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(Original Signature of Member)

111TH CONGRESS  
1ST SESSION

# H. R.

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

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## IN THE HOUSE OF REPRESENTATIVES

Ms. ESHOO introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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# 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”.

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.

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.

1           **TITLE I—AMENDMENTS TO**  
2           **PUBLIC HEALTH SERVICE ACT**

3   **SEC. 101. LICENSURE PATHWAY FOR BIOSIMILAR BIOLOGI-**  
4                           **CAL PRODUCTS.**

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

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

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

12           “(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-  
13 SIMILAR.—

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

17                     “(2) CONTENT.—

18                           “(A) REQUIRED INFORMATION.—An appli-  
19                           cation submitted under this subsection shall in-  
20                           clude information demonstrating that—

1                   “(i) the biological product is bio-  
2 similar to a reference product based upon  
3 data derived from—

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

9                   “(II) animal studies (including  
10 the assessment of toxicity); and

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

19                   “(ii) the biological product and ref-  
20 erence product utilize the same mechanism  
21 or mechanisms of action for the condition  
22 or conditions of use prescribed, rec-  
23 ommended, or suggested in the proposed  
24 labeling, but only to the extent the mecha-

1 nism or mechanisms of action are known  
2 for the reference product;

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

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

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

17 “(B) WAIVER REGARDING ANALYTICAL  
18 STUDIES, ANIMAL STUDIES, AND CLINICAL  
19 STUDIES.—

20 “(i) IN GENERAL.—The Secretary  
21 may, in the Secretary’s discretion, deter-  
22 mine that an element described in sub-  
23 clause (I), (II), or (III) of subparagraph  
24 (A)(i) is unnecessary and waive the re-

1           requirement that such element be submitted  
2           in an application under this subsection.

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

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

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

23                   “(C) ADDITIONAL INFORMATION.—An ap-  
24          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 of alternating or switching

1           between use of the biological product and  
2           the reference product (in terms of safety,  
3           diminished efficacy, and reduced or en-  
4           hanced potency) is not greater than the  
5           risk of using the reference product without  
6           such alternation or switching.

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

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

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

22          “(C) PRESERVATION OF STATE AUTHOR-  
23          ITY.—Nothing in this subsection shall be con-  
24          strued as preempting or otherwise affecting the



1 authority of a State to require or regulate pre-  
2 scriptions.

3 “(5) GENERAL RULES.—

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

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

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

23 “(D) RESTRICTIONS ON BIOLOGICAL PROD-  
24 UCTS CONTAINING DANGEROUS INGREDI-  
25 ENTS.—If information in an application sub-

1           mitted under this subsection, in a supplement  
2           to such an application, or otherwise available to  
3           the Secretary shows that a biological product—

4                   “(i) is, bears, or contains a select  
5                   agent or toxin listed in section 73.3 or  
6                   73.4 of title 42, section 121.3 or 121.4 of  
7                   title 9, or section 331.3 of title 7, Code of  
8                   Federal Regulations (or any successor reg-  
9                   ulations); or

10                   “(ii) is, bears, or contains a controlled  
11                   substance in schedule I or II of section  
12                   202 of the Controlled Substances Act, as  
13                   listed in part 1308 of title 21, Code of  
14                   Federal Regulations (or any successor reg-  
15                   ulations);

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

24                   “(6) EXCLUSIVITY FOR FIRST INTERCHANGE-  
25           ABLE BIOLOGICAL PRODUCT.—The Secretary shall

1 not make a determination under paragraph (4) that  
2 a second or subsequent biological product is inter-  
3 changeable with the same reference product for  
4 which a prior biological product has received a deter-  
5 mination of interchangeability until 24 months after  
6 the later of—

7 “(A) the date of the first commercial mar-  
8 keting of the first biosimilar biological product  
9 determined to be interchangeable for that ref-  
10 erence product; or

11 “(B) with respect to a product marketed  
12 before the date the product is determined to be  
13 interchangeable, the date that the product is  
14 determined to be interchangeable.

15 “(7) EXCLUSIVITY FOR REFERENCE PROD-  
16 UCT.—

17 “(A) EFFECTIVE DATE OF BIOSIMILAR AP-  
18 PPLICATION LICENSURE.—Subject to subpara-  
19 graph (D) and paragraph (8), approval of an  
20 application under this subsection may not be  
21 made effective by the Secretary until the date  
22 that is 12 years after the date on which the ref-  
23 erence product was first licensed under sub-  
24 section (a).

1           “(B) FILING PERIOD.—An application  
2 under this subsection may not be submitted to  
3 the Secretary until the later of—

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

10           “(ii) the date that is 4 years after the  
11 date on which the reference product was  
12 first licensed under subsection (a).

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

21           “(D) MEDICALLY SIGNIFICANT NEW INDI-  
22 CATION.—If, during the 8-year period following  
23 licensure of the reference product, the Secretary  
24 approves a supplement to the application for  
25 the reference product that seeks approval to

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

10 “(8) PEDIATRIC STUDIES.—

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

1           505A(d)(3) of the Federal Food, Drug, and  
2           Cosmetic Act—

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

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

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

18                  “(C) APPLICATION OF CERTAIN PROVI-  
19                  SIONS.—The provisions of subsections (a), (d),  
20                  (e), (f), (h), (j), (k), and (l) of section 505A of  
21                  the Federal Food, Drug, and Cosmetic Act  
22                  shall apply with respect to the extension of a  
23                  period under subparagraph (A) of this para-  
24                  graph to the same extent and in the same man-  
25                  ner as such provisions apply with respect to the

1 extension of a period under subsection (b) or  
2 (c) of section 505A of the Federal Food, Drug,  
3 and Cosmetic Act.

4 “(9) GUIDANCE DOCUMENTS.—

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

13 “(B) PUBLIC COMMENT.—

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

21 “(ii) INPUT REGARDING MOST VALU-  
22 ABLE GUIDANCE.—The Secretary shall es-  
23 tablish a process through which the public  
24 may provide the Secretary with input re-  
25 garding priorities for issuing guidance.

1 “(C) CERTAIN PRODUCT CLASSES.—

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

10 “(ii) MODIFICATION OR REVERSAL.—  
11 The Secretary may issue a subsequent  
12 guidance document under subparagraph  
13 (A) to modify or reverse a guidance docu-  
14 ment under clause (i).

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



1           tionale for the request. For guidance petitioned  
2           under this subparagraph, the Secretary shall,  
3           within 2 years of such petition, issue final guid-  
4           ance with respect to that product class.

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

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

22                  “(i) the criteria that the Secretary will  
23                  use to determine whether a biological prod-  
24                  uct is biosimilar to a reference product in  
25                  such product class;

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

6           “(iii) the criteria, if available, that the  
7           Secretary will use to assess  
8           immunogenicity.

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

17          “(1) PATENT NOTICES; RELATIONSHIP TO FINAL AP-  
18          PROVAL.—

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

21                 “(A) ‘biosimilar product’ means the bio-  
22                 logical product that is the subject of the appli-  
23                 cation under subsection (k);

24                 “(B) ‘relevant patent’ means a patent  
25                 that—

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

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

14 “(C) ‘reference product sponsor’ means the  
15 holder of an approved application or license for  
16 the reference product; and

17 “(D) ‘interested third party’ means a per-  
18 son other than the reference product sponsor  
19 that owns a relevant patent, or has the right to  
20 commence or participate in an action for in-  
21 fringement of a relevant patent.

22 “(2) HANDLING OF CONFIDENTIAL INFORMA-  
23 TION.—Any entity receiving confidential information  
24 pursuant to this subsection shall designate one or  
25 more individuals to receive such information. Each

1 individual so designated shall execute an agreement  
2 in accordance with regulations promulgated by the  
3 Secretary. The regulations shall require each such  
4 individual to take reasonable steps to maintain the  
5 confidentiality of information received pursuant to  
6 this subsection and use the information solely for  
7 purposes authorized by this subsection. The obliga-  
8 tions imposed on an individual who has received con-  
9 fidential information pursuant to this subsection  
10 shall continue until the individual returns or de-  
11 stroys the confidential information, a court imposes  
12 a protective order that governs the use or handling  
13 of the confidential information, or the party pro-  
14 viding the confidential information agrees to other  
15 terms or conditions regarding the handling or use of  
16 the confidential information.

17 “(3) PUBLIC NOTICE BY SECRETARY.—Within  
18 30 days of acceptance by the Secretary of an appli-  
19 cation filed under subsection (k), the Secretary shall  
20 publish a notice identifying—

21 “(A) the reference product identified in the  
22 application; and

23 “(B) the name and address of an agent  
24 designated by the applicant to receive notices  
25 pursuant to paragraph (4)(B).

1           “(4) EXCHANGES CONCERNING PATENTS.—

2                   “(A) EXCHANGES WITH REFERENCE  
3           PRODUCT SPONSOR.—

4                   “(i) Within 30 days of the date of ac-  
5                   ceptance of the application by the Sec-  
6                   retary, the applicant shall provide the ref-  
7                   erence product sponsor with a copy of the  
8                   application and information concerning the  
9                   biosimilar product and its production. This  
10                  information shall include a detailed de-  
11                  scription of the biosimilar product, its  
12                  method of manufacture, and the materials  
13                  used in the manufacture of the product.

14                  “(ii) Within 60 days of the date of re-  
15                  ceipt of the information required to be pro-  
16                  vided under clause (i), the reference prod-  
17                  uct sponsor shall provide to the applicant  
18                  a list of relevant patents owned by the ref-  
19                  erence product sponsor, or in respect of  
20                  which the reference product sponsor has  
21                  the right to commence an action of in-  
22                  fringement or otherwise has an interest in  
23                  the patent as such patent concerns the bio-  
24                  similar product.

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

11          “(B) EXCHANGES WITH INTERESTED  
12          THIRD PARTIES.—

13               “(i) At any time after the date on  
14               which the Secretary publishes a notice for  
15               an application under paragraph (3), any  
16               interested third party may provide notice  
17               to the designated agent of the applicant  
18               that the interested third party owns or has  
19               rights under 1 or more patents that may  
20               be relevant patents. The notice shall iden-  
21               tify at least 1 patent and shall designate  
22               an individual who has executed an agree-  
23               ment in accordance with paragraph (2) to  
24               receive confidential information from the  
25               applicant.

1           “(ii) Within 30 days of the date of re-  
2           ceiving notice pursuant to clause (i), the  
3           applicant shall send to the individual des-  
4           ignated by the interested third party the  
5           information specified in subparagraph  
6           (A)(i), unless the applicant and interested  
7           third party otherwise agree.

8           “(iii) Within 90 days of the date of  
9           receiving information pursuant to clause  
10          (ii), the interested third party shall provide  
11          to the applicant a list of relevant patents  
12          which the interested third party owns, or  
13          in respect of which the interested third  
14          party has the right to commence or partici-  
15          pate in an action for infringement.

16          “(iv) If the interested third party is  
17          issued or acquires an interest in a relevant  
18          patent after the date on which the inter-  
19          ested third party provides the list required  
20          by clause (iii), the interested third party  
21          shall identify that patent within 30 days of  
22          the date of issue of the patent, or the date  
23          of acquisition of the interest in the patent,  
24          as applicable.

1           “(C) IDENTIFICATION OF BASIS FOR IN-  
2 FRINGEMENT.—For any patent identified under  
3 clause (ii) or (iii) of subparagraph (A) or under  
4 clause (iii) or (iv) of subparagraph (B), the ref-  
5 erence product sponsor or the interested third  
6 party, as applicable—

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

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

18           “(iii) shall specify the number and  
19 date of expiration of the relevant patent.

20           “(D) CERTIFICATION BY APPLICANT CON-  
21 CERNING IDENTIFIED RELEVANT PATENTS.—  
22 Not later than 45 days after the date on which  
23 a patent is identified under clause (ii) or (iii) of  
24 subparagraph (A) or under clause (iii) or (iv) of  
25 subparagraph (B), the applicant shall send a



1 written statement regarding each identified pat-  
2 ent to the party that identified the patent. Such  
3 statement shall either—

4 “(i) state that the applicant will not  
5 commence marketing of the biosimilar  
6 product and has requested the Secretary to  
7 not grant final approval of the application  
8 before the date of expiration of the noticed  
9 patent; or

10 “(ii) provide a detailed written expla-  
11 nation setting forth the reasons why the  
12 applicant believes—

13 “(I) the making, use, sale, or  
14 offer for sale within the United  
15 States, or the importation into the  
16 United States, of the biosimilar prod-  
17 uct, or the use of the biosimilar prod-  
18 uct in a treatment indicated in the ap-  
19 plication, would not infringe the pat-  
20 ent; or

21 “(II) the patent is invalid or un-  
22 enforceable.

23 “(5) ACTION FOR INFRINGEMENT INVOLVING  
24 REFERENCE PRODUCT SPONSOR.—If an action for  
25 infringement concerning a relevant patent identified

1 by the reference product sponsor under clause (ii) or  
2 (iii) of paragraph (4)(A), or by an interested third  
3 party under clause (iii) or (iv) of paragraph (4)(B),  
4 is brought within 60 days of the date of receipt of  
5 a statement under paragraph (4)(D)(ii), and the  
6 court in which such action has been commenced de-  
7 termines the patent is infringed prior to the date ap-  
8 plicable under subsection (k)(7)(A), (k)(7)(D), or  
9 (k)(8) the Secretary shall make approval of the ap-  
10 plication effective on the day after the date of expi-  
11 ration of the patent that has been found to be in-  
12 fringed. If more than one such patent is found to be  
13 infringed by the court, the approval of the applica-  
14 tion shall be made effective on the day after the date  
15 that the last such patent expires.

16 “(6) LIMITATIONS ON ACTIONS FOR DECLARA-  
17 TORY JUDGMENT.—With respect to a patent that is  
18 the subject of an explanation under paragraph  
19 (4)(D)(ii), no action for a declaratory judgment that  
20 the patent is invalid, unenforceable, or not infringed  
21 may be brought under section 2201 of title 28,  
22 United States Code, by an applicant prior to the  
23 date that is the later of—

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

1                   “(B) 120 days after such explanation has  
2                   been provided.”.

3           (b) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-  
4   TION 505.—

5           (1) REQUIREMENT TO FOLLOW SECTION 351.—  
6           Except as provided in paragraph (2), an application  
7           for a biological product shall be submitted under  
8           section 351 of the Public Health Service Act (42  
9           U.S.C. 262) (as amended by this Act).

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

14                (A) such biological product is in a product  
15                class for which a biological product in such  
16                product class is the subject of an application  
17                approved under such section 505 not later than  
18                the date of enactment of this Act; and

19                (B) such application—

20                       (i) has been submitted to the Sec-  
21                       retary of Health and Human Services (re-  
22                       ferred to in this Act as the “Secretary”)  
23                       before the date of enactment of this Act;  
24                       or

1                   (ii) is submitted to the Secretary not  
2                   later than the date that is 10 years after  
3                   the date of enactment of this Act.

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

14          (4) DEEMED APPROVED UNDER SECTION 351.—  
15          An approved application for a biological product  
16          under section 505 of the Federal Food, Drug, and  
17          Cosmetic Act (21 U.S.C. 355) shall be deemed to be  
18          a license for the biological product under such sec-  
19          tion 351 on the date that is 10 years after the date  
20          of enactment of this Act.

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

1 **SEC. 102. FEES RELATING TO BIOSIMILAR BIOLOGICAL**  
2 **PRODUCTS.**

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

8 **TITLE II—AMENDMENTS TO**  
9 **PATENT ACT**

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

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

13 (1) in subparagraph (A), by striking “or” after  
14 “patent”;

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

17 (3) by inserting the following after subpara-  
18 graph (B):

19 “(C) a statement under section  
20 351(l)(4)(D)(ii) of the Public Health Service  
21 Act,”.