director has notified the Secretary of a determination under subparagraph (B)(ii), for each patent identified in a submission pursuant to subparagraph (B)(i), and for each patent issuing based upon an application for patent so identified, the Director shall, within the 3-month period beginning on the date of the submission, extend the patent to expire at the end of the protection period for the dormant therapy, if the patent would otherwise expire before the end of the protection period. If the Director has so notified the Secretary under sub-

paragraph (B)(ii), the Director shall extend one such patent, selected by the sponsor, for the period that would have been applicable had an application for extension been filed under section 156 of title 35, United States Code, with respect to such patent.

(ii) APPLICATION OF CERTAIN PROVISIONS.—During the period of an extension under clause (i)—

(I) the rights under the patent shall be limited in the manner provided under section 156(b) of title 35, United States Code; and

(II) the terms ''product'' and ''approved product'' in such section 156(b) shall be deemed to include forms of the active moiety of the dormant therapy and highly similar active moieties that might be approved or licensed by the Secretary based upon an application filed under section 505(b)(2) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2), (j)) or under

section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that references or otherwise relies upon the dormant therapy.

(D) INTERIM PATENT EXTENSIONS.—Notwithstanding any provision of title 35, United States Code, with respect to any patent listed (or patent issuing on an application listed) under subsection (b)(1) that would otherwise expire before the sponsor could make a submission under subparagraph (B), the Director, upon application of the patentee, shall grant to the patentee an interim extension of such patent, subject to the limitations in section 156(d)(5)(F) of such title 35, for such period as may be necessary to permit the sponsor to submit the listing under subparagraph (B) and, if the patent is therein listed, to extend the patent as provided under subparagraph (C). The Director may require, for any patent extended under this subparagraph, that the sponsor of the dormant therapy to which the patent relates provide periodic certifications that development of the dormant therapy is continuing. The Director may terminate any interim extension for

which a required certification has not been made.

(E) NOTICE OF EXTENSION.—For each patent that is extended under this paragraph, the Director shall publish a notice of such extension and issue a certificate of extension described in section 156(e)(1) of title 35, United States Code.

(F) NOTICE OF WAIVER.—For each patent identified in a submission under subparagraph (B)(i), and each patent issuing based upon an application for patent so identified, that expires after the end of the protection period for the dormant therapy, the Director shall publish a notice that the patent is subject to the limited waiver of the right to enforce described in subsection (c)(1).

(f) CERTAIN FDA PROTECTIONS INAPPLICABLE.—If a medicine has been designated as a dormant therapy under subsection (a), the protections otherwise applicable with respect to such medicine under sections 505A, 505E, and 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355f, 360cc) shall not apply. The preceding sentence shall not be construed to affect any protections applicable with respect to a medicine, including

a medicine designated under section 526 of such Act (21 U.S.C. 360bb) for a rare disease or condition, under provisions other than such sections 505A, 505E, and 527.

(g) DEVELOPMENT CERTIFICATIONS.—

(1) IN GENERAL.—The Secretary shall require that the sponsor of a dormant therapy provide a certification that the clinical plan under subsection (a)(2)(B) has been completed, and, that the initial marketing approval or licensure for the qualifying medicine was based on the investigations set forth in such clinical plan (including modifications to the initial plan approved by the Food and Drug Administration). Prior to receiving such certifications, the Secretary shall require periodic certifications that the clinical plan under subsection (a)(2)(B) is continuing.

(2) DETERMINATION OF NONCOMPLIANCE.—If the Secretary concludes that the sponsor has not complied with paragraph (1), after providing the sponsor the opportunity to remedy any insufficiency, the Secretary shall, for purposes of subsection (d)(1), determine that the sponsor is not in compliance with the certification requirement under paragraph (1).

(h) COLLABORATION.—Nothing in this section shall be construed as preventing a sponsor from collaborating with other entities in developing a dormant therapy or applying for a dormant therapy designation.

SEC. 5. IMPLEMENTATION AND EFFECT.

(a) EFFECTIVE DATE.—Subject to the provisions of this section, this Act shall take effect on the date of enactment.

(b) IMPLEMENTING REGULATIONS.—The Secretary, in consultation with the Secretary of Commerce, shall promulgate such regulations and finalize such guidance as necessary to implement the provisions of section 4. Such regulations or guidance shall take effect 18 months after the date of enactment of this Act.

(c) LIMITATION ON DETERMINATIONS AND DESIGNATIONS.—Notwithstanding any provision of section 4, the Secretary may not make a determination on a request for designation by a manufacturer or sponsor under section 4(a) prior to the effective date of the regulations under subsection (b) or 30 months after the date of enactment of this Act, whichever occurs first, and the Secretary may not designate a medicine under section 4(a) unless the requirement under section 4(a)(2)(D) is met for such medicine as of the effective date of the regulations under sub-

section (b) or 30 months after the date of enactment of this Act, whichever occurs first.

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