

110TH CONGRESS
1ST SESSION

S. 1695

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.

IN THE SENATE OF THE UNITED STATES

JUNE 26, 2007

Mr. KENNEDY (for himself, Mr. HATCH, Mrs. CLINTON, and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

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.

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 “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

1 reference product notwith-
2 standing minor differences in
3 clinically inactive components;
4 “(bb) animal studies; and
5 “(cc) a clinical study or
6 studies (including the assessment
7 of immunogenicity and pharma-
8 cokinetics or pharmacodynamics)
9 that are—
10 “(AA) sufficient to
11 demonstrate safety, purity,
12 and potency in 1 or more
13 appropriate conditions of use
14 for which the reference
15 product is licensed and in-
16 tended to be used and for
17 which licensure is sought for
18 the biological product; and
19 “(BB) designed to
20 avoid needlessly duplicative
21 or unethical clinical testing;
22 “(II) the biological product and
23 reference product utilize the same
24 mechanism or mechanisms of action
25 for the condition or conditions of use

1 prescribed, recommended, or sug-
2 gested in the proposed labeling, but
3 only to the extent the mechanism or
4 mechanisms of action are known for
5 the reference product;

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

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

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

23 “(ii) DETERMINATION BY SEC-
24 RETARY.—The Secretary may determine,
25 in the Secretary’s discretion, that an ele-

1 ment described in clause (i)(I) is unneces-
2 sary in an application submitted under this
3 subsection.

4 “(iii) ADDITIONAL INFORMATION.—
5 An application submitted under this sub-
6 section may include—

7 “(I) at the applicant’s option,
8 publicly-available information regard-
9 ing the Secretary’s previous deter-
10 mination that the reference product is
11 safe, pure, and potent; and

12 “(II) any additional information
13 in support of the application, includ-
14 ing publicly-available information with
15 respect to the reference product or an-
16 other biological product.

17 “(B) INTERCHANGEABILITY.—An applica-
18 tion (or a supplement to an application) sub-
19 mitted under this subsection may include infor-
20 mation demonstrating that the biological prod-
21 uct is interchangeable with the reference prod-
22 uct.

23 “(3) EVALUATION BY SECRETARY.—Upon re-
24 view of an application (or a supplement to an appli-
25 cation) submitted under this subsection, the Sec-

1 retary shall license the biological product under this
2 subsection if the Secretary determines that the infor-
3 mation submitted in the application (or the supple-
4 ment) is sufficient to show that the biological prod-
5 uct—

6 “(A) is biosimilar to the reference product;

7 or

8 “(B) is interchangeable with the reference
9 product.

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

19 “(A) the biological product—

20 “(i) is biosimilar to the reference
21 product; and

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

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

8 “(5) GENERAL RULES.—

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

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

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

1 ner as such authority applies to biological prod-
2 ucts licensed under subsection (a).

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

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

17 “(B) 18 months after—

18 “(i) a final court decision on all pat-
19 ents in suit in an action instituted under
20 subsection (l)(6) against the applicant that
21 submitted the application for the first ap-
22 proved interchangeable biosimilar biological
23 product; or

24 “(ii) the dismissal with or without
25 prejudice of an action instituted under sub-

1 section (l)(6) against the applicant that
2 submitted the application for the first ap-
3 proved interchangeable biosimilar biological
4 product; or

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

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

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

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

22 “(A) EFFECTIVE DATE OF BIOSIMILAR AP-
23 PPLICATION APPROVAL.—Approval of an applica-
24 tion under this subsection may not be made ef-
25 fective by the Secretary until the date that is

1 12 years after the date on which the reference
2 product was first licensed under subsection (a).

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

8 “(8) GUIDANCE DOCUMENTS.—

9 “(A) IN GENERAL.—The Secretary may,
10 after opportunity for public comment, issue
11 guidance in accordance, except as provided in
12 subparagraph (B)(i), with section 701(h) of the
13 Federal Food, Drug, and Cosmetic Act with re-
14 spect to the process for the submission of appli-
15 cations for, and licensure of, a biological prod-
16 uct under this subsection. Any such guidance
17 may be general or specific.

18 “(B) PUBLIC COMMENT.—

19 “(i) IN GENERAL.—The Secretary
20 shall provide the public an opportunity to
21 comment on any proposed guidance issued
22 under subparagraph (A) before issuing
23 final guidance.

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

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

4 “(C) NO REQUIREMENT FOR APPLICATION
5 CONSIDERATION.—The issuance (or non-
6 issuance) of guidance under subparagraph (A)
7 shall not preclude the review of, or action on,
8 an application submitted under this subsection.

9 “(D) REQUIREMENT FOR PRODUCT CLASS-
10 SPECIFIC GUIDANCE.—If the Secretary issues
11 product class-specific guidance under subpara-
12 graph (A), such guidance shall include a de-
13 scription of—

14 “(i) the criteria that the Secretary will
15 use to determine whether a biological prod-
16 uct is highly similar to a reference product
17 in such product class; and

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

22 “(E) CERTAIN PRODUCT CLASSES.—

23 “(i) GUIDANCE.—The Secretary may
24 indicate in a guidance document that the
25 science and experience, as of the date of

1 such guidance, with respect to a product or
2 product class (not including any recom-
3 binant protein) does not allow approval of
4 an application for a license as provided
5 under this subsection for such product or
6 product class.

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

12 “(iii) NO EFFECT ON ABILITY TO
13 DENY LICENSE.—Clause (i) shall not be
14 construed to require the Secretary to ap-
15 prove a product with respect to which the
16 Secretary has not indicated in a guidance
17 document that the science and experience,
18 as described in clause (i), does not allow
19 approval of such an application.

20 “(l) PATENTS.—

21 “(1) CONFIDENTIAL ACCESS TO SUBSECTION
22 (k) APPLICATION.—

23 “(A) APPLICATION OF PARAGRAPH.—Un-
24 less otherwise agreed to by a person that sub-
25 mits an application under subsection (k) (re-

1 ferred to in this subsection as the ‘subsection
2 (k) applicant’) and the sponsor of the applica-
3 tion for the reference product (referred to in
4 this paragraph as the ‘reference product spon-
5 sor’), the provisions of this paragraph shall
6 apply to the exchange of information described
7 in this subsection.

8 “(B) IN GENERAL.—

9 “(i) PROVISION OF CONFIDENTIAL IN-
10 FORMATION.—When a subsection (k) ap-
11 plicant submits an application under sub-
12 section (k), such applicant shall provide to
13 the persons described in clause (ii), subject
14 to the terms of this paragraph, confidential
15 access to the information required to be
16 produced pursuant to paragraph (2) and
17 any other information that the subsection
18 (k) applicant determines, in its sole discre-
19 tion, to be appropriate (referred to in this
20 subsection as the ‘confidential informa-
21 tion’).

22 “(ii) RECIPIENTS OF INFORMATION.—

23 The persons described in this clause are
24 the following:

1 “(I) OUTSIDE COUNSEL.—One or
2 more attorneys designated by the ref-
3 erence product sponsor who are em-
4 ployees of an entity other than the
5 reference product sponsor (referred to
6 in this paragraph as the ‘outside
7 counsel’), provided that such attor-
8 neys do not engage, formally or infor-
9 mally, in patent prosecution relevant
10 or related to the reference product.

11 “(II) IN-HOUSE COUNSEL.—One
12 attorney that represents the reference
13 product sponsor who is an employee
14 of the reference product sponsor, pro-
15 vided that such attorney does not en-
16 gage, formally or informally, in patent
17 prosecution relevant or related to the
18 reference product.

19 “(C) LIMITATION ON DISCLOSURE.—No
20 person that receives confidential information
21 pursuant to subparagraph (B) shall disclose
22 any confidential information to any other per-
23 son or entity, including the reference product
24 sponsor employees, outside scientific consult-
25 ants, or other outside counsel retained by the

1 reference product sponsor, without the prior
2 written consent of the subsection (k) applicant,
3 which shall not be unreasonably withheld.

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

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

1 purposes other than those specified in subpara-
2 graph (D).

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

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

1 “(i) as an admission by the subsection
2 (k) applicant regarding the validity, en-
3 forceability, or infringement of any patent;
4 or

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

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

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

23 “(A) shall provide to the reference product
24 sponsor a copy of the application submitted to
25 the Secretary under subsection (k), and such

1 other information that describes the process or
2 processes used to manufacture the biological
3 product that is the subject of such application;
4 and

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

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

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

14 “(i) a list of patents for which the ref-
15 erence product sponsor believes a claim of
16 patent infringement could reasonably be
17 asserted by the reference product sponsor
18 if a person not licensed by the reference
19 product sponsor engaged in the making,
20 using, offering to sell, selling, or importing
21 into the United States of the biological
22 product that is the subject of the sub-
23 section (k) application; and

24 “(ii) an identification of the patents
25 on such list that the reference product

1 sponsor would be prepared to license to the
2 subsection (k) applicant.

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

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

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

23 “(I) a detailed statement that de-
24 scribes, on a claim by claim basis, the
25 factual and legal basis of the opinion

1 of the subsection (k) applicant that
2 such patent is invalid, unenforceable,
3 or will not be infringed by the com-
4 mercial marketing of the biological
5 product that is the subject of the sub-
6 section (k) application; or

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

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

16 “(C) DESCRIPTION BY REFERENCE PROD-
17 UCT SPONSOR.—Not later than 60 days after
18 receipt of the list and statement under subpara-
19 graph (B), the reference product sponsor shall
20 provide to the subsection (k) applicant a de-
21 tailed statement that describes, with respect to
22 each patent described in subparagraph
23 (B)(ii)(I), on a claim by claim basis, the factual
24 and legal basis of the opinion of the reference
25 product sponsor that such patent will be in-

1 fringed by the commercial marketing of the bio-
2 logical product that is the subject of the sub-
3 section (k) application and a response to the
4 statement concerning validity and enforceability
5 provided under subparagraph (B)(ii)(I).

6 “(4) PATENT RESOLUTION NEGOTIATIONS.—

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

17 “(B) FAILURE TO REACH AGREEMENT.—

18 If, within 15 days of beginning negotiations
19 under subparagraph (A), the subsection (k) ap-
20 plicant and the reference product sponsor fail to
21 agree on a final and complete list of which, if
22 any, patents listed under paragraph (3) by the
23 subsection (k) applicant or the reference prod-
24 uct sponsor shall be the subject of an action for
25 patent infringement under paragraph (6), the

1 provisions of paragraph (5) shall apply to the
2 parties.

3 “(5) PATENT RESOLUTION IF NO AGREE-
4 MENT.—

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

10 “(B) EXCHANGE OF PATENT LISTS.—

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

20 “(I) the list of patents that the
21 subsection (k) applicant believes
22 should be the subject of an action for
23 patent infringement under paragraph
24 (6); and

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

6 “(ii) NUMBER OF PATENTS LISTED BY
 7 REFERENCE PRODUCT SPONSOR.—

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

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

20 “(6) IMMEDIATE PATENT INFRINGEMENT AC-
 21 TION.—

22 “(A) ACTION IF AGREEMENT ON PATENT
 23 LIST.—If the subsection (k) applicant and the
 24 reference product sponsor agree on patents as
 25 described in paragraph (4), not later than 30

1 days after such agreement, the reference prod-
2 uct sponsor shall bring an action for patent in-
3 fringement with respect to each such patent.

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

12 “(C) NOTIFICATION AND PUBLICATION OF
13 COMPLAINT.—

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

21 “(ii) PUBLICATION BY SECRETARY.—
22 The Secretary shall publish in the Federal
23 Register notice of a complaint received
24 under clause (i).

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

2 In the case of a patent that—

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

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

1 cordance with paragraph (3)(B), and such patent
2 shall be subject to paragraph (8).

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

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

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

22 “(i) included in the list provided by
23 the reference product sponsor under para-
24 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 serting “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 there
16 are no clinically meaningful differences between the
17 biological product and the reference product in
18 terms of the safety, purity, and potency of the prod-
19 uct.

20 “(3) The term ‘interchangeable’ or ‘inter-
21 changeability’, in reference to a biological product
22 that is the subject of an application under sub-
23 section (k), means that the biological product may
24 be substituted for the reference product without the

1 intervention of the health care provider who pre-
2 scribed the reference product.

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

7 (c) CONFORMING AMENDMENTS RELATING TO PAT-
8 ENTS.—

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

11 (A) in paragraph (2)—

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

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

16 (iii) by inserting after subparagraph
17 (B) the following:

18 “(C)(i) with respect to a patent that is identi-
19 fied in the list of patents described in section
20 351(l)(3) of the Public Health Service Act (including
21 as provided under section 351(l)(7) of such Act), an
22 application seeking approval of a biological product,
23 or

24 “(ii) if the applicant for the application fails to
25 provide the application and information required

1 under section 351(l)(2)(A) of such Act, an applica-
2 tion seeking approval of a biological product for a
3 patent that could be identified pursuant to section
4 351(l)(3)(A)(i) of such Act,”; and

5 (iv) in the matter following subpara-
6 graph (C) (as added by clause (iii)), by
7 striking “or veterinary biological product”
8 and inserting “, veterinary biological prod-
9 uct, or biological product”;

10 (B) in paragraph (4)—

11 (i) in subparagraph (B), by—

12 (I) striking “or veterinary bio-
13 logical product” and inserting “, vet-
14 erinary biological product, or biologi-
15 cal product”; and

16 (II) striking “and” at the end;

17 (ii) in subparagraph (C), by—

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

22 (II) striking the period and in-
23 serting “, and”;

24 (iii) by inserting after subparagraph
25 (C) the following:

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

13 (iv) in the matter following subpara-
14 graph (D) (as added by clause (iii)), by
15 striking “and (C)” and inserting “(C), and
16 (D)”;

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

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

20 “(i) that is identified, as applicable, in the list
21 of patents described in section 351(l)(4) of the Pub-
22 lic Health Service Act or the lists of patents de-
23 scribed in section 351(l)(5)(B) of such Act with re-
24 spect to a biological product; and

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

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

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

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

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

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

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

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

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

20 “(i) NEW ACTIVE INGREDIENT.—A biological prod-
21 uct that is interchangeable with a reference product under
22 section 351 of the Public Health Service Act shall not be
23 considered to have a new active ingredient under this sec-
24 tion.”.

1 (e) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-
2 TION 505.—

3 (1) REQUIREMENT TO FOLLOW SECTION 351.—

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

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

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

17 (B) such application—

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

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

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

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

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

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

24 (1) DEVELOPMENT OF USER FEES FOR BIO-
25 SIMILAR BIOLOGICAL PRODUCTS.—

1 (A) IN GENERAL.—Beginning not later
2 than October 1, 2010, the Secretary shall de-
3 velop recommendations to present to Congress
4 with respect to the goals, and plans for meeting
5 the goals, for the process for the review of bio-
6 similar biological product applications sub-
7 mitted under section 351(k) of the Public
8 Health Service Act (as added by this Act) for
9 the first 5 fiscal years after fiscal year 2012. In
10 developing such recommendations, the Sec-
11 retary shall consult with—

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

14 (ii) the Committee on Energy and
15 Commerce of the House of Representa-
16 tives;

17 (iii) scientific and academic experts;

18 (iv) health care professionals;

19 (v) representatives of patient and con-
20 sumer advocacy groups; and

21 (vi) the regulated industry.

22 (B) PUBLIC REVIEW OF RECOMMENDA-
23 TIONS.—After negotiations with the regulated
24 industry, the Secretary shall—

1 (i) present the recommendations de-
2 veloped under subparagraph (A) to the
3 Congressional committees specified in such
4 subparagraph;

5 (ii) publish such recommendations in
6 the Federal Register;

7 (iii) provide for a period of 30 days
8 for the public to provide written comments
9 on such recommendations;

10 (iv) hold a meeting at which the pub-
11 lic may present its views on such rec-
12 ommendations; and

13 (v) after consideration of such public
14 views and comments, revise such rec-
15 ommendations as necessary.

16 (C) TRANSMITTAL OF RECOMMENDA-
17 TIONS.—Not later than January 15, 2012, the
18 Secretary shall transmit to Congress the revised
19 recommendations under subparagraph (B), a
20 summary of the views and comments received
21 under such subparagraph, and any changes
22 made to the recommendations in response to
23 such views and comments.

24 (2) ESTABLISHMENT OF USER FEE PRO-
25 GRAM.—It is the sense of the Senate that, based on

1 the recommendations transmitted to Congress by the
2 Secretary pursuant to paragraph (1)(C), Congress
3 should authorize a program, effective on October 1,
4 2012, for the collection of user fees relating to the
5 submission of biosimilar biological product applica-
6 tions under section 351(k) of the Public Health
7 Service Act (as added by this Act).

8 (3) TRANSITIONAL PROVISIONS FOR USER FEES
9 FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

10 (A) APPLICATION OF THE PRESCRIPTION
11 DRUG USER FEE PROVISIONS.—Section
12 735(1)(C) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 379g(1)(C)) is amended
14 by striking “section 351” and inserting “sub-
15 section (a) or (k) of section 351”.

16 (B) EVALUATION OF COSTS OF REVIEWING
17 BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-
18 TIONS.—During the period beginning on the
19 date of enactment of this Act and ending on
20 October 1, 2010, the Secretary shall collect and
21 evaluate data regarding the costs of reviewing
22 applications for biological products submitted
23 under section 351(k) of the Public Health Serv-
24 ice Act (as added by this Act) during such pe-
25 riod.

1 (C) AUDIT.—

2 (i) IN GENERAL.—On the date that is
3 2 years after first receiving a user fee ap-
4 plicable to an application for a biological
5 product under section 351(k) of the Public
6 Health Service Act (as added by this Act),
7 and on a biennial basis thereafter until Oc-
8 tober 1, 2013, the Secretary shall perform
9 an audit of the costs of reviewing such ap-
10 plications under such section 351(k). Such
11 an audit shall compare—

12 (I) the costs of reviewing such
13 applications under such section
14 351(k) to the amount of the user fee
15 applicable to such applications; and

16 (II)(aa) such ratio determined
17 under subclause (I); to

18 (bb) the ratio of the costs of re-
19 viewing applications for biological
20 products under section 351(a) of such
21 Act (as amended by this Act) to the
22 amount of the user fee applicable to
23 such applications under such section
24 351(a).

1 (ii) ALTERATION OF USER FEE.—If
2 the audit performed under clause (i) indi-
3 cates that the ratios compared under sub-
4 clause (II) of such clause differ by more
5 than 5 percent, then the Secretary shall
6 alter the user fee applicable to applications
7 submitted under such section 351(k) to
8 more appropriately account for the costs of
9 reviewing such applications.

10 (iii) ACCOUNTING STANDARDS.—The
11 Secretary shall perform an audit under
12 clause (i) in conformance with the account-
13 ing principles, standards, and requirements
14 prescribed by the Comptroller General of
15 the United States under section 3511 of
16 title 31, United State Code, to ensure the
17 validity of any potential variability.

18 (4) AUTHORIZATION OF APPROPRIATIONS.—
19 There is authorized to be appropriated to carry out
20 this subsection such sums as may be necessary for
21 each of fiscal years 2008 through 2012.

22 (g) ALLOCATION OF SAVINGS; SPECIAL RESERVE
23 FUND.—

24 (1) DETERMINATION OF SAVINGS.—The Sec-
25 retary of the Treasury, in consultation with the Sec-

1 retary, shall for each fiscal year determine the
2 amount of the savings to the Federal Government as
3 a result of the enactment of this Act and shall trans-
4 fer such amount to the Fund established under
5 paragraph (2) pursuant to a relevant appropriations
6 Act.

7 (2) SPECIAL RESERVE FUND.—

8 (A) IN GENERAL.—There is established in
9 the Treasury of the United States a fund to be
10 designated as the “Biological Product Savings
11 Fund” to be made available to the Secretary
12 without fiscal year limitation.

13 (B) USE OF FUND.—The amounts made
14 available to the Secretary through the Fund
15 under subparagraph (A) shall be expended on
16 activities authorized under the Public Health
17 Service Act.

18 (3) AUTHORIZATION OF APPROPRIATIONS.—
19 There is authorized to be appropriated for each fis-
20 cal year to the Fund established under paragraph
21 (2), the amount of the savings determined for such
22 fiscal year under paragraph (1).

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