



AMENDMENT NO.

Calendar No.

Purpose: To provide a complete substitute.

IN THE SENATE OF THE UNITED STATES—110th Cong., 1st Sess.

S.

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

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by

Viz: **MR. KENNEDY, MR. HATCH, MRS. CLINTON AND MR. ENZI**

1 Strike all after the enacting clause and insert the fol-

2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Biologics Price Com-

5 petition and Innovation Act of 2007".

1 **SEC. 2. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGICAL**
2 **PRODUCTS.**

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

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

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

10 “(k) **LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-**
11 **SIMILAR OR INTERCHANGEABLE.**—

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

15 “(2) **CONTENT.**—

16 “(A) **IN GENERAL.**—

17 “(i) **REQUIRED INFORMATION.**—An
18 application submitted under this subsection
19 shall include information demonstrating
20 that—

21 “(I) the biological product is bio-
22 similar to a reference product based
23 upon data derived from—

24 “(aa) analytical studies that
25 demonstrate that the biological
26 product is highly similar to the

3

1 reference product notwith-
2 standing minor differences in
3 clinically inactive components;
4 “(bb) animal studies (includ-
5 ing the assessment of toxicity);
6 and
7 “(cc) a clinical study or
8 studies (including the assessment
9 of immunogenicity and phar-
10 macokinetics or
11 pharmacodynamics) that are suf-
12 ficient to demonstrate safety, pu-
13 rity, and potency in 1 or more
14 appropriate conditions of use for
15 which the reference product is li-
16 censed and intended to be used
17 and for which licensure is sought
18 for the biological product;
19 “(II) the biological product and
20 reference product utilize the same
21 mechanism or mechanisms of action
22 for the condition or conditions of use
23 prescribed, recommended, or sug-
24 gested in the proposed labeling, but
25 only to the extent the mechanism or

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

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

9 “(IV) the route of administra-
10 tion, the dosage form, and the
11 strength of the biological product are
12 the same as those of the reference
13 product; and

14 “(V) the facility in which the bio-
15 logical product is manufactured, proc-
16 essed, packed, or held meets stand-
17 ards designed to assure that the bio-
18 logical product continues to be safe,
19 pure, and potent.

20 “(ii) DETERMINATION BY SEC-
21 RETARY.—The Secretary may determine,
22 in the Secretary’s discretion, that an ele-
23 ment described in clause (i)(I) is unneces-
24 sary in an application submitted under this
25 subsection.

1 “(iii) ADDITIONAL INFORMATION.—

2 An application submitted under this sub-
3 section—

4 “(I) shall include publicly-avail-
5 able information regarding the Sec-
6 retary’s previous determination that
7 the reference product is safe, pure,
8 and potent; and

9 “(II) may include any additional
10 information in support of the applica-
11 tion, including publicly-available infor-
12 mation with respect to the reference
13 product or another biological product.

14 “(B) INTERCHANGEABILITY.—An applica-
15 tion (or a supplement to an application) sub-
16 mitted under this subsection may include infor-
17 mation demonstrating that the biological prod-
18 uct meets the standards described in paragraph
19 (4).

20 “(3) EVALUATION BY SECRETARY.—Upon re-
21 view of an application (or a supplement to an appli-
22 cation) submitted under this subsection, the Sec-
23 retary shall license the biological product under this
24 subsection if—

1 “(A) the Secretary determines that the in-
2 formation submitted in the application (or the
3 supplement) is sufficient to show that the bio-
4 logical product—

5 “(i) is biosimilar to the reference
6 product; or

7 “(ii) meets the standards described in
8 paragraph (4), and therefore is inter-
9 changeable with the reference product; and

10 “(B) the applicant (or other appropriate
11 person) consents to the inspection of the facility
12 that is the subject of the application, in accord-
13 ance with subsection (c).

14 “(4) SAFETY STANDARDS FOR DETERMINING
15 INTERCHANGEABILITY.—Upon review of an applica-
16 tion submitted under this subsection or any supple-
17 ment to such application, the Secretary shall deter-
18 mine the biological product to be interchangeable
19 with the reference product if the Secretary deter-
20 mines that the information submitted in the applica-
21 tion (or a supplement to such application) is suffi-
22 cient to show that—

23 “(A) the biological product—

24 “(i) is biosimilar to the reference
25 product; and

1 “(ii) can be expected to produce the
2 same clinical result as the reference prod-
3 uct in any given patient; and

4 “(B) for a biological product that is ad-
5 ministered more than once to an individual, the
6 risk in terms of safety or diminished efficacy of
7 alternating or switching between use of the bio-
8 logical product and the reference product is not
9 greater than the risk of using the reference
10 product without such alternation or switch.

11 “(5) GENERAL RULES.—

12 “(A) ONE REFERENCE PRODUCT PER AP-
13 PLICATION.—A biological product, in an appli-
14 cation submitted under this subsection, may not
15 be evaluated against more than 1 reference
16 product.

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

23 “(C) RISK EVALUATION AND MITIGATION
24 STRATEGIES.—The authority of the Secretary
25 with respect to risk evaluation and mitigation

1 strategies under the Federal Food, Drug, and
2 Cosmetic Act shall apply to biological products
3 licensed under this subsection in the same man-
4 ner as such authority applies to biological prod-
5 ucts licensed under subsection (a).

6 “(6) EXCLUSIVITY FOR FIRST INTERCHANGE-
7 ABLE BIOLOGICAL PRODUCT.—Upon review of an
8 application submitted under this subsection relying
9 on the same reference product for which a prior bio-
10 logical product has received a determination of inter-
11 changeability for any condition of use, the Secretary
12 shall not make a determination under paragraph (4)
13 that the second or subsequent biological product is
14 interchangeable for any condition of use until the
15 earlier of—

16 “(A) 1 year after the first commercial
17 marketing of the first interchangeable bio-
18 similar biological product to be approved as
19 interchangeable for that reference product;

20 “(B) 18 months after—

21 “(i) a final court decision on all pat-
22 ents in suit in an action instituted under
23 subsection (1)(6) against the applicant that
24 submitted the application for the first ap-

1 proved interchangeable biosimilar biological
2 product; or

3 “(ii) the dismissal with or without
4 prejudice of an action instituted under sub-
5 section (l)(6) against the applicant that
6 submitted the application for the first ap-
7 proved interchangeable biosimilar biological
8 product; or

9 “(C)(i) 42 months after approval of the
10 first interchangeable biosimilar biological prod-
11 uct if the applicant that submitted such appli-
12 cation has been sued under subsection (l)(6)
13 and such litigation is still ongoing within such
14 36-month period; or

15 “(ii) 18 months after approval of the first
16 interchangeable biosimilar biological product if
17 the applicant that submitted such application
18 has not been sued under subsection (l)(6).

19 For purposes of this paragraph, the term ‘final court
20 decision’ means a final decision of a court from
21 which no appeal (other than a petition to the United
22 States Supreme Court for a writ of certiorari) has
23 been or can be taken.

24 “(7) EXCLUSIVITY FOR REFERENCE PROD-
25 UCT.—

1 “(A) EFFECTIVE DATE OF BIOSIMILAR AP-
2 PLICATION APPROVAL.—Approval of an applica-
3 tion under this subsection may not be made ef-
4 fective by the Secretary until the date that is
5 12 years after the date on which the reference
6 product was first licensed under subsection (a).

7 “(B) FILING PERIOD.—An application
8 under this subsection may not be submitted to
9 the Secretary until the date that is 4 years
10 after the date on which the reference product
11 was first licensed under subsection (a).

12 “(C) FIRST LICENSURE.—The date on
13 which the reference product was first licensed
14 under subsection (a) does not include the date
15 of approval of a supplement or of a subsequent
16 application for a new indication, route of ad-
17 ministration, dosage form, or strength for the
18 previously licensed reference product.

19 “(8) GUIDANCE DOCUMENTS.—

20 “(A) IN GENERAL.—The Secretary may,
21 after opportunity for public comment, issue
22 guidance in accordance, except as provided in
23 subparagraph (B)(i), with section 701(h) of the
24 Federal Food, Drug, and Cosmetic Act with re-
25 spect to the licensure of a biological product

1 under this subsection. Any such guidance may
2 be general or specific.

3 “(B) PUBLIC COMMENT.—

4 “(i) IN GENERAL.—The Secretary
5 shall provide the public an opportunity to
6 comment on any proposed guidance issued
7 under subparagraph (A) before issuing
8 final guidance.

9 “(ii) INPUT REGARDING MOST VALU-
10 ABLE GUIDANCE.—The Secretary shall es-
11 tablish a process through which the public
12 may provide the Secretary with input re-
13 garding priorities for issuing guidance.

14 “(C) NO REQUIREMENT FOR APPLICATION
15 CONSIDERATION.—The issuance (or non-
16 issuance) of guidance under subparagraph (A)
17 shall not preclude the review of, or action on,
18 an application submitted under this subsection.

19 “(D) REQUIREMENT FOR PRODUCT CLASS-
20 SPECIFIC GUIDANCE.—If the Secretary issues
21 product class-specific guidance under subpara-
22 graph (A), such guidance shall include a de-
23 scription of—

24 “(i) the criteria that the Secretary will
25 use to determine whether a biological prod-

1 uct is highly similar to a reference product
2 in such product class; and

3 “(ii) the criteria, if available, that the
4 Secretary will use to determine whether a
5 biological product meets the standards de-
6 scribed in paragraph (4).

7 “(E) CERTAIN PRODUCT CLASSES.—

8 “(i) GUIDANCE.—The Secretary may
9 indicate in a guidance document that the
10 science and experience, as of the date of
11 such guidance, with respect to a product or
12 product class (not including any recom-
13 binant protein) does not allow approval of
14 an application for a license as provided
15 under this subsection for such product or
16 product class.

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

22 “(iii) NO EFFECT ON ABILITY TO
23 DENY LICENSE.—Clause (i) shall not be
24 construed to require the Secretary to ap-
25 prove a product with respect to which the

1 Secretary has not indicated in a guidance
2 document that the science and experience,
3 as described in clause (i), does not allow
4 approval of such an application.

5 “(l) PATENTS.—

6 “(1) CONFIDENTIAL ACCESS TO SUBSECTION
7 (k) APPLICATION.—

8 “(A) APPLICATION OF PARAGRAPH.—Un-
9 less otherwise agreed to by a person that sub-
10 mits an application under subsection (k) (re-
11 ferred to in this subsection as the ‘subsection
12 (k) applicant’) and the sponsor of the applica-
13 tion for the reference product (referred to in
14 this paragraph as the ‘reference product spon-
15 sor’), the provisions of this paragraph shall
16 apply to the exchange of information described
17 in this subsection.

18 “(B) IN GENERAL.—

19 “(i) PROVISION OF CONFIDENTIAL IN-
20 FORMATION.—When a subsection (k) ap-
21 plicant submits an application under sub-
22 section (k), such applicant shall provide to
23 the persons described in clause (ii), subject
24 to the terms of this paragraph, confidential
25 access to the information required to be

1 produced pursuant to paragraph (2) and
2 any other information that the subsection
3 (k) applicant determines, in its sole discre-
4 tion, to be appropriate (referred to in this
5 subsection as the ‘confidential informa-
6 tion’).

7 “(ii) RECIPIENTS OF INFORMATION.—
8 The persons described in this clause are
9 the following:

10 “(I) OUTSIDE COUNSEL.—One or
11 more attorneys designated by the ref-
12 erence product sponsor who are em-
13 ployees of an entity other than the
14 reference product sponsor (referred to
15 in this paragraph as the ‘outside
16 counsel’), provided that such attor-
17 neys do not engage, formally or infor-
18 mally, in patent prosecution relevant
19 or related to the reference product.

20 “(II) IN-HOUSE COUNSEL.—One
21 attorney that represents the reference
22 product sponsor who is an employee
23 of the reference product sponsor, pro-
24 vided that such attorney does not en-
25 gage, formally or informally, in patent

1 prosecution relevant or related to the
2 reference product.

3 “(iii) PATENT OWNER ACCESS.—A
4 representative of the owner of a patent ex-
5 clusively licensed to a reference product
6 sponsor with respect to the reference prod-
7 uct and who has retained a right to assert
8 the patent or participate in litigation con-
9 cerning the patent may be provided the
10 confidential information, provided that the
11 representative informs the reference prod-
12 uct sponsor and the subsection (k) appli-
13 cant of his or her agreement to be subject
14 to the confidentiality provisions set forth in
15 this paragraph, including those under
16 clause (ii).

17 “(C) LIMITATION ON DISCLOSURE.—No
18 person that receives confidential information
19 pursuant to subparagraph (B) shall disclose
20 any confidential information to any other per-
21 son or entity, including the reference product
22 sponsor employees, outside scientific consult-
23 ants, or other outside counsel retained by the
24 reference product sponsor, without the prior

1 written consent of the subsection (k) applicant,
2 which shall not be unreasonably withheld.

3 “(D) USE OF CONFIDENTIAL INFORMA-
4 TION.—Confidential information shall be used
5 for the sole and exclusive purpose of deter-
6 mining, with respect to each patent assigned to
7 or exclusively licensed by the reference product
8 sponsor, whether a claim of patent infringement
9 could reasonably be asserted if the subsection
10 (k) applicant engaged in the manufacture, use,
11 offering for sale, sale, or importation into the
12 United States of the biological product that is
13 the subject of the application under subsection
14 (k).

15 “(E) OWNERSHIP OF CONFIDENTIAL IN-
16 FORMATION.—The confidential information dis-
17 closed under this paragraph is, and shall re-
18 main, the property of the subsection (k) appli-
19 cant. By providing the confidential information
20 pursuant to this paragraph, the subsection (k)
21 applicant does not provide the reference product
22 sponsor or the outside counsel any interest in or
23 license to use the confidential information, for
24 purposes other than those specified in subpara-
25 graph (D).

1 “(F) EFFECT OF INFRINGEMENT AC-
2 TION.—In the event that the reference product
3 sponsor files a patent infringement suit, the use
4 of confidential information shall continue to be
5 governed by the terms of this paragraph until
6 such time as a court enters a protective order
7 regarding the information. Upon entry of such
8 order, the subsection (k) applicant may redesign-
9 nate confidential information in accordance
10 with the terms of that order. No confidential in-
11 formation shall be included in any publicly-
12 available complaint or other pleading. In the
13 event that the reference product sponsor does
14 not file an infringement action by the date spec-
15 ified in paragraph (6), the reference product
16 sponsor shall return or destroy all confidential
17 information received under this paragraph, pro-
18 vided that if the reference product sponsor opts
19 to destroy such information, it will confirm de-
20 struction in writing to the subsection (k) appli-
21 cant.

22 “(G) RULE OF CONSTRUCTION.—Nothing
23 in this paragraph shall be construed—

24 “(i) as an admission by the subsection
25 (k) applicant regarding the validity, en-

1 forceability, or infringement of any patent;

2 or

3 “(ii) an agreement or admission by
4 the subsection (k) applicant with respect to
5 the competency, relevance, or materiality
6 of any confidential information.

7 “(H) EFFECT OF VIOLATION.—The disclo-
8 sure of any confidential information in violation
9 of this paragraph shall be deemed to cause the
10 subsection (k) applicant to suffer irreparable
11 harm for which there is no adequate legal rem-
12 edy and the court shall consider immediate in-
13 junctive relief to be an appropriate and nec-
14 essary remedy for any violation or threatened
15 violation of this paragraph.

16 “(2) SUBSECTION (k) APPLICATION INFORMA-
17 TION.—Not later than 20 days after the Secretary
18 notifies the subsection (k) applicant that the applica-
19 tion has been accepted for review, the subsection (k)
20 applicant—

21 “(A) shall provide to the reference product
22 sponsor a copy of the application submitted to
23 the Secretary under subsection (k), and such
24 other information that describes the process or
25 processes used to manufacture the biological

1 product that is the subject of such application;
2 and

3 “(B) may provide to the reference product
4 sponsor additional information requested by or
5 on behalf of the reference product sponsor.

6 “(3) LIST AND DESCRIPTION OF PATENTS.—

7 “(A) LIST BY REFERENCE PRODUCT SPON-
8 SOR.—Not later than 60 days after the receipt
9 of the application and information under para-
10 graph (2), the reference product sponsor shall
11 provide to the subsection (k) applicant—

12 “(i) a list of patents for which the ref-
13 erence product sponsor believes a claim of
14 patent infringement could reasonably be
15 asserted by the reference product sponsor,
16 or by a patent owner that has granted an
17 exclusive license to the reference product
18 sponsor with respect to the reference prod-
19 uct, if a person not licensed by the ref-
20 erence product sponsor engaged in the
21 making, using, offering to sell, selling, or
22 importing into the United States of the bi-
23 ological product that is the subject of the
24 subsection (k) application; and

1 “(ii) an identification of the patents
2 on such list that the reference product
3 sponsor would be prepared to license to the
4 subsection (k) applicant.

5 “(B) LIST AND DESCRIPTION BY SUB-
6 SECTION (k) APPLICANT.—Not later than 60
7 days after receipt of the list under subpara-
8 graph (A), the subsection (k) applicant—

9 “(i) may provide to the reference
10 product sponsor a list of patents to which
11 the subsection (k) applicant believes a
12 claim of patent infringement could reason-
13 ably be asserted by the reference product
14 sponsor if a person not licensed by the ref-
15 erence product sponsor engaged in the
16 making, using, offering to sell, selling, or
17 importing into the United States of the bi-
18 ological product that is the subject of the
19 subsection (k) application;

20 “(ii) shall provide to the reference
21 product sponsor, with respect to each pat-
22 ent listed by the reference product sponsor
23 under subparagraph (A) or listed by the
24 subsection (k) applicant under clause (i)—

1 “(I) a detailed statement that de-
2 scribes, on a claim by claim basis, the
3 factual and legal basis of the opinion
4 of the subsection (k) applicant that
5 such patent is invalid, unenforceable,
6 or will not be infringed by the com-
7 mercial marketing of the biological
8 product that is the subject of the sub-
9 section (k) application; or

10 “(II) a statement that the sub-
11 section (k) applicant does not intend
12 to begin commercial marketing of the
13 biological product before the date that
14 such patent expires; and

15 “(iii) shall provide to the reference
16 product sponsor a response regarding each
17 patent identified by the reference product
18 sponsor under subparagraph (A)(ii).

19 “(C) DESCRIPTION BY REFERENCE PROD-
20 UCT SPONSOR.—Not later than 60 days after
21 receipt of the list and statement under subpara-
22 graph (B), the reference product sponsor shall
23 provide to the subsection (k) applicant a de-
24 tailed statement that describes, with respect to
25 each patent described in subparagraph

1 (B)(ii)(I), on a claim by claim basis, the factual
2 and legal basis of the opinion of the reference
3 product sponsor that such patent will be in-
4 fringed by the commercial marketing of the bio-
5 logical product that is the subject of the sub-
6 section (k) application and a response to the
7 statement concerning validity and enforceability
8 provided under subparagraph (B)(ii)(I).

9 “(4) PATENT RESOLUTION NEGOTIATIONS.—

10 “(A) IN GENERAL.—After receipt by the
11 subsection (k) applicant of the statement under
12 paragraph (3)(C), the reference product spon-
13 sor and the subsection (k) applicant shall en-
14 gage in good faith negotiations to agree on
15 which, if any, patents listed under paragraph
16 (3) by the subsection (k) applicant or the ref-
17 erence product sponsor shall be the subject of
18 an action for patent infringement under para-
19 graph (6).

20 “(B) FAILURE TO REACH AGREEMENT.—

21 If, within 15 days of beginning negotiations
22 under subparagraph (A), the subsection (k) ap-
23 plicant and the reference product sponsor fail to
24 agree on a final and complete list of which, if
25 any, patents listed under paragraph (3) by the

1 subsection (k) applicant or the reference prod-
2 uct sponsor shall be the subject of an action for
3 patent infringement under paragraph (6), the
4 provisions of paragraph (5) shall apply to the
5 parties.

6 “(5) PATENT RESOLUTION IF NO AGREE-
7 MENT.—

8 “(A) NUMBER OF PATENTS.—The sub-
9 section (k) applicant shall notify the reference
10 product sponsor of the number of patents that
11 such applicant will provide to the reference
12 product sponsor under subparagraph (B)(i)(I).

13 “(B) EXCHANGE OF PATENT LISTS.—

14 “(i) IN GENERAL.—On a date agreed
15 to by the subsection (k) applicant and the
16 reference product sponsor, but in no case
17 later than 5 days after the subsection (k)
18 application notifies the reference product
19 sponsor under subparagraph (A), the sub-
20 section (k) applicant and the reference
21 product sponsor shall simultaneously ex-
22 change—

23 “(I) the list of patents that the
24 subsection (k) applicant believes
25 should be the subject of an action for

1 patent infringement under paragraph
2 (6); and

3 “(II) the list of patents, in ac-
4 cordance with clause (ii), that the ref-
5 erence product sponsor believes should
6 be the subject of an action for patent
7 infringement under paragraph (6).

8 “(ii) NUMBER OF PATENTS LISTED BY
9 REFERENCE PRODUCT SPONSOR.—

10 “(I) IN GENERAL.—Subject to
11 subclause (II), the number of patents
12 listed by the reference product spon-
13 sor under clause (i)(II) may not ex-
14 ceed the number of patents listed by
15 the subsection (k) applicant under
16 clause (i)(I).

17 “(II) EXCEPTION.—If a sub-
18 section (k) applicant does not list any
19 patent under clause (i)(I), the ref-
20 erence product sponsor may list 1 pat-
21 ent under clause (i)(II).

22 “(6) IMMEDIATE PATENT INFRINGEMENT AC-
23 TION.—

24 “(A) ACTION IF AGREEMENT ON PATENT
25 LIST.—If the subsection (k) applicant and the

1 reference product sponsor agree on patents as
2 described in paragraph (4), not later than 30
3 days after such agreement, the reference prod-
4 uct sponsor shall bring an action for patent in-
5 fringement with respect to each such patent.

6 “(B) ACTION IF NO AGREEMENT ON PAT-
7 ENT LIST.—If the provisions of paragraph (5)
8 apply to the parties as described in paragraph
9 (4)(B), not later than 30 days after the ex-
10 change of lists under paragraph (5)(B), the ref-
11 erence product sponsor shall bring an action for
12 patent infringement with respect to each patent
13 that is included on such lists.

14 “(C) NOTIFICATION AND PUBLICATION OF
15 COMPLAINT.—

16 “(i) NOTIFICATION TO SECRETARY.—
17 Not later than 30 days after a complaint
18 is served to a subsection (k) applicant in
19 an action for patent infringement described
20 under this paragraph, the subsection (k)
21 applicant shall provide the Secretary with
22 notice and a copy of such complaint.

23 “(ii) PUBLICATION BY SECRETARY.—
24 The Secretary shall publish in the Federal

1 Register notice of a complaint received
2 under clause (i).

3 “(7) NEWLY ISSUED OR LICENSED PATENTS.—

4 In the case of a patent that—

5 “(A) is issued to, or exclusively licensed by,
6 the reference product sponsor after the date
7 that the reference product sponsor provided the
8 list to the subsection (k) applicant under para-
9 graph (3)(A); and

10 “(B) the reference product sponsor reason-
11 ably believes that, due to the issuance of such
12 patent, a claim of patent infringement could
13 reasonably be asserted by the reference product
14 sponsor if a person not licensed by the ref-
15 erence product sponsor engaged in the making,
16 using, offering to sell, selling, or importing into
17 the United States of the biological product that
18 is the subject of the subsection (k) application,
19 not later than 30 days after such issuance or licens-
20 ing, the reference product sponsor shall provide to
21 the subsection (k) applicant a supplement to the list
22 provided by the reference product sponsor under
23 paragraph (3)(A) that includes such patent, not
24 later than 30 days after such supplement is pro-
25 vided, the subsection (k) applicant shall provide a

1 statement to the reference product sponsor in ac-
2 cordance with paragraph (3)(B), and such patent
3 shall be subject to paragraph (8).

4 “(8) NOTICE OF COMMERCIAL MARKETING AND
5 PRELIMINARY INJUNCTION.—

6 “(A) NOTICE OF COMMERCIAL MAR-
7 KETING.—The subsection (k) applicant shall
8 provide notice to the reference product sponsor
9 not later than 180 days before the date of the
10 first commercial marketing of the biological
11 product licensed under subsection (k).

12 “(B) PRELIMINARY INJUNCTION.—After
13 receiving the notice under subparagraph (A)
14 and before such date of the first commercial
15 marketing of such biological product, the ref-
16 erence product sponsor may seek a preliminary
17 injunction prohibiting the subsection (k) appli-
18 cant from engaging in the commercial manufac-
19 ture or sale of such biological product until the
20 court decides the issue of patent validity, en-
21 forcement, and infringement with respect to any
22 patent that is—

23 “(i) included in the list provided by
24 the reference product sponsor under para-
25 graph (3)(A) or in the list provided by the

1 subsection (k) applicant under paragraph
2 (3)(B); and

3 “(ii) not included, as applicable, on—

4 “(I) the list of patents described
5 in paragraph (4); or

6 “(II) the lists of patents de-
7 scribed in paragraph (5)(B).

8 “(C) REASONABLE COOPERATION.—If the
9 reference product sponsor has sought a prelimi-
10 nary injunction under subparagraph (B), the
11 reference product sponsor and the subsection
12 (k) applicant shall reasonably cooperate to ex-
13 pedite such further discovery as is needed in
14 connection with the preliminary injunction mo-
15 tion.

16 “(9) LIMITATION ON DECLARATORY JUDGMENT
17 ACTION.—

18 “(A) SUBSECTION (k) APPLICATION PRO-
19 VIDED.—If a subsection (k) applicant provides
20 the application and information required under
21 paragraph (2)(A), neither the reference product
22 sponsor nor the subsection (k) applicant may,
23 prior to the date notice is received under para-
24 graph (8)(A), bring any action under section
25 2201 of title 28, United States Code, for a dec-

1 laration of infringement, validity, or enforce-
2 ability of any patent that is described in clauses
3 (i) and (ii) of paragraph (8)(B).

4 “(B) SUBSEQUENT FAILURE TO ACT BY
5 SUBSECTION (k) APPLICANT.—If a subsection
6 (k) applicant fails to complete an action re-
7 quired of the subsection (k) applicant under
8 paragraph (3)(B)(ii), paragraph (5), paragraph
9 (6)(C)(i), paragraph (7), or paragraph (8)(A),
10 the reference product sponsor, but not the sub-
11 section (k) applicant, may bring an action
12 under section 2201 of title 28, United States
13 Code, for a declaration of infringement, validity,
14 or enforceability of any patent included in the
15 list described in paragraph (3)(A), including as
16 provided under paragraph (7).

17 “(C) SUBSECTION (k) APPLICATION NOT
18 PROVIDED.—If a subsection (k) applicant fails
19 to provide the application and information re-
20 quired under paragraph (2)(A), the reference
21 product sponsor, but not the subsection (k) ap-
22 plicant, may bring an action under section 2201
23 of title 28, United States Code, for a declara-
24 tion of infringement, validity, or enforceability

1 of any patent that claims the biological product
2 or a use of the biological product.”.

3 (b) DEFINITIONS.—Section 351(i) of the Public
4 Health Service Act (42 U.S.C. 262(i)) is amended—

5 (1) by striking “In this section, the term ‘bio-
6 logical product’ means” and inserting the following:

7 “In this section:

8 “(1) The term ‘biological product’ means”;

9 (2) in paragraph (1), as so designated, by in-
10 sserting “protein (except any chemically synthesized
11 polypeptide),” after “allergenic product,”; and

12 (3) by adding at the end the following:

13 “(2) The term ‘biosimilar’ or ‘biosimilarity’, in
14 reference to a biological product that is the subject
15 of an application under subsection (k), means—

16 “(A) that the biological product is highly
17 similar to the reference product notwith-
18 standing minor differences in clinically inactive
19 components; and

20 “(B) there are no clinically meaningful dif-
21 ferences between the biological product and the
22 reference product in terms of the safety, purity,
23 and potency of the product.

24 “(3) The term ‘interchangeable’ or ‘inter-
25 changeability’, in reference to a biological product

1 that is shown to meet the standards described in
2 subsection (k)(4), means that the biological product
3 may be substituted for the reference product without
4 the intervention of the health care provider who pre-
5 scribed the reference product.

6 “(4) The term ‘reference product’ means the
7 single biological product licensed under subsection
8 (a) against which a biological product is evaluated in
9 an application submitted under subsection (k).”

10 (c) CONFORMING AMENDMENTS RELATING TO PAT-
11 ENTS.—

12 (1) PATENTS.—Section 271(e) of title 35,
13 United States Code, is amended—

14 (A) in paragraph (2)—

15 (i) in subparagraph (A), by striking
16 “or” at the end;

17 (ii) in subparagraph (B), by adding
18 “or” at the end; and

19 (iii) by inserting after subparagraph
20 (B) the following:

21 “(C)(i) with respect to a patent that is identi-
22 fied in the list of patents described in section
23 351(l)(3) of the Public Health Service Act (including
24 as provided under section 351(l)(7) of such Act), an

1 application seeking approval of a biological product,
2 or

3 “(ii) if the applicant for the application fails to
4 provide the application and information required
5 under section 351(l)(2)(A) of such Act, an applica-
6 tion seeking approval of a biological product for a
7 patent that could be identified pursuant to section
8 351(l)(3)(A)(i) of such Act,”; and

9 (iv) in the matter following subpara-
10 graph (C) (as added by clause (iii)), by
11 striking “or veterinary biological product”
12 and inserting “, veterinary biological prod-
13 uct, or biological product”;

14 (B) in paragraph (4)—

15 (i) in subparagraph (B), by—

16 (I) striking “or veterinary bio-
17 logical product” and inserting “, vet-
18 erinary biological product, or biologi-
19 cal product”; and

20 (II) striking “and” at the end;

21 (ii) in subparagraph (C), by—

22 (I) striking “or veterinary bio-
23 logical product” and inserting “, vet-
24 erinary biological product, or biologi-
25 cal product”; and

1 (II) striking the period and in-
2 serting “, and”;

3 (iii) by inserting after subparagraph
4 (C) the following:

5 “(D) the court shall order a permanent injunc-
6 tion prohibiting any infringement of the patent by
7 the biological product involved in the infringement
8 until a date which is not earlier than the date of the
9 expiration of the patent that has been infringed
10 under paragraph (2)(C), provided the patent is the
11 subject of a final court decision, as defined in sec-
12 tion 351(k)(6) of the Public Health Service Act, in
13 an action for infringement of the patent under sec-
14 tion 351(l)(6) of such Act, and the biological prod-
15 uct has not yet been approved because of section
16 351(k)(7) of such Act.”; and

17 (iv) in the matter following subpara-
18 graph (D) (as added by clause (iii)), by
19 striking “and (C)” and inserting “(C), and
20 (D)”;

21 (C) by adding at the end the following:

22 “(6)(A) Subparagraph (B) applies, in lieu of para-
23 graph (4), in the case of a patent—

24 “(i) that is identified, as applicable, in the list
25 of patents described in section 351(l)(4) of the Pub-

1 lic Health Service Act or the lists of patents de-
2 scribed in section 351(l)(5)(B) of such Act with re-
3 spect to a biological product; and

4 “(ii) for which an action for infringement of the
5 patent with respect to the biological product—

6 “(I) was brought after the expiration of
7 the 30-day period described in subparagraph
8 (A) or (B), as applicable, of section 351(l)(6) of
9 such Act; or

10 “(II) was brought before the expiration of
11 the 30-day period described in subclause (I),
12 but which was dismissed without prejudice or
13 was not prosecuted to judgment in good faith.

14 “(B) In an action for infringement of a patent de-
15 scribed in subparagraph (A), the sole and exclusive remedy
16 that may be granted by a court, upon a finding that the
17 making, using, offering to sell, selling, or importation into
18 the United States of the biological product that is the sub-
19 ject of the action infringed the patent, shall be a reason-
20 able royalty.

21 “(C) The owner of a patent that should have been
22 included in the list described in section 351(l)(3)(A) of
23 the Public Health Service Act, including as provided under
24 section 351(l)(7) of such Act for a biological product, but
25 was not timely included in such list, may not bring an

1 action under this section for infringement of the patent
2 with respect to the biological product.”.

3 (2) CONFORMING AMENDMENT UNDER TITLE
4 28.—Section 2201(b) of title 28, United States
5 Code, is amended by inserting before the period the
6 following: “, or section 351 of the Public Health
7 Service Act”.

8 (d) CONFORMING AMENDMENTS UNDER THE FED-
9 ERAL FOOD, DRUG, AND COSMETIC ACT.—

10 (1) CONTENT AND REVIEW OF APPLICA-
11 TIONS.—Section 505(b)(5)(B) of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is
13 amended by inserting before the period at the end
14 of the first sentence the following: “or, with respect
15 to an applicant for approval of a biological product
16 under section 351(k) of the Public Health Service
17 Act, any necessary clinical study or studies”.

18 (2) NEW ACTIVE INGREDIENT.—Section 505B
19 of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 355c) is amended by adding at the end the
21 following:

22 “(i) NEW ACTIVE INGREDIENT.—

23 “(1) NON-INTERCHANGEABLE BIOSIMILAR BIO-
24 LOGICAL PRODUCT.—A biological product that is
25 biosimilar to a reference product under section 351

1 of the Public Health Service Act, and that the Sec-
2 retary has not determined to meet the standards de-
3 scribed in subsection (k)(4) of such section for inter-
4 changeability with the reference product, shall be
5 considered to have a new active ingredient under
6 this section.

7 “(2) INTERCHANGEABLE BIOSIMILAR BIOLOGI-
8 CAL PRODUCT.—A biological product that is inter-
9 changeable with a reference product under section
10 351 of the Public Health Service Act shall not be
11 considered to have a new active ingredient under
12 this section.”

13 (e) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-
14 TION 505.—

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

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

24 (A) such biological product is in a product
25 class for which a biological product in such

1 product class is the subject of an application
2 approved under such section 505 not later than
3 the date of enactment of this Act; and

4 (B) such application—

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

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

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

23 (4) DEEMED APPROVED UNDER SECTION
24 351.—An approved application for a biological prod-
25 uct under section 505 of the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 355) shall be deemed
2 to be a license for the biological product under such
3 section 351 on the date that is 10 years after the
4 date of enactment of this Act.

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

10 (f) FOLLOW-ON BIOLOGICS USER FEES.—

11 (1) DEVELOPMENT OF USER FEES FOR BIO-
12 SIMILAR BIOLOGICAL PRODUCTS.—

13 (A) IN GENERAL.—Beginning not later
14 than October 1, 2010, the Secretary shall de-
15 velop recommendations to present to Congress
16 with respect to the goals, and plans for meeting
17 the goals, for the process for the review of bio-
18 similar biological product applications sub-
19 mitted under section 351(k) of the Public
20 Health Service Act (as added by this Act) for
21 the first 5 fiscal years after fiscal year 2012. In
22 developing such recommendations, the Sec-
23 retary shall consult with—

24 (i) the Committee on Health, Edu-
25 cation, Labor, and Pensions of the Senate;

1 (ii) the Committee on Energy and
2 Commerce of the House of Representa-
3 tives;

4 (iii) scientific and academic experts;

5 (iv) health care professionals;

6 (v) representatives of patient and con-
7 sumer advocacy groups; and

8 (vi) the regulated industry.

9 (B) PUBLIC REVIEW OF RECOMMENDA-
10 TIONS.—After negotiations with the regulated
11 industry, the Secretary shall—

12 (i) present the recommendations de-
13 veloped under subparagraph (A) to the
14 Congressional committees specified in such
15 subparagraph;

16 (ii) publish such recommendations in
17 the Federal Register;

18 (iii) provide for a period of 30 days
19 for the public to provide written comments
20 on such recommendations;

21 (iv) hold a meeting at which the pub-
22 lic may present its views on such rec-
23 ommendations; and

1 (v) after consideration of such public
2 views and comments, revise such rec-
3 ommendations as necessary.

4 (C) TRANSMITTAL OF RECOMMENDA-
5 TIONS.—Not later than January 15, 2012, the
6 Secretary shall transmit to Congress the revised
7 recommendations under subparagraph (B), a
8 summary of the views and comments received
9 under such subparagraph, and any changes
10 made to the recommendations in response to
11 such views and comments.

12 (2) ESTABLISHMENT OF USER FEE PRO-
13 GRAM.—It is the sense of the Senate that, based on
14 the recommendations transmitted to Congress by the
15 Secretary pursuant to paragraph (1)(C), Congress
16 should authorize a program, effective on October 1,
17 2012, for the collection of user fees relating to the
18 submission of biosimilar biological product applica-
19 tions under section 351(k) of the Public Health
20 Service Act (as added by this Act).

21 (3) TRANSITIONAL PROVISIONS FOR USER FEES
22 FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

23 (A) APPLICATION OF THE PRESCRIPTION
24 DRUG USER FEE PROVISIONS.—Section
25 735(1)(C) of the Federal Food, Drug, and Cos-

1 metic Act (21 U.S.C. 379g(1)(C)) is amended
2 by striking “section 351” and inserting “sub-
3 section (a) or (k) of section 351”.

4 (B) EVALUATION OF COSTS OF REVIEWING
5 BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-
6 TIONS.—During the period beginning on the
7 date of enactment of this Act and ending on
8 October 1, 2010, the Secretary shall collect and
9 evaluate data regarding the costs of reviewing
10 applications for biological products submitted
11 under section 351(k) of the Public Health Serv-
12 ice Act (as added by this Act) during such pe-
13 riod.

14 (C) AUDIT.—

15 (i) IN GENERAL.—On the date that is
16 2 years after first receiving a user fee ap-
17 plicable to an application for a biological
18 product under section 351(k) of the Public
19 Health Service Act (as added by this Act),
20 and on a biennial basis thereafter until Oc-
21 tober 1, 2013, the Secretary shall perform
22 an audit of the costs of reviewing such ap-
23 plications under such section 351(k). Such
24 an audit shall compare—

1 (I) the costs of reviewing such
2 applications under such section
3 351(k) to the amount of the user fee
4 applicable to such applications; and

5 (II)(aa) such ratio determined
6 under subclause (I); to

7 (bb) the ratio of the costs of re-
8 viewing applications for biological
9 products under section 351(a) of such
10 Act (as amended by this Act) to the
11 amount of the user fee applicable to
12 such applications under such section
13 351(a).

14 (ii) ALTERATION OF USER FEE.—If
15 the audit performed under clause (i) indi-
16 cates that the ratios compared under sub-
17 clause (II) of such clause differ by more
18 than 5 percent, then the Secretary shall
19 alter the user fee applicable to applications
20 submitted under such section 351(k) to
21 more appropriately account for the costs of
22 reviewing such applications.

23 (iii) ACCOUNTING STANDARDS.—The
24 Secretary shall perform an audit under
25 clause (i) in conformance with the account-

1 ing principles, standards, and requirements
2 prescribed by the Comptroller General of
3 the United States under section 3511 of
4 title 31, United State Code, to ensure the
5 validity of any potential variability.

6 (4) AUTHORIZATION OF APPROPRIATIONS.—

7 There is authorized to be appropriated to carry out
8 this subsection such sums as may be necessary for
9 each of fiscal years 2008 through 2012.

10 (g) ALLOCATION OF SAVINGS; SPECIAL RESERVE
11 FUND.—

12 (1) DETERMINATION OF SAVINGS.—The Sec-
13 retary of the Treasury, in consultation with the Sec-
14 retary, shall for each fiscal year determine the
15 amount of the savings to the Federal Government as
16 a result of the enactment of this Act and shall trans-
17 fer such amount to the Fund established under
18 paragraph (2) pursuant to a relevant appropriations
19 Act.

20 (2) SPECIAL RESERVE FUND.—

21 (A) IN GENERAL.—There is established in
22 the Treasury of the United States a fund to be
23 designated as the “Biological Product Savings
24 Fund” to be made available to the Secretary
25 without fiscal year limitation.

1 (B) USE OF FUND.—The amounts made
2 available to the Secretary through the Fund
3 under subparagraph (A) shall be expended on
4 activities authorized under the Public Health
5 Service Act.

6 (3) AUTHORIZATION OF APPROPRIATIONS.—
7 There is authorized to be appropriated for each fis-
8 cal year to the Fund established under paragraph
9 (2), the amount of the savings determined for such
10 fiscal year under paragraph (1).

11 (h) GOVERNMENT ACCOUNTABILITY OFFICE
12 STUDY.—

13 (1) IN GENERAL.—Not later than 3 years after
14 the date of enactment of this Act, the Comptroller
15 General of the United States shall study and report
16 to Congress regarding—

17 (A) the extent to which pediatric studies of
18 biological products are being required under the
19 Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 301 et seq.); and

21 (B) any pediatric needs not being met
22 under existing authority.

23 (2) CONTENT OF STUDY.—The study under
24 paragraph (1) shall review and assess—

1 (A) the extent to which pediatric studies of
2 biological products are required under sub-
3 sections (a) and (b) of section 505B of the Fed-
4 eral Food, Drug and Cosmetic Act (21 U.S.C.
5 355e);

6 (B) the extent to which pediatric studies of
7 biological products are required as part of risk
8 evaluation and mitigation strategies under such
9 Act;

10 (C) the number, importance, and
11 prioritization of any biological products that are
12 not being tested for pediatric use; and

13 (D) recommendations for ensuring pedi-
14 atric testing of products identified in subpara-
15 graph (C), including the consideration of any
16 incentives, such as those provided under the
17 Best Pharmaceuticals for Children Act.

18 (i) ORPHAN PRODUCTS.—If a reference product, as
19 defined in section 351 of the Public Health Service Act
20 (42 U.S.C. 262) (as amended by this Act) has been des-
21 ignated under section 526 of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 360bb) for a rare disease or con-
23 dition, a biological product seeking approval for such dis-
24 ease or condition under subsection (k) of such section 351
25 as biosimilar to, or interchangeable with, such reference

1 product may be licensed by the Secretary only after the
2 expiration for such reference product of the later of—

3 (1) the 7-year period described in section
4 527(a) of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 360cc(a)); and

6 (2) the 12-year period described in subsection
7 (k)(7) of such section 351.