

113TH CONGRESS
2^D 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

A BILL

To promote the development of meaningful treatments for patients.

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 “Dormant Therapies
5 Act of 2014”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. Definitions.
- Sec. 4. Capturing lost opportunities and creating new cures for patients.
- Sec. 5. Implementation and effect.

1 **SEC. 3. DEFINITIONS.**

2 In this Act:

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

6 (2) The term “Director” means the Under Sec-
7 retary of Commerce for Intellectual Property and
8 Director of the United States Patent and Trade-
9 mark Office.

10 (3) The term “dormant therapy” means a med-
11 icine designated as a dormant therapy under section
12 4(a).

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

16 (5) The term “medicine” means a biological
17 product or a drug.

18 (6) The term “protection period”, with respect
19 to a dormant therapy, means the period that—

20 (A) begins on the date on which the Sec-
21 retary first approves an application under sec-
22 tion 505(b) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 355(b)) or section
24 351(a) of the Public Health Service Act (42
25 U.S.C. 262(a)) for the dormant therapy for any
26 indication; and

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

3 (7) The term “Secretary” means the Secretary
4 of Health and Human Services.

5 (8) The term “sponsor”, with respect to a dor-
6 mant therapy, is the person who takes responsibility
7 for the designation and development of the dormant
8 therapy. The sponsor may be a single entity or an
9 entity collaborating with one or more other entities.

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

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

15 (1) the sponsor of the medicine submits a re-
16 quest for such designation meeting the requirements
17 under subsection (b), and the request has not been
18 withdrawn under subsection (d)(1); and

19 (2) the Secretary determines that—

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

23 (B) a suitable clinical plan for such inves-
24 tigation of the medicine has been developed by
25 the sponsor;

1 (C) the sponsor intends to file an applica-
2 tion pursuant to section 505(b) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(b)) or section 351(a) of the Public Health
5 Service Act (42 U.S.C. 262(a)) for approval or
6 licensing of the medicine for an indication de-
7 scribed in subparagraph (A); and

8 (D) at the time the request for designation
9 is made, the medicine for which designation is
10 being requested contains, in the case of a drug
11 an active moiety that is not the same as, and
12 in the case of a biological product an active
13 moiety that is not highly similar to, an active
14 moiety in a medicine for which an application
15 under section 505 of the Federal Food, Drug,
16 and Cosmetic Act (21 U.S.C. 355) or section
17 351 of the Public Health Service Act (42
18 U.S.C. 262) has been submitted.

19 (b) REQUIREMENTS FOR REQUEST FOR DESIGNA-
20 TION AS DORMANT THERAPY.—A request under sub-
21 section (a)(1) with respect to a medicine may be made only
22 by the sponsor of the medicine and shall contain each of
23 the following:

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

1 rights and that may be reasonably construed to pro-
2 vide protection for the medicine.

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

6 (3) Such additional information as the Sec-
7 retary may require by regulation in order to deter-
8 mine eligibility for designation under subsection (a).

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

11 (1) PATENT WAIVER.—

12 (A) IN GENERAL.—Subject to subpara-
13 graph (B), the request under this subsection
14 shall include a waiver of the right to enforce or
15 otherwise assert any patent described in sub-
16 section (b)(1) (or any patent issued on the basis
17 of an application described in subsection
18 (b)(1)), which may expire after the end of the
19 protection period for the dormant therapy,
20 against any applicable product described in
21 paragraph (2). The waiver shall be made by the
22 owner of the patent or application for patent,
23 as the case may be.

1 (B) LIMITATIONS ON PATENT WAIVER.—

2 Any patent waiver provided pursuant to this
3 section, should it become effective—

4 (i) shall have no effect during the pro-
5 tection period for the medicine to which
6 the waiver relates; and

7 (ii) shall have no effect with respect to
8 the subject matter of a claimed invention
9 in a patent that does not provide any pro-
10 tection for such medicine with respect to
11 an applicable product described in para-
12 graph (2).

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

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

18 (i) is filed under section 505(b)(2) or
19 505(j) of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 355(b)(2), (j)) or
21 section 351(k) of the Public Health Service
22 Act (42 U.S.C. 262(k)); and

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

1 (B) the approval or licensure of the prod-
2 uct occurs after the expiration of the protection
3 period applicable to the medicine to which the
4 request under subsection (a)(1) relates.

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

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

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

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

1 or the Secretary denies a designation request or re-
2 vokes a designation with respect to the medicine—

3 (A) any patent waiver submitted under
4 this section with respect to the medicine, but
5 not yet effective, is canceled and deemed a nul-
6 lity;

7 (B) any patent waiver that has taken ef-
8 fect under this section with respect to the medi-
9 cine shall remain in effect;

10 (C) any patent term extension granted by
11 the Director under subsection (e)(2) with re-
12 spect to the medicine shall be canceled, except
13 that the Director shall maintain the patent
14 term extension for one patent, to be selected by
15 the sponsor of the medicine, for the period of
16 extension that would have been applicable under
17 section 156 of title 35, United States Code; and

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

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

1 (e) GUARANTEED PROTECTIONS FOR DORMANT
2 THERAPIES.—

3 (1) APPLICATIONS FILED DURING THE PROTEC-
4 TION PERIOD.—During the protection period for a
5 dormant therapy, notwithstanding any other provi-
6 sion of the Federal Food, Drug, and Cosmetic Act
7 (21 U.S.C. 301 et seq.) or the Public Health Service
8 Act (42 U.S.C. 201 et seq.)—

9 (A) absent a right of reference from the
10 holder of such approved application for the dor-
11 mant therapy, the Secretary shall not approve
12 an application filed pursuant to section
13 505(b)(2) or section 505(j) of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C.
15 355(b)(2), (j)) or section 351(k) of the Public
16 Health Service Act (42 U.S.C. 262(k)) ref-
17 erencing or otherwise relying on the approval of
18 the dormant therapy;

19 (B) the Secretary shall not approve—

20 (i) an application filed pursuant to
21 such section 505(b)(2) or 505(j) that ref-
22 erences or otherwise relies on the approval
23 of a medicine that is not the dormant ther-
24 apy, was approved subsequent to the ap-
25 proval of the dormant therapy, and con-

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

6 (ii) an application filed pursuant to
7 such section 351(k) that references or oth-
8 erwise relies on the licensure of a medicine
9 that is not the dormant therapy, was li-
10 censed subsequent to the licensure of the
11 dormant therapy, and contains an active
12 moiety that is highly similar to the active
13 moiety in the dormant therapy (or if the
14 dormant therapy contains more than one
15 active moiety, all of the active moieties are
16 highly similar); and

17 (C) the Secretary shall not approve an ap-
18 plication filed pursuant to section 505(b)(1) of
19 the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 355(b)(1)) for a drug that contains the
21 same active moiety as the active moiety in the
22 qualifying medicine (or if the qualifying medi-
23 cine contains more than one active moiety, all
24 of the active moieties are the same), or an ap-
25 plication filed pursuant to section 351(a) of the

1 Public Health Service Act (42 U.S.C. 262(a))
2 for a biological product that contains an active
3 moiety that is highly similar to the active moi-
4 ety in the qualifying medicine (or if the quali-
5 fying medicine contains more than one active
6 moiety, all of the active moieties are highly
7 similar), unless the information provided to
8 support approval of such application is com-
9 parable in scope and extent, including with re-
10 spect to design and extent of preclinical and
11 clinical testing, to the information provided to
12 support approval of the application for the
13 qualifying medicine under section 505(b) of the
14 Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 355(b)) or section 351(a) of the Public
16 Health Service Act (42 U.S.C. 262(a)).

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

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

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

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

9 (i) SUBMISSION.—The sponsor of the
10 dormant therapy, within a period to be set
11 by the Director of not less than 2 months
12 beginning on the date the Secretary ap-
13 proves or licenses the dormant therapy,
14 shall submit to the Director—

15 (I) the listing of patents and ap-
16 plications for patents provided to the
17 Secretary under subsection (b)(1);

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

21 (III) any documentation the Di-
22 rector may require from the patentee
23 or patent applicant (as the case may
24 be) of the waiver of patent rights re-
25 quired under subsection (b)(2).

1 (ii) FAILURE TO PROVIDE SUFFICIENT
2 DOCUMENTATION OF WAIVER.—If the Di-
3 rector determines that the sponsor has not
4 complied with the waiver requirements
5 under subsection (c), after providing the
6 sponsor the opportunity to remedy any in-
7 sufficiency, the Director shall so notify the
8 Secretary that the patent waiver require-
9 ments for designation have not been satis-
10 fied.

11 (C) EXTENSION OF PATENTS.—

12 (i) IN GENERAL.—Unless the Director
13 has notified the Secretary of a determina-
14 tion under subparagraph (B)(ii), for each
15 patent identified in a submission pursuant
16 to subparagraph (B)(i), and for each pat-
17 ent issuing based upon an application for
18 patent so identified, the Director shall,
19 within the 3-month period beginning on
20 the date of the submission, extend the pat-
21 ent to expire at the end of the protection
22 period for the dormant therapy, if the pat-
23 ent would otherwise expire before the end
24 of the protection period. If the Director
25 has so notified the Secretary under sub-

1 paragraph (B)(ii), the Director shall ex-
2 tend one such patent, selected by the spon-
3 sor, for the period that would have been
4 applicable had an application for extension
5 been filed under section 156 of title 35,
6 United States Code, with respect to such
7 patent.

8 (ii) APPLICATION OF CERTAIN PROVI-
9 SIONS.—During the period of an extension
10 under clause (i)—

11 (I) the rights under the patent
12 shall be limited in the manner pro-
13 vided under section 156(b) of title 35,
14 United States Code; and

15 (II) the terms “product” and
16 “approved product” in such section
17 156(b) shall be deemed to include
18 forms of the active moiety of the dor-
19 mant therapy and highly similar ac-
20 tive moieties that might be approved
21 or licensed by the Secretary based
22 upon an application filed under sec-
23 tion 505(b)(2) or 505(j) of the Fed-
24 eral Food, Drug, and Cosmetic Act
25 (21 U.S.C. 355(b)(2), (j)) or under

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

5 (D) INTERIM PATENT EXTENSIONS.—Not-
6 withstanding any provision of title 35, United
7 States Code, with respect to any patent listed
8 (or patent issuing on an application listed)
9 under subsection (b)(1) that would otherwise
10 expire before the sponsor could make a submis-
11 sion under subparagraph (B), the Director,
12 upon application of the patentee, shall grant to
13 the patentee an interim extension of such pat-
14 ent, subject to the limitations in section
15 156(d)(5)(F) of such title 35, for such period
16 as may be necessary to permit the sponsor to
17 submit the listing under subparagraph (B) and,
18 if the patent is therein listed, to extend the pat-
19 ent as provided under subparagraph (C). The
20 Director may require, for any patent extended
21 under this subparagraph, that the sponsor of
22 the dormant therapy to which the patent relates
23 provide periodic certifications that development
24 of the dormant therapy is continuing. The Di-
25 rector may terminate any interim extension for

1 which a required certification has not been
2 made.

3 (E) NOTICE OF EXTENSION.—For each
4 patent that is extended under this paragraph,
5 the Director shall publish a notice of such ex-
6 tension and issue a certificate of extension de-
7 scribed in section 156(e)(1) of title 35, United
8 States Code.

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

18 (f) CERTAIN FDA PROTECTIONS INAPPLICABLE.—If
19 a medicine has been designated as a dormant therapy
20 under subsection (a), the protections otherwise applicable
21 with respect to such medicine under sections 505A, 505E,
22 and 527 of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 355a, 355f, 360cc) shall not apply. The pre-
24 ceding sentence shall not be construed to affect any pro-
25 tections applicable with respect to a medicine, including

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

4 (g) DEVELOPMENT CERTIFICATIONS.—

5 (1) IN GENERAL.—The Secretary shall require
6 that the sponsor of a dormant therapy provide a cer-
7 tification that the clinical plan under subsection
8 (a)(2)(B) has been completed, and, that the initial
9 marketing approval or licensure for the qualifying
10 medicine was based on the investigations set forth in
11 such clinical plan (including modifications to the ini-
12 tial plan approved by the Food and Drug Adminis-
13 tration). Prior to receiving such certifications, the
14 Secretary shall require periodic certifications that
15 the clinical plan under subsection (a)(2)(B) is con-
16 tinuing.

17 (2) DETERMINATION OF NONCOMPLIANCE.—If
18 the Secretary concludes that the sponsor has not
19 complied with paragraph (1), after providing the
20 sponsor the opportunity to remedy any insufficiency,
21 the Secretary shall, for purposes of subsection
22 (d)(1), determine that the sponsor is not in compli-
23 ance with the certification requirement under para-
24 graph (1).

1 (h) COLLABORATION.—Nothing in this section shall
2 be construed as preventing a sponsor from collaborating
3 with other entities in developing a dormant therapy or ap-
4 plying for a dormant therapy designation.

5 **SEC. 5. IMPLEMENTATION AND EFFECT.**

6 (a) EFFECTIVE DATE.—Subject to the provisions of
7 this section, this Act shall take effect on the date of enact-
8 ment.

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

15 (c) LIMITATION ON DETERMINATIONS AND DESIGNA-
16 TIONS.—Notwithstanding any provision of section 4, the
17 Secretary may not make a determination on a request for
18 designation by a manufacturer or sponsor under section
19 4(a) prior to the effective date of the regulations under
20 subsection (b) or 30 months after the date of enactment
21 of this Act, whichever occurs first, and the Secretary may
22 not designate a medicine under section 4(a) unless the re-
23 quirement under section 4(a)(2)(D) is met for such medi-
24 cine as of the effective date of the regulations under sub-

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

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