

110TH CONGRESS
2D SESSION

H. R. 5629

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 13, 2008

Ms. ESHOO (for herself, Mr. BARTON of Texas, Mr. HILL, Mr. UPTON, Mr. WYNN, Mr. PITTS, Ms. ZOE LOFGREN of California, Mr. ROGERS of Michigan, Mr. CAPUANO, Mr. BUYER, Mr. MCGOVERN, Mr. TIM MURPHY of Pennsylvania, Mr. LYNCH, and Mr. FERGUSON) 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pathway for
5 Biosimilars Act”.

1 **SEC. 2. TABLE OF CONTENTS.**

2 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.

3 **TITLE I—AMENDMENTS TO**
 4 **PUBLIC HEALTH SERVICE ACT**

5 **SEC. 101. LICENSURE PATHWAY FOR BIOSIMILAR BIOLOGI-**
 6 **CAL PRODUCTS.**

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

10 (1) in subsection (a)(1)(A), by inserting “under
 11 this subsection or subsection (k)” after “biologics li-
 12 cense”; and

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

14 “(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-
 15 SIMILAR.—

16 “(1) IN GENERAL.—Any person may submit an
 17 application for licensure of a biological product
 18 under this subsection.

19 “(2) CONTENT.—

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

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

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

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

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

22 “(ii) the biological product and ref-
23 erence product utilize the same mechanism
24 or mechanisms of action for the condition
25 or conditions of use prescribed, rec-

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

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

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

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

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

22 “(i) IN GENERAL.—The Secretary
23 may, in the Secretary’s discretion, deter-
24 mine that an element described in sub-
25 clause (I), (II), or (III) of subparagraph

1 (A)(i) is unnecessary and waive the re-
2 quirement that such element be submitted
3 in an application under this subsection.

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

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

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

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

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

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

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

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

22 “(B) the applicant (or other appropriate
23 person) consents to the inspection of the facility
24 that is the subject of the application, in accord-
25 ance with subsection (c).

1 “(4) SAFETY STANDARDS FOR DETERMINING
2 INTERCHANGEABILITY.—

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

11 “(i) the biological product—

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

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

23 “(ii) for a biological product that is
24 administered more than once to an indi-
25 vidual, the risk in terms of safety or dimin-

1 ished efficacy of alternating or switching
2 between use of the biological product and
3 the reference product is not greater than
4 the risk of using the reference product
5 without such alternation or switch.

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

14 “(i) advising that it is feasible in the
15 current state of scientific knowledge to
16 make such determinations with respect to
17 products in the product class to which that
18 biological product belongs; and

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

21 “(5) GENERAL RULES.—

22 “(A) ONE REFERENCE PRODUCT PER AP-
23 PLICATION.—A biological product, in an appli-
24 cation submitted under this subsection, may not

1 be evaluated against more than 1 reference
2 product.

3 “(B) REVIEW.—An application submitted
4 under this subsection shall be reviewed by the
5 division within the Food and Drug Administra-
6 tion that is responsible for the review and ap-
7 proval of the application under which the ref-
8 erence product is licensed.

9 “(C) RISK EVALUATION AND MITIGATION
10 STRATEGIES.—The authority of the Secretary
11 with respect to risk evaluation and mitigation
12 strategies under the Federal Food, Drug, and
13 Cosmetic Act shall apply to biological products
14 licensed under this subsection in the same man-
15 ner as such authority applies to biological prod-
16 ucts licensed under subsection (a).

17 “(D) LISTED SELECT AGENTS AND TOX-
18 INS.—If information in an application sub-
19 mitted under this subsection, in a supplement
20 to such an application, or otherwise available to
21 the Secretary shows that a biological product is,
22 bears, or contains a select agent or toxin listed
23 in section 73.3 or 73.4 of title 42, section 121.3
24 or 121.4 of title 9, or section 331.3 of title 7
25 of the Code of Federal Regulations (or any suc-

1 cessor regulations), the Secretary shall not li-
2 cense the biological product under this sub-
3 section.

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

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

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

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

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

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

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

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

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

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

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

15 “(8) PEDIATRIC STUDIES.—

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

1 quest, such studies are completed using appro-
2 priate formulations for each age group for
3 which the study is requested within any such
4 timeframe, and the reports thereof are sub-
5 mitted and accepted in accordance with section
6 505A(d)(3) of the Federal Food, Drug, and
7 Cosmetic Act—

8 “(i) the period referred to in para-
9 graph (7)(A) of this subsection is deemed
10 to be 12 years and 6 months rather than
11 12 years; and

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

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

23 “(C) APPLICATION OF CERTAIN PROVI-
24 SIONS.—The provisions of subsections (a), (d),
25 (e), (f), (h), (j), (k), and (l) of section 505A of

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

9 “(9) GUIDANCE DOCUMENTS.—

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

18 “(B) PUBLIC COMMENT.—

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

1 “(ii) INPUT REGARDING MOST VALU-
2 ABLE GUIDANCE.—The Secretary shall es-
3 tablish a process through which the public
4 may provide the Secretary with input re-
5 garding priorities for issuing guidance.

6 “(C) CERTAIN PRODUCT CLASSES.—

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

15 “(ii) MODIFICATION OR REVERSAL.—
16 The Secretary may issue a subsequent
17 guidance document under subparagraph
18 (A) to modify or reverse a guidance docu-
19 ment under clause (i).

20 “(D) PETITION FOR INITIATION OF GUID-
21 ANCE FOR CERTAIN PRODUCTS.—In the case of
22 a reference product that was licensed by the
23 Secretary more than 7 years prior to the date
24 of the enactment of the Pathway for
25 Biosimilars Act, a person may petition the Sec-

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

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

23 “(F) REQUIREMENT FOR PRODUCT CLASS-
24 SPECIFIC GUIDANCE.—Product class-specific

1 guidance issued under subparagraph (A) shall
2 include a description of—

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

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

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

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

23 “(1) PATENT NOTICES; RELATIONSHIP TO FINAL AP-
24 PROVAL.—

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

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

6 “(B) ‘relevant patent’ means a patent
7 that—

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

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

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

24 “(D) ‘interested third party’ means a per-
25 son other than the reference product sponsor

1 that owns a relevant patent, or has the right to
2 commence or participate in an action for in-
3 fringement of a relevant patent.

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

24 “(3) PUBLIC NOTICE BY SECRETARY.—Within
25 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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