

111TH CONGRESS
1ST SESSION

H. R. 1548

To amend the Public Health Service Act to establish a pathway for the licensure of biosimilar biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 17, 2009

Ms. ESHOO (for herself, Mr. INSLEE, Mr. BARTON of Texas, Mr. GENE GREEN of Texas, Ms. BALDWIN, Mr. ROGERS of Michigan, Mrs. BONO MACK, Mr. HILL, Mr. UPTON, Mr. BARROW, Mr. PITTS, Mr. THOMPSON of California, Mr. CAPUANO, Mrs. DAVIS of California, Mr. BILBRAY, Mr. DREIER, Mr. ELLSWORTH, Mr. MCGOVERN, Mr. HERGER, Mr. DENT, Mr. GERLACH, Mr. BISHOP of New York, Ms. ZOE LOFGREN of California, Mr. PENCE, Mr. SOUDER, Mr. HONDA, Mrs. TAUSCHER, Mr. SCALISE, Mr. TOWNS, Mr. CROWLEY, Mr. ISSA, Mr. PATRICK J. MURPHY of Pennsylvania, Ms. BEAN, Mr. DELAHUNT, Mr. SMITH of Washington, Mr. MCCARTHY of California, Mr. NEAL of Massachusetts, Mr. LYNCH, Mr. DONNELLY of Indiana, Mr. HALL of Texas, Mr. LANCE, Mr. HOLT, Mr. NUNES, and Mr. KIND) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act to establish a pathway for the licensure of biosimilar biological products, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Pathway for
3 Biosimilars Act”.

4 **SEC. 2. TABLE OF CONTENTS.**

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

Sec. 1. Short title.

Sec. 2. Table of contents.

TITLE I—AMENDMENTS TO PUBLIC HEALTH SERVICE ACT

Sec. 101. Approval pathway for biosimilar biological products.

Sec. 102. Fees relating to biosimilar biological products.

TITLE II—AMENDMENTS TO PATENT ACT

Sec. 201. Amendments to certain patent provisions.

6 **TITLE I—AMENDMENTS TO**
7 **PUBLIC HEALTH SERVICE ACT**

8 **SEC. 101. LICENSURE PATHWAY FOR BIOSIMILAR BIOLOGI-**
9 **CAL PRODUCTS.**

10 (a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-
11 SIMILAR OR INTERCHANGEABLE.—Section 351 of the
12 Public Health Service Act (42 U.S.C. 262) is amended—

13 (1) in subsection (a)(1)(A), by inserting “under
14 this subsection or subsection (k)” after “biologics li-
15 cense”; and

16 (2) by adding at the end the following:

17 “(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-
18 SIMILAR.—

19 “(1) IN GENERAL.—Any person may submit an
20 application for licensure of a biological product
21 under this subsection.

1 “(2) CONTENT.—

2 “(A) REQUIRED INFORMATION.—An appli-
3 cation submitted under this subsection shall in-
4 clude information demonstrating that—

5 “(i) the biological product is bio-
6 similar to a reference product based upon
7 data derived from—

8 “(I) analytical studies that dem-
9 onstrate that the biological product is
10 highly similar to the reference product
11 notwithstanding minor differences in
12 clinically inactive components;

13 “(II) animal studies (including
14 the assessment of toxicity); and

15 “(III) a clinical study or studies
16 (including, but not limited to, the as-
17 sessment of immunogenicity and phar-
18 macokinetics or pharmacodynamics)
19 that are sufficient to demonstrate
20 safety, purity, and potency for each
21 condition of use for which the ref-
22 erence product is approved;

23 “(ii) the biological product and ref-
24 erence product utilize the same mechanism
25 or mechanisms of action for the condition

1 or conditions of use prescribed, rec-
2 ommended, or suggested in the proposed
3 labeling, but only to the extent the mecha-
4 nism or mechanisms of action are known
5 for the reference product;

6 “(iii) the condition or conditions of
7 use prescribed, recommended, or suggested
8 in the labeling proposed for the biological
9 product have been previously approved for
10 the reference product;

11 “(iv) the route of administration, the
12 dosage form, and the strength of the bio-
13 logical product are the same as those of
14 the reference product; and

15 “(v) the facility in which the biological
16 product is manufactured, processed,
17 packed, or held meets standards designed
18 to assure that the biological product con-
19 tinues to be safe, pure, and potent.

20 “(B) WAIVER REGARDING ANALYTICAL
21 STUDIES, ANIMAL STUDIES, AND CLINICAL
22 STUDIES.—

23 “(i) IN GENERAL.—The Secretary
24 may, in the Secretary’s discretion, deter-
25 mine that an element described in sub-

1 clause (I), (II), or (III) of subparagraph
2 (A)(i) is unnecessary and waive the re-
3 quirement that such element be submitted
4 in an application under this subsection.

5 “(ii) ASSESSMENTS OF
6 IMMUNOGENICITY.—Notwithstanding
7 clause (i), the Secretary may determine
8 that an assessment of immunogenicity de-
9 scribed in subparagraph (A)(i)(III) is un-
10 necessary and waive the requirement that
11 such an assessment be submitted in an ap-
12 plication under this subsection only if the
13 Secretary has published a final guidance,
14 following receipt and consideration of pub-
15 lic comments on a draft guidance—

16 “(I) advising that it is feasible in
17 the current state of scientific knowl-
18 edge to make determinations on
19 immunogenicity with respect to prod-
20 ucts in the product class to which the
21 biological product belongs; and

22 “(II) explaining the data that
23 will be required to support such a de-
24 termination.

1 “(C) ADDITIONAL INFORMATION.—An ap-
2 plication submitted under this subsection—

3 “(i) shall include publicly available in-
4 formation regarding the Secretary’s pre-
5 vious determination that the reference
6 product is safe, pure, and potent; and

7 “(ii) may include any additional infor-
8 mation in support of the application, in-
9 cluding publicly available information with
10 respect to the reference product or another
11 biological product.

12 “(3) EVALUATION BY SECRETARY.—Upon re-
13 view of an application (or a supplement to an appli-
14 cation) submitted under this subsection, the Sec-
15 retary shall approve the application (or the supple-
16 ment) if—

17 “(A) the Secretary determines that the in-
18 formation submitted in the application (or the
19 supplement) is sufficient to show that the bio-
20 logical product is biosimilar to the reference
21 product with respect to each condition of use
22 for which the reference product is approved;
23 and

24 “(B) the applicant (or other appropriate
25 person) consents to the inspection of the facility

1 that is the subject of the application, in accord-
2 ance with subsection (c).

3 “(4) SAFETY STANDARDS FOR DETERMINING
4 INTERCHANGEABILITY.—

5 “(A) DETERMINATION.—Upon review of
6 an application submitted under this subsection
7 or any supplement to such application, the Sec-
8 retary shall determine the biological product to
9 be interchangeable with the reference product if
10 the Secretary determines that the information
11 submitted in the application (or a supplement
12 to such application) is sufficient to show that—

13 “(i) the biological product—

14 “(I) is biosimilar to the reference
15 product and any biological product li-
16 censed under this subsection that has
17 been determined to be interchangeable
18 with the reference product; and

19 “(II) can be expected to produce
20 the same clinical result as the ref-
21 erence product in any given patient
22 for each condition of use prescribed,
23 recommended, or suggested in the la-
24 beling of the reference product; and

1 “(ii) for a biological product that is
2 administered more than once to an indi-
3 vidual, the risk of alternating or switching
4 between use of the biological product and
5 the reference product (in terms of safety,
6 diminished efficacy, and reduced or en-
7 hanced potency) is not greater than the
8 risk of using the reference product without
9 such alternation or switching.

10 “(B) GUIDELINES.—Notwithstanding sub-
11 paragraph (A), the Secretary may not make a
12 determination that a biological product licensed
13 under this subsection is interchangeable with
14 the reference product unless the Secretary has
15 published a final guidance, following receipt and
16 consideration of public comments on a draft
17 guidance—

18 “(i) advising that it is feasible in the
19 current state of scientific knowledge to
20 make such determinations with respect to
21 products in the product class to which that
22 biological product belongs; and

23 “(ii) explaining the data that will be
24 required to support such a determination.

1 “(C) PRESERVATION OF STATE AUTHOR-
2 ITY.—Nothing in this subsection shall be con-
3 strued as preempting or otherwise affecting the
4 authority of a State to require or regulate pre-
5 scriptions.

6 “(5) GENERAL RULES.—

7 “(A) ONE REFERENCE PRODUCT PER AP-
8 PLICATION.—A biological product, in an appli-
9 cation submitted under this subsection, may not
10 be evaluated against more than 1 reference
11 product.

12 “(B) REVIEW.—An application submitted
13 under this subsection shall be reviewed by the
14 division within the Food and Drug Administra-
15 tion that is responsible for the review and ap-
16 proval of the application under which the ref-
17 erence product is licensed.

18 “(C) RISK EVALUATION AND MITIGATION
19 STRATEGIES.—The authority of the Secretary
20 with respect to risk evaluation and mitigation
21 strategies under the Federal Food, Drug, and
22 Cosmetic Act shall apply to biological products
23 licensed under this subsection in the same man-
24 ner as such authority applies to biological prod-
25 ucts licensed under subsection (a).

1 “(D) RESTRICTIONS ON BIOLOGICAL PROD-
2 UCTS CONTAINING DANGEROUS INGREDI-
3 ENTS.—If information in an application sub-
4 mitted under this subsection, in a supplement
5 to such an application, or otherwise available to
6 the Secretary shows that a biological product—

7 “(i) is, bears, or contains a select
8 agent or toxin listed in section 73.3 or
9 73.4 of title 42, section 121.3 or 121.4 of
10 title 9, or section 331.3 of title 7, Code of
11 Federal Regulations (or any successor reg-
12 ulations); or

13 “(ii) is, bears, or contains a controlled
14 substance in schedule I or II of section
15 202 of the Controlled Substances Act, as
16 listed in part 1308 of title 21, Code of
17 Federal Regulations (or any successor reg-
18 ulations);

19 the Secretary shall not license the biological
20 product under this subsection unless the Sec-
21 retary determines, after consultation with ap-
22 propriate national security and drug enforce-
23 ment agencies, that there would be no increased
24 risk to the security or health of the public from

1 licensing such biological product under this sub-
2 section.

3 “(6) EXCLUSIVITY FOR FIRST INTERCHANGE-
4 ABLE BIOLOGICAL PRODUCT.—The Secretary shall
5 not make a determination under paragraph (4) that
6 a second or subsequent biological product is inter-
7 changeable with the same reference product for
8 which a prior biological product has received a deter-
9 mination of interchangeability until 24 months after
10 the later of—

11 “(A) the date of the first commercial mar-
12 keting of the first biosimilar biological product
13 determined to be interchangeable for that ref-
14 erence product; or

15 “(B) with respect to a product marketed
16 before the date the product is determined to be
17 interchangeable, the date that the product is
18 determined to be interchangeable.

19 “(7) EXCLUSIVITY FOR REFERENCE PROD-
20 UCT.—

21 “(A) EFFECTIVE DATE OF BIOSIMILAR AP-
22 PLICATION LICENSURE.—Subject to subpara-
23 graph (D) and paragraph (8), approval of an
24 application under this subsection may not be
25 made effective by the Secretary until the date

1 that is 12 years after the date on which the ref-
2 erence product was first licensed under sub-
3 section (a).

4 “(B) FILING PERIOD.—An application
5 under this subsection may not be submitted to
6 the Secretary until the later of—

7 “(i) the date of commencement of a
8 proceeding for issuance of guidance pursu-
9 ant to paragraph (9) with respect to the
10 product class within which the product
11 that is the subject of such application falls;
12 or

13 “(ii) the date that is 4 years after the
14 date on which the reference product was
15 first licensed under subsection (a).

16 “(C) FIRST LICENSURE.—For purposes of
17 this paragraph, the date on which the reference
18 product was first licensed under subsection (a)
19 does not include the date of approval of a sup-
20 plement or of a subsequent application for a
21 new indication, route of administration, dosage
22 form, or strength for the previously licensed ref-
23 erence product.

24 “(D) MEDICALLY SIGNIFICANT NEW INDI-
25 CATION.—If, during the 8-year period following

1 licensure of the reference product, the Secretary
2 approves a supplement to the application for
3 the reference product that seeks approval to
4 market the reference product for a new indica-
5 tion that, if approved, would be a significant
6 improvement, compared to marketed products,
7 in the treatment, diagnosis, or prevention of
8 disease, approval of an application submitted
9 under this subsection may not be made effective
10 by the Secretary until the date that is 14 years
11 after the date on which the reference product
12 was first licensed under subsection (a).

13 “(8) PEDIATRIC STUDIES.—

14 “(A) EXCLUSIVITY.—If, before or after li-
15 censure of the reference product under sub-
16 section (a) of this section, the Secretary deter-
17 mines that information relating to the use of
18 such product in the pediatric population may
19 produce health benefits in that population, the
20 Secretary makes a written request for pediatric
21 studies (which shall include a timeframe for
22 completing such studies), the applicant or hold-
23 er of the approved application agrees to the re-
24 quest, such studies are completed using appro-
25 priate formulations for each age group for

1 which the study is requested within any such
2 timeframe, and the reports thereof are sub-
3 mitted and accepted in accordance with section
4 505A(d)(3) of the Federal Food, Drug, and
5 Cosmetic Act—

6 “(i) the period referred to in para-
7 graph (7)(A) of this subsection is deemed
8 to be 12 years and 6 months rather than
9 12 years; and

10 “(ii) if paragraph (7)(D) of this sub-
11 section applies, the period referred to in
12 such paragraph is deemed to be 14 years
13 and 6 months rather than 14 years.

14 “(B) EXCEPTION.—The Secretary shall
15 not extend the period referred to in subpara-
16 graph (A)(i) or (A)(ii) of this paragraph if the
17 determination under section 505A(d)(3) of the
18 Federal Food, Drug, and Cosmetic Act is made
19 later than 9 months prior to the expiration of
20 such period.

21 “(C) APPLICATION OF CERTAIN PROVI-
22 SIONS.—The provisions of subsections (a), (d),
23 (e), (f), (h), (j), (k), and (l) of section 505A of
24 the Federal Food, Drug, and Cosmetic Act
25 shall apply with respect to the extension of a

1 period under subparagraph (A) of this para-
2 graph to the same extent and in the same man-
3 ner as such provisions apply with respect to the
4 extension of a period under subsection (b) or
5 (c) of section 505A of the Federal Food, Drug,
6 and Cosmetic Act.

7 “(9) GUIDANCE DOCUMENTS.—

8 “(A) IN GENERAL.—The Secretary shall,
9 after opportunity for public comment, issue
10 final guidance with respect to the licensure
11 under this subsection of a biological product or
12 product class. Such guidance shall be issued in
13 accordance, except as provided in subparagraph
14 (B)(i), with section 701(h) of the Federal Food,
15 Drug, and Cosmetic Act.

16 “(B) PUBLIC COMMENT.—

17 “(i) IN GENERAL.—Before issuing
18 final guidance under subparagraph (A),
19 the Secretary shall publish a proposed
20 guidance, provide an opportunity for the
21 public to comment on the proposed guid-
22 ance, and publish a response to comments
23 received under this clause.

24 “(ii) INPUT REGARDING MOST VALU-
25 ABLE GUIDANCE.—The Secretary shall es-

1 tablish a process through which the public
2 may provide the Secretary with input re-
3 garding priorities for issuing guidance.

4 “(C) CERTAIN PRODUCT CLASSES.—

5 “(i) GUIDANCE.—The Secretary may
6 indicate in a guidance document under
7 subparagraph (A) that the Secretary will
8 not license a product or product class (not
9 including any recombinant protein) under
10 this subsection because the science and ex-
11 perience, as of the date of such guidance,
12 does not allow such licensure.

13 “(ii) MODIFICATION OR REVERSAL.—

14 The Secretary may issue a subsequent
15 guidance document under subparagraph
16 (A) to modify or reverse a guidance docu-
17 ment under clause (i).

18 “(D) PETITION FOR INITIATION OF GUID-
19 ANCE FOR CERTAIN PRODUCTS.—In the case of
20 a reference product that was licensed by the
21 Secretary more than 7 years prior to the date
22 of the enactment of the Pathway for
23 Biosimilars Act, a person may petition the Sec-
24 retary at any time to commence the process for
25 issuing final guidance under subparagraph (A)

1 for the product class to which the reference
2 product belongs. Any such petition shall include
3 a description of the scientific feasibility and ra-
4 tionale for the request. For guidance petitioned
5 under this subparagraph, the Secretary shall,
6 within 2 years of such petition, issue final guid-
7 ance with respect to that product class.

8 “(E) REQUIREMENT FOR APPLICATION
9 CONSIDERATION.—The Secretary may not ac-
10 cept an application under this subsection until
11 the Secretary has initiated a proceeding for
12 issuance of guidance with respect to the product
13 class within which the product that is the sub-
14 ject of the application falls. The Secretary may
15 not approve an application under this sub-
16 section until the Secretary has completed the
17 proceeding for issuance of guidance with re-
18 spect to the product class within which the
19 product that is the subject of the application
20 falls.

21 “(F) REQUIREMENT FOR PRODUCT CLASS-
22 SPECIFIC GUIDANCE.—Product class-specific
23 guidance issued under subparagraph (A) shall
24 include a description of—

1 “(i) the criteria that the Secretary will
2 use to determine whether a biological prod-
3 uct is biosimilar to a reference product in
4 such product class;

5 “(ii) the criteria, if available, that the
6 Secretary will use to determine whether a
7 biological product meets the standards for
8 interchangeability described in paragraph
9 (4); and

10 “(iii) the criteria, if available, that the
11 Secretary will use to assess
12 immunogenicity.

13 “(10) NAMING.—The Secretary shall ensure
14 that the labeling and packaging of each biological
15 product licensed under this subsection bears a name
16 that uniquely identifies the biological product and
17 distinguishes it from the reference product and any
18 other biological products licensed under this sub-
19 section following evaluation against such reference
20 product.

21 “(l) PATENT NOTICES; RELATIONSHIP TO FINAL AP-
22 PROVAL.—

23 “(1) DEFINITIONS.—For the purposes of this
24 subsection, the term—

1 “(A) ‘biosimilar product’ means the bio-
2 logical product that is the subject of the appli-
3 cation under subsection (k);

4 “(B) ‘relevant patent’ means a patent
5 that—

6 “(i) expires after the date specified in
7 subsection (k)(7)(A) that applies to the
8 reference product; and

9 “(ii) could reasonably be asserted
10 against the applicant due to the unauthor-
11 ized making, use, sale, or offer for sale
12 within the United States, or the importa-
13 tion into the United States of the bio-
14 similar product, or materials used in the
15 manufacture of the biosimilar product, or
16 due to a use of the biosimilar product in
17 a method of treatment that is indicated in
18 the application;

19 “(C) ‘reference product sponsor’ means the
20 holder of an approved application or license for
21 the reference product; and

22 “(D) ‘interested third party’ means a per-
23 son other than the reference product sponsor
24 that owns a relevant patent, or has the right to

1 commence or participate in an action for in-
2 fringement of a relevant patent.

3 “(2) HANDLING OF CONFIDENTIAL INFORMA-
4 TION.—Any entity receiving confidential information
5 pursuant to this subsection shall designate one or
6 more individuals to receive such information. Each
7 individual so designated shall execute an agreement
8 in accordance with regulations promulgated by the
9 Secretary. The regulations shall require each such
10 individual to take reasonable steps to maintain the
11 confidentiality of information received pursuant to
12 this subsection and use the information solely for
13 purposes authorized by this subsection. The obliga-
14 tions imposed on an individual who has received con-
15 fidential information pursuant to this subsection
16 shall continue until the individual returns or de-
17 stroys the confidential information, a court imposes
18 a protective order that governs the use or handling
19 of the confidential information, or the party pro-
20 viding the confidential information agrees to other
21 terms or conditions regarding the handling or use of
22 the confidential information.

23 “(3) PUBLIC NOTICE BY SECRETARY.—Within
24 30 days of acceptance by the Secretary of an appli-

1 cation filed under subsection (k), the Secretary shall
2 publish a notice identifying—

3 “(A) the reference product identified in the
4 application; and

5 “(B) the name and address of an agent
6 designated by the applicant to receive notices
7 pursuant to paragraph (4)(B).

8 “(4) EXCHANGES CONCERNING PATENTS.—

9 “(A) EXCHANGES WITH REFERENCE
10 PRODUCT SPONSOR.—

11 “(i) Within 30 days of the date of ac-
12 ceptance of the application by the Sec-
13 retary, the applicant shall provide the ref-
14 erence product sponsor with a copy of the
15 application and information concerning the
16 biosimilar product and its production. This
17 information shall include a detailed de-
18 scription of the biosimilar product, its
19 method of manufacture, and the materials
20 used in the manufacture of the product.

21 “(ii) Within 60 days of the date of re-
22 ceipt of the information required to be pro-
23 vided under clause (i), the reference prod-
24 uct sponsor shall provide to the applicant
25 a list of relevant patents owned by the ref-

1 erence product sponsor, or in respect of
2 which the reference product sponsor has
3 the right to commence an action of in-
4 fringement or otherwise has an interest in
5 the patent as such patent concerns the bio-
6 similar product.

7 “(iii) If the reference product sponsor
8 is issued or acquires an interest in a rel-
9 evant patent after the date on which the
10 reference product sponsor provides the list
11 required by clause (ii) to the applicant, the
12 reference product sponsor shall identify
13 that patent to the applicant within 30 days
14 of the date of issue of the patent, or the
15 date of acquisition of the interest in the
16 patent, as applicable.

17 “(B) EXCHANGES WITH INTERESTED
18 THIRD PARTIES.—

19 “(i) At any time after the date on
20 which the Secretary publishes a notice for
21 an application under paragraph (3), any
22 interested third party may provide notice
23 to the designated agent of the applicant
24 that the interested third party owns or has
25 rights under 1 or more patents that may

1 be relevant patents. The notice shall iden-
2 tify at least 1 patent and shall designate
3 an individual who has executed an agree-
4 ment in accordance with paragraph (2) to
5 receive confidential information from the
6 applicant.

7 “(ii) Within 30 days of the date of re-
8 ceiving notice pursuant to clause (i), the
9 applicant shall send to the individual des-
10 ignated by the interested third party the
11 information specified in subparagraph
12 (A)(i), unless the applicant and interested
13 third party otherwise agree.

14 “(iii) Within 90 days of the date of
15 receiving information pursuant to clause
16 (ii), the interested third party shall provide
17 to the applicant a list of relevant patents
18 which the interested third party owns, or
19 in respect of which the interested third
20 party has the right to commence or partici-
21 pate in an action for infringement.

22 “(iv) If the interested third party is
23 issued or acquires an interest in a relevant
24 patent after the date on which the inter-
25 ested third party provides the list required

1 by clause (iii), the interested third party
2 shall identify that patent within 30 days of
3 the date of issue of the patent, or the date
4 of acquisition of the interest in the patent,
5 as applicable.

6 “(C) IDENTIFICATION OF BASIS FOR IN-
7 FRINGEMENT.—For any patent identified under
8 clause (ii) or (iii) of subparagraph (A) or under
9 clause (iii) or (iv) of subparagraph (B), the ref-
10 erence product sponsor or the interested third
11 party, as applicable—

12 “(i) shall explain in writing why the
13 sponsor or the interested third party be-
14 lieves the relevant patent would be in-
15 fringed by the making, use, sale, or offer
16 for sale within the United States, or im-
17 portation into the United States, of the
18 biosimilar product or by a use of the bio-
19 similar product in treatment that is indi-
20 cated in the application;

21 “(ii) may specify whether the relevant
22 patent is available for licensing; and

23 “(iii) shall specify the number and
24 date of expiration of the relevant patent.

1 “(D) CERTIFICATION BY APPLICANT CON-
2 CERNING IDENTIFIED RELEVANT PATENTS.—
3 Not later than 45 days after the date on which
4 a patent is identified under clause (ii) or (iii) of
5 subparagraph (A) or under clause (iii) or (iv) of
6 subparagraph (B), the applicant shall send a
7 written statement regarding each identified pat-
8 ent to the party that identified the patent. Such
9 statement shall either—

10 “(i) state that the applicant will not
11 commence marketing of the biosimilar
12 product and has requested the Secretary to
13 not grant final approval of the application
14 before the date of expiration of the noticed
15 patent; or

16 “(ii) provide a detailed written expla-
17 nation setting forth the reasons why the
18 applicant believes—

19 “(I) the making, use, sale, or
20 offer for sale within the United
21 States, or the importation into the
22 United States, of the biosimilar prod-
23 uct, or the use of the biosimilar prod-
24 uct in a treatment indicated in the ap-

1 plication, would not infringe the pat-
2 ent; or

3 “(II) the patent is invalid or un-
4 enforceable.

5 “(5) ACTION FOR INFRINGEMENT INVOLVING
6 REFERENCE PRODUCT SPONSOR.—If an action for
7 infringement concerning a relevant patent identified
8 by the reference product sponsor under clause (ii) or
9 (iii) of paragraph (4)(A), or by an interested third
10 party under clause (iii) or (iv) of paragraph (4)(B),
11 is brought within 60 days of the date of receipt of
12 a statement under paragraph (4)(D)(ii), and the
13 court in which such action has been commenced de-
14 termines the patent is infringed prior to the date ap-
15 plicable under subsection (k)(7)(A), (k)(7)(D), or
16 (k)(8) the Secretary shall make approval of the ap-
17 plication effective on the day after the date of expi-
18 ration of the patent that has been found to be in-
19 fringed. If more than one such patent is found to be
20 infringed by the court, the approval of the applica-
21 tion shall be made effective on the day after the date
22 that the last such patent expires.

23 “(6) LIMITATIONS ON ACTIONS FOR DECLARA-
24 TORY JUDGMENT.—With respect to a patent that is
25 the subject of an explanation under paragraph

1 (4)(D)(ii), no action for a declaratory judgment that
2 the patent is invalid, unenforceable, or not infringed
3 may be brought under section 2201 of title 28,
4 United States Code, by an applicant prior to the
5 date that is the later of—

6 “(A) 3 years prior to the date applicable
7 under subsection (k)(7)(A); or

8 “(B) 120 days after such explanation has
9 been provided.”.

10 (b) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-
11 TION 505.—

12 (1) REQUIREMENT TO FOLLOW SECTION 351.—

13 Except as provided in paragraph (2), an application
14 for a biological product shall be submitted under
15 section 351 of the Public Health Service Act (42
16 U.S.C. 262) (as amended by this Act).

17 (2) EXCEPTION.—An application for a biologi-
18 cal product may be submitted under section 505 of
19 the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 355) if—

21 (A) such biological product is in a product
22 class for which a biological product in such
23 product class is the subject of an application
24 approved under such section 505 not later than
25 the date of enactment of this Act; and

1 (B) such application—

2 (i) has been submitted to the Sec-
3 retary of Health and Human Services (re-
4 ferred to in this Act as the “Secretary”)
5 before the date of enactment of this Act;
6 or

7 (ii) is submitted to the Secretary not
8 later than the date that is 10 years after
9 the date of enactment of this Act.

10 (3) LIMITATION.—Notwithstanding paragraph
11 (2), an application for a biological product may not
12 be submitted under section 505 of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 355) if there is
14 another biological product approved under sub-
15 section (a) of section 351 of the Public Health Serv-
16 ice Act that could be a reference product with re-
17 spect to such application (within the meaning of
18 such section 351) if such application were submitted
19 under subsection (k) of such section 351.

20 (4) DEEMED APPROVED UNDER SECTION 351.—
21 An approved application for a biological product
22 under section 505 of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 355) shall be deemed to be
24 a license for the biological product under such sec-

1 tion 351 on the date that is 10 years after the date
2 of enactment of this Act.

3 (5) DEFINITIONS.—For purposes of this sub-
4 section, the term “biological product” has the mean-
5 ing given such term under section 351 of the Public
6 Health Service Act (42 U.S.C. 262) (as amended by
7 this Act).

8 **SEC. 102. FEES RELATING TO BIOSIMILAR BIOLOGICAL**
9 **PRODUCTS.**

10 Subparagraph (B) of section 735(1) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) is
12 amended by inserting “, including licensure of a biological
13 product under section 351(k) of such Act” before the pe-
14 riod at the end.

15 **TITLE II—AMENDMENTS TO**
16 **PATENT ACT**

17 **SEC. 201. AMENDMENTS TO CERTAIN PATENT PROVISIONS.**

18 Section 271(e)(2) of title 35, United States Code is
19 amended—

20 (1) in subparagraph (A), by striking “or” after
21 “patent”;

22 (2) in subparagraph (B), by adding “or” after
23 the comma at the end; and

24 (3) by inserting the following after subpara-
25 graph (B):

1 “(C) a statement under section
2 351(l)(4)(D)(ii) of the Public Health Service
3 Act,”.

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