

McCain #207

S.L.C.

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: To provide for biologics price competition and innovation.

IN THE SENATE OF THE UNITED STATES—111th Cong., 1st Sess.

S. \_\_\_\_\_

To make quality, affordable health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce.

Referred to the Committee on \_\_\_\_\_ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by

\_\_\_\_\_

Viz:

- 1 On page 596, after line 17, insert the following:
- 2 **SEC. 601. SHORT TITLE.**
- 3 This subtitle may be cited as the “Biologics Price
- 4 Competition and Innovation Act of 2009”.

1 SEC. 602. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGI-  
2 CAL 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 (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)(A).

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)(A), and therefore is inter-  
9                   changeable with the reference product;

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); and

14           “(C) the biological product has undergone  
15           1 or more clinical studies to establish that the  
16           biological product is safe, pure, and potent.

17           “(4) SAFETY STANDARDS FOR DETERMINING  
18           INTERCHANGEABILITY.—

19                   “(A) DETERMINATION BY THE SEC-  
20                   RETARY.—Upon review of an application sub-  
21                   mitted under this subsection or any supplement  
22                   to such application, the Secretary shall deter-  
23                   mine the biological product to be interchange-  
24                   able with the reference product if the Secretary  
25                   determines that the information submitted in

1           the application (or a supplement to such appli-  
2           cation) is sufficient to show that—

3                   “(i) the biological product—

4                           “(I) is biosimilar to the reference  
5                           product; and

6                           “(II) can be expected to produce  
7                           the same clinical result as the ref-  
8                           erence product in any given patient;  
9                           and

10                   “(ii) for a biological product that is  
11                   administered more than once to an indi-  
12                   vidual, the risk in terms of safety or dimin-  
13                   ished efficacy of alternating or switching  
14                   between use of the biological product and  
15                   the reference product is not greater than  
16                   the risk of using the reference product  
17                   without such alternation or switch.

18                   “(B) APPLICATION OF INTERCHANGE-  
19                   ABILITY ONLY WITH PRESCRIPTION.—Notwith-  
20                   standing any other provision of law, no biologi-  
21                   cal product may be interchanged with a ref-  
22                   erence product with respect to an individual un-  
23                   less such interchange is prescribed by a physi-  
24                   cian for such individual.

25                   “(5) GENERAL RULES.—

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

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

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

20          “(6) EXCLUSIVITY FOR FIRST INTERCHANGE-  
21          ABLE BIOLOGICAL PRODUCT.—Upon review of an  
22          application submitted under this subsection relying  
23          on the same reference product for which a prior bio-  
24          logical product has received a determination of inter-  
25          changeability for any condition of use, the Secretary



1 shall not make a determination under paragraph  
2 (4)(A) that the second or subsequent biological prod-  
3 uct is interchangeable for any condition of use until  
4 the earlier of—

5 “(A) 1 year after the first commercial  
6 marketing of the first interchangeable bio-  
7 similar biological product to be approved as  
8 interchangeable for that reference product;

9 “(B) 18 months after—

10 “(i) a final court decision on all pat-  
11 ents in suit in an action instituted under  
12 subsection (1)(6) against the applicant that  
13 submitted the application for the first ap-  
14 proved interchangeable biosimilar biological  
15 product; or

16 “(ii) the dismissal with or without  
17 prejudice of an action instituted under sub-  
18 section (1)(6) against the applicant that  
19 submitted the application for the first ap-  
20 proved interchangeable biosimilar biological  
21 product; or

22 “(C)(i) 42 months after approval of the  
23 first interchangeable biosimilar biological prod-  
24 uct if the applicant that submitted such appli-  
25 cation has been sued under subsection (1)(6)

1 and such litigation is still ongoing within such  
2 42-month period; or

3 “(ii) 18 months after approval of the first  
4 interchangeable biosimilar biological product if  
5 the applicant that submitted such application  
6 has not been sued under subsection (1)(6).

7 For purposes of this paragraph, the term ‘final court  
8 decision’ means a final decision of a court from  
9 which no appeal (other than a petition to the United  
10 States Supreme Court for a writ of certiorari) has  
11 been or can be taken.

12 “(7) EXCLUSIVITY FOR REFERENCE PROD-  
13 UCT.—

14 “(A) EFFECTIVE DATE OF BIOSIMILAR AP-  
15 PPLICATION APPROVAL.—

16 “(i) IN GENERAL.—Except as pro-  
17 vided in clause (ii), approval of an applica-  
18 tion under this subsection may not be  
19 made effective by the Secretary until the  
20 date that is 10 years after the date on  
21 which the reference product was first li-  
22 censed under subsection (a).

23 “(ii) EXTENSION OF EXCLUSIVITY.—  
24 The period of exclusivity described in  
25 clause (i) shall be extended for an addi-

1            tional 2 years beyond the 10 years pro-  
2            vided in such clause if there has been sig-  
3            nificant therapeutic advancements with re-  
4            spect to the reference product.

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

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

17           “(8) GUIDANCE DOCUMENTS.—

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

1 “(B) PUBLIC COMMENT.—

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

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

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

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

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

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

5                   “(E) CERTAIN PRODUCT CLASSES.—

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

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

20                  “(iii) NO EFFECT ON ABILITY TO  
21                  DENY LICENSE.—Clause (i) shall not be  
22                  construed to require the Secretary to ap-  
23                  prove a product with respect to which the  
24                  Secretary has not indicated in a guidance  
25                  document that the science and experience,

1 as described in clause (i), does not allow  
2 approval of such an application.

3 “(l) PATENTS.—

4 “(1) CONFIDENTIAL ACCESS TO SUBSECTION  
5 (k) APPLICATION.—

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

16 “(B) IN GENERAL.—

17 “(i) PROVISION OF CONFIDENTIAL IN-  
18 FORMATION.—When a subsection (k) ap-  
19 plicant submits an application under sub-  
20 section (k), such applicant shall provide to  
21 the persons described in clause (ii), subject  
22 to the terms of this paragraph, confidential  
23 access to the information required to be  
24 produced pursuant to paragraph (2) and  
25 any other information that the subsection

1 (k) applicant determines, in its sole discre-  
2 tion, to be appropriate (referred to in this  
3 subsection as the ‘confidential informa-  
4 tion’).

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

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

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

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

15          “(C) LIMITATION ON DISCLOSURE.—No  
16          person that receives confidential information  
17          pursuant to subparagraph (B) shall disclose  
18          any confidential information to any other per-  
19          son or entity, including the reference product  
20          sponsor employees, outside scientific consult-  
21          ants, or other outside counsel retained by the  
22          reference product sponsor, without the prior  
23          written consent of the subsection (k) applicant,  
24          which shall not be unreasonably withheld.



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

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

24           “(F) EFFECT OF INFRINGEMENT AC-  
25          TION.—In the event that the reference product

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

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

22 “(i) as an admission by the subsection  
23 (k) applicant regarding the validity, en-  
24 forceability, or infringement of any patent;  
25 or

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

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

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

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

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

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

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

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

23           “(ii) an identification of the patents  
24 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 applicant 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—

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 sserting “, 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 “(n) 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)(B) of the Federal Food, Drug, and Cos-

1           metec Act (21 U.S.C. 379g(1)(B)) 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 2010 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 355c);

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 10-year period described in subsection  
7 (k)(7) of such section 351.