

MARCH 5, 2020

RULES COMMITTEE PRINT 116-52
TEXT OF HOUSE AMENDMENT TO THE SENATE
AMENDMENT TO H.R. 2486

**[Showing the text of H.R. 2214, NO BAN Act, as reported by
the Committee on the Judiciary, with modifications]**

In the matter proposed to be inserted by the amendment of the Senate, strike sections 1, 2, and 3 and insert the following:

1 **TITLE I—NO BAN ACT**

2 **SEC. 101. SHORT TITLES.**

3 This title may be cited as the “National Origin-Based
4 Antidiscrimination for Nonimmigrants Act” or the “NO
5 BAN Act”.

6 **SEC. 102. EXPANSION OF NONDISCRIMINATION PROVISION.**

7 Section 202(a)(1)(A) of the Immigration and Nation-
8 ality Act (8 U.S.C. 1152(a)(1)(A)) is amended—

9 (1) by inserting “or a nonimmigrant visa, ad-
10 mission or other entry into the United States, or the
11 approval or revocation of any immigration benefit”
12 after “immigrant visa”;

13 (2) by inserting “religion,” after “sex,”; and

1 (3) by inserting “, except if expressly required
2 by statute, or if a statutorily authorized benefit
3 takes into consideration such factors” before the pe-
4 riod at the end.

5 **SEC. 103. TRANSFER AND LIMITATIONS ON AUTHORITY TO**
6 **SUSPEND OR RESTRICT THE ENTRY OF A**
7 **CLASS OF ALIENS.**

8 Section 212(f) of the Immigration and Nationality
9 Act (8 U.S.C. 1182(f)) is amended to read as follows:

10 “(f) **AUTHORITY TO SUSPEND OR RESTRICT THE**
11 **ENTRY OF A CLASS OF ALIENS.—**

12 “(1) **IN GENERAL.—**Subject to paragraph (2),
13 if the Secretary of State, in consultation with the
14 Secretary of Homeland Security, determines, based
15 on specific and credible facts, that the entry of any
16 aliens or any class of aliens into the United States
17 would undermine the security or public safety of the
18 United States or the preservation of human rights,
19 democratic processes or institutions, or international
20 stability, the President may temporarily—

21 “(A) suspend the entry of such aliens or
22 class of aliens as immigrants or nonimmigrants;
23 or

1 “(B) impose any restrictions on the entry
2 of such aliens that the President deems appro-
3 priate.

4 “(2) LIMITATIONS.—In carrying out paragraph
5 (1), the President, the Secretary of State, and the
6 Secretary of Homeland Security shall—

7 “(A) only issue a suspension or restriction
8 when required to address specific acts impli-
9 cating a compelling government interest in a
10 factor identified in paragraph (1);

11 “(B) narrowly tailor the suspension or re-
12 striction, using the least restrictive means, to
13 achieve such compelling government interest;

14 “(C) specify the duration of the suspension
15 or restriction; and

16 “(D) consider waivers to any class-based
17 restriction or suspension and apply a rebuttable
18 presumption in favor of granting family-based
19 and humanitarian waivers.

20 “(3) CONGRESSIONAL NOTIFICATION.—

21 “(A) IN GENERAL.—Prior to the President
22 exercising the authority under paragraph (1),
23 the Secretary of State and the Secretary of
24 Homeland Security shall consult Congress and
25 provide Congress with specific evidence sup-

1 porting the need for the suspension or restric-
2 tion and its proposed duration.

3 “(B) BRIEFING AND REPORT.—Not later
4 than 48 hours after the President exercises the
5 authority under paragraph (1), the Secretary of
6 State and the Secretary of Homeland Security
7 shall provide a briefing and submit a written re-
8 port to Congress that describes—

9 “(i) the action taken pursuant to
10 paragraph (1) and the specified objective
11 of such action;

12 “(ii) the estimated number of individ-
13 uals who will be impacted by such action;

14 “(iii) the constitutional and legislative
15 authority under which such action took
16 place; and

17 “(iv) the circumstances necessitating
18 such action, including how such action
19 complies with paragraph (2), as well as
20 any intelligence informing such actions.

21 “(C) TERMINATION.—If the briefing and
22 report described in subparagraph (B) are not
23 provided to Congress during the 48 hours that
24 begin when the President exercises the author-
25 ity under paragraph (1), the suspension or re-

1 restriction shall immediately terminate absent in-
2 tervening congressional action.

3 “(D) CONGRESSIONAL COMMITTEES.—The
4 term ‘Congress’, as used in this paragraph, re-
5 fers to the Select Committee on Intelligence of
6 the Senate, the Committee on Foreign Rela-
7 tions of the Senate, the Committee on the Judi-
8 ciary of the Senate, the Committee on Home-
9 land Security and Governmental Affairs of the
10 Senate, the Permanent Select Committee on In-
11 telligence of the House of Representatives, the
12 Committee on Foreign Affairs of the House of
13 Representatives, the Committee on the Judici-
14 ary of the House of Representatives, and the
15 Committee on Homeland Security of the House
16 of Representatives.

17 “(4) PUBLICATION.—The Secretary of State
18 and the Secretary of Homeland Security shall pub-
19 licly announce and publish an unclassified version of
20 the report described in paragraph (3)(B) in the Fed-
21 eral Register.

22 “(5) JUDICIAL REVIEW.—

23 “(A) IN GENERAL.—Notwithstanding any
24 other provision of law, an individual or entity
25 who is present in the United States and has

1 been harmed by a violation of this subsection
2 may file an action in an appropriate district
3 court of the United States to seek declaratory
4 or injunctive relief.

5 “(B) CLASS ACTION.—Nothing in this Act
6 may be construed to preclude an action filed
7 pursuant to subparagraph (A) from proceeding
8 as a class action.

9 “(6) TREATMENT OF COMMERCIAL AIRLINES.—
10 Whenever the Secretary of Homeland Security finds
11 that a commercial airline has failed to comply with
12 regulations of the Secretary of Homeland Security
13 relating to requirements of airlines for the detection
14 of fraudulent documents used by passengers trav-
15 eling to the United States (including the training of
16 personnel in such detection), the Secretary of Home-
17 land Security may suspend the entry of some or all
18 aliens transported to the United States by such air-
19 line.

20 “(7) RULE OF CONSTRUCTION.—Nothing in
21 this section may be construed as authorizing the
22 President, the Secretary of State, or the Secretary
23 of Homeland Security to act in a manner incon-
24 sistent with the policy decisions expressed in the im-
25 migration laws.

1 “(8) CLARIFICATION.—For purposes of para-
2 graph (1), the term ‘public safety of the United
3 States’ includes efforts necessary to contain a com-
4 municable disease of public health significance (as
5 defined in section 34.2(b) of title 42, Code of Fed-
6 eral Regulations (or any successor regulation)).”.

7 **SEC. 104. TERMINATION OF CERTAIN EXECUTIVE ACTIONS.**

8 (a) TERMINATION.—Presidential Proclamations
9 9645, 9822, and 9983 and Executive Orders 13769,
10 13780, and 13815 shall be void beginning on the date of
11 the enactment of this Act.

12 (b) EFFECT.—All actions taken pursuant to any
13 proclamation or executive order terminated under sub-
14 section (a) shall cease on the date of the enactment of
15 this Act.

16 **SEC. 105. VISA APPLICANTS REPORT.**

17 (a) INITIAL REPORTS.—

18 (1) IN GENERAL.—Not later than 90 days after
19 the date of the enactment of this Act, the Secretary
20 of State, in coordination with the Secretary of
21 Homeland Security and the heads of other relevant
22 Federal agencies, shall submit a report to the con-
23 gressional committees referred to in section
24 212(f)(3)(D) of the Immigration and Nationality
25 Act, as amended by section 103 of this title, that de-

1 scribes the implementation of each of the presi-
2 dential proclamations and executive orders referred
3 to in section 104.

4 (2) PRESIDENTIAL PROCLAMATION 9645 AND
5 9983.—In addition to the content described in para-
6 graph (1), the report submitted with respect to Pres-
7 idential Proclamation 9645, issued on September 24,
8 2017, and Presidential Proclamation 9983, issued
9 on January 31, 2020, shall include, for each country
10 listed in such proclamation—

11 (A) the total number of individuals who
12 applied for a visa during the time period the
13 proclamation was in effect, disaggregated by
14 country and visa category;

15 (B) the total number of visa applicants de-
16 scribed in subparagraph (A) who were ap-
17 proved, disaggregated by country and visa cat-
18 egory;

19 (C) the total number of visa applicants de-
20 scribed in subparagraph (A) who were refused,
21 disaggregated by country and visa category,
22 and the reasons they were refused;

23 (D) the total number of visa applicants de-
24 scribed in subparagraph (A) whose applications

1 remain pending, disaggregated by country and
2 visa category;

3 (E) the total number of visa applicants de-
4 scribed in subparagraph (A) who were granted
5 a waiver, disaggregated by country and visa
6 category;

7 (F) the total number of visa applicants de-
8 scribed in subparagraph (A) who were denied a
9 waiver, disaggregated by country and visa cat-
10 egory, and the reasons such waiver requests
11 were denied;

12 (G) the total number of refugees admitted,
13 disaggregated by country; and

14 (H) the complete reports that have been
15 submitted to the President every 180 days in
16 accordance with section 4 of Presidential Proc-
17 lamation 9645 in its original form, and as
18 amended by Presidential Proclamation 9983.

19 (b) ADDITIONAL REPORTS.—Not later than 30 days
20 after the date on which the President exercises the author-
21 ity under section 212(f) of the Immigration and Nation-
22 ality Act (8 U.S.C. 1182(f)), as amended by section 103
23 of this title, and every 30 days thereafter, the Secretary
24 of State, in coordination with the Secretary of Homeland
25 Security and heads of other relevant Federal agencies,

1 shall submit a report to the congressional committees re-
2 ferred to in paragraph (3)(D) of such section 212(f) that
3 identifies, with respect to countries affected by a suspen-
4 sion or restriction, the information described in subpara-
5 graphs (A) through (H) of subsection (a)(2) of this section
6 and specific evidence supporting the need for the contin-
7 ued exercise of presidential authority under such section
8 212(f), including the information described in paragraph
9 (3)(B) of such section 212(f). If the report described in
10 this subsection is not provided to Congress in the time
11 specified, the suspension or restriction shall immediately
12 terminate absent intervening congressional action. A final
13 report with such information shall be prepared and sub-
14 mitted to such congressional committees not later than 30
15 days after the suspension or restriction is lifted.

16 (c) FORM; AVAILABILITY.—The reports required
17 under subsections (a) and (b) shall be made publicly avail-
18 able online in unclassified form.

19 **TITLE II—AFFORDABLE PRE-**
20 **SCRIPTIONS FOR PATIENTS**
21 **ACT OF 2020**

22 **SEC. 201. SHORT TITLE.**

23 This title may be cited as the “Affordable Prescrip-
24 tions for Patients Act of 2020”.

1 **SEC. 202. PRODUCT HOPPING.**

2 (a) IN GENERAL.—The Federal Trade Commission
3 Act (15 U.S.C. 41 et seq.) is amended by inserting after
4 section 26 (15 U.S.C. 57c–2) the following:

5 **“SEC. 27. PRODUCT HOPPING.**

6 “(a) DEFINITIONS.—In this section:

7 “(1) ABBREVIATED NEW DRUG APPLICATION.—
8 The term ‘abbreviated new drug application’ means
9 an application under subsection (b)(2) or (j) of sec-
10 tion 505 of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 355).

12 “(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The
13 term ‘biosimilar biological product’ means a biologi-
14 cal product licensed under section 351(k) of the
15 Public Health Service Act (42 U.S.C. 262(k)).

16 “(3) BIOSIMILAR BIOLOGICAL PRODUCT LI-
17 CENSE APPLICATION.—The term ‘biosimilar biologi-
18 cal product license application’ means an application
19 submitted under section 351(k) of the Public Health
20 Service Act (42 U.S.C. 262(k)).

21 “(4) FOLLOW-ON PRODUCT.—The term ‘follow-
22 on product’—

23 “(A) means a drug approved through an
24 application or supplement to an application sub-
25 mitted under section 505(b) of the Federal
26 Food, Drug, and Cosmetic Act (21 U.S.C.

1 355(b)) or a biological product licensed through
2 an application or supplement to an application
3 submitted under section 351(a) of the Public
4 Health Service Act (42 U.S.C. 262(a)) for a
5 change, modification, or reformulation to the
6 same manufacturer’s previously approved drug
7 or biological product that treats the same med-
8 ical condition; and

9 “(B) excludes such an application or sup-
10 plement to an application for a change, modi-
11 fication, or reformulation of a drug or biological
12 product that is requested by the Secretary or
13 necessary to comply with law, including sections
14 505A and 505B of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 355a, 355c).

16 “(5) GENERIC DRUG.—The term ‘generic drug’
17 means a drug approved under an application sub-
18 mitted under subsection (b)(2) or (j) of section 505
19 of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 355).

21 “(6) LISTED DRUG.—The term ‘listed drug’
22 means a drug listed under section 505(j)(7) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 355(j)(7)).

1 “(7) MANUFACTURER.—The term ‘manufac-
2 turer’ means the holder, licensee, or assignee of—

3 “(A) an approved application for a drug
4 under section 505(c) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 355(c)); or

6 “(B) a biological product license under sec-
7 tion 351(a) of the Public Health Service Act
8 (42 U.S.C. 262(a)).

9 “(8) REFERENCE PRODUCT.—The term ‘ref-
10 erence product’ has the meaning given the term in
11 section 351(i) of the Public Health Service Act (42
12 U.S.C. 262(i)).

13 “(9) SECRETARY.—The term ‘Secretary’ means
14 the Secretary of Health and Human Services.

15 “(10) ULTIMATE PARENT ENTITY.—The term
16 ‘ultimate parent entity’ has the meaning given the
17 term in section 801.1 of title 16, Code of Federal
18 Regulations, or any successor regulation.

19 “(b) PROHIBITION ON PRODUCT HOPPING.—

20 “(1) PRIMA FACIE.—Except as provided in
21 paragraph (2), a manufacturer of a reference prod-
22 uct or listed drug shall be considered to have en-
23 gaged in an unfair method of competition in or af-
24 fecting commerce in violation of section 5(a) if the
25 Commission demonstrates by a preponderance of the

1 evidence in a proceeding initiated by the Commission
2 under subsection (c)(1)(A), or in a suit brought
3 under subparagraph (B) or (C) of subsection (c)(1),
4 that, during the period beginning on the date on
5 which the manufacturer of the reference product or
6 listed drug first receives notice that an applicant has
7 submitted to the Commissioner of Food and Drugs
8 an abbreviated new drug application or biosimilar bi-
9 ological product license application and ending on
10 the date that is 180 days after the date on which
11 that generic drug or biosimilar biological product is
12 first marketed, the manufacturer engaged in either
13 of the following actions:

14 “(A) The manufacturer engaged in a hard
15 switch, which shall be established by dem-
16 onstrating that the manufacturer engaged in ei-
17 ther of the following actions:

18 “(i) Upon the request of the manufac-
19 turer of the listed drug or reference prod-
20 uct, the Commissioner of Food and Drugs
21 withdrew the approval of the application
22 for the listed drug or reference product or
23 placed the listed drug or reference product
24 on the discontinued products list and the

1 manufacturer marketed or sold a follow-on
2 product.

3 “(ii) The manufacturer of the listed
4 drug or reference product—

5 “(I)(aa) announced withdrawal
6 of, discontinuance of the manufacture
7 of, or intent to withdraw the applica-
8 tion with respect to the drug or ref-
9 erence product in a manner that im-
10 pedes competition from a generic drug
11 or a biosimilar biological product, as
12 established by objective circumstances;
13 or

14 “(bb) destroyed the inventory of
15 the listed drug or reference product in
16 a manner that impedes competition
17 from a generic drug or a biosimilar bi-
18 ological product, which may be estab-
19 lished by objective circumstances; and

20 “(II) marketed or sold a follow-
21 on product.

22 “(B) The manufacturer engaged in a soft
23 switch, which shall be established by dem-
24 onstrating that the manufacturer engaged in
25 both of the following actions:

1 “(i) The manufacturer took actions
2 with respect to the listed drug or reference
3 product other than those described in sub-
4 paragraph (A) that unfairly disadvantage
5 the listed drug or reference product rel-
6 ative to the follow-on product described in
7 clause (ii) in a manner that impedes com-
8 petition from a generic drug or a bio-
9 similar biological product that is highly
10 similar to, and has no clinically meaningful
11 difference with respect to safety, purity,
12 and potency from, the reference product,
13 which may be established by objective cir-
14 cumstances.

15 “(ii) The manufacturer marketed or
16 sold a follow-on product.

17 “(2) JUSTIFICATION.—

18 “(A) IN GENERAL.—Subject to paragraph
19 (3), the actions described in paragraph (1) by
20 a manufacturer of a listed drug or reference
21 product shall not be considered to be an unfair
22 method of competition in or affecting commerce
23 if—

24 “(i) the manufacturer demonstrates to
25 the Commission or a district court of the

1 United States, as applicable, by a prepon-
2 derance of the evidence in a proceeding ini-
3 tiated by the Commission under subsection
4 (c)(1)(A), or in a suit brought under sub-
5 paragraph (B) or (C) of subsection (c)(1),
6 that—

7 “(I) the manufacturer would
8 have taken the actions regardless of
9 whether a generic drug that ref-
10 erences the listed drug or biosimilar
11 biological product that references the
12 reference product had already entered
13 the market; and

14 “(II)(aa) with respect to a hard
15 switch under paragraph (1)(A), the
16 manufacturer took the action for rea-
17 sons relating to the safety risk to pa-
18 tients of the listed drug or reference
19 product;

20 “(bb) with respect to an action
21 described in item (aa) or (bb) of para-
22 graph (1)(A)(ii)(I), there is a supply
23 disruption that—

24 “(AA) is outside of the con-
25 trol of the manufacturer;

1 “(BB) prevents the produc-
2 tion or distribution of the appli-
3 cable listed drug or reference
4 product; and

5 “(CC) cannot be remedied
6 by reasonable efforts; or

7 “(cc) with respect to a soft
8 switch under paragraph (1)(B), the
9 manufacturer had legitimate pro-com-
10 petitive reasons, apart from the finan-
11 cial effects of reduced competition, to
12 take the action.

13 “(B) RULE OF CONSTRUCTION.—Nothing
14 in subparagraph (A) may be construed to limit
15 the information that the Commission may oth-
16 erwise obtain in any proceeding or action insti-
17 tuted with respect to a violation of this section.

18 “(3) RESPONSE.—With respect to a justifica-
19 tion offered by a manufacturer under paragraph (2),
20 the Commission may—

21 “(A) rebut any evidence presented by a
22 manufacturer during that justification; or

23 “(B) establish by a preponderance of the
24 evidence that, on balance, the pro-competitive
25 benefits from the conduct described in subpara-

1 graph (A) or (B) of paragraph (1), as applica-
2 ble, do not outweigh any anticompetitive effects
3 of the conduct, even in consideration of the jus-
4 tification so offered.

5 “(c) ENFORCEMENT.—

6 “(1) IN GENERAL.—If the Commission has rea-
7 son to believe that any manufacturer has violated, is
8 violating, or is about to violate this section, the
9 Commission may take any of the following actions:

10 “(A) Institute a proceeding—

11 “(i) that, except as provided in para-
12 graph (2), complies with the requirements
13 under section 5(b); and

14 “(ii) in which the Commission may
15 impose on the manufacturer any penalty
16 that the Commission may impose for a vio-
17 lation of section 5.

18 “(B) In the same manner and to the same
19 extent as provided in section 13(b), bring suit
20 in a district court of the United States to tem-
21 porarily enjoin the action of the manufacturer.

22 “(C) Bring suit in a district court of the
23 United States, in which the Commission may
24 seek—

1 “(i) to permanently enjoin the action
2 of the manufacturer;

3 “(ii) any of the remedies described in
4 paragraph (3); and

5 “(iii) any other equitable remedy, in-
6 cluding ancillary equitable relief.

7 “(2) JUDICIAL REVIEW.—

8 “(A) IN GENERAL.—Notwithstanding any
9 provision of section 5, any manufacturer that is
10 subject to a final order of the Commission that
11 is issued in a proceeding instituted under para-
12 graph (1)(A) may, not later than 30 days after
13 the date on which the Commission issues the
14 order, petition for review of the order in—

15 “(i) the United States Court of Ap-
16 peals for the District of Columbia Circuit;
17 or

18 “(ii) the court of appeals of the
19 United States for the circuit in which the
20 ultimate parent entity of the manufacturer
21 is incorporated.

22 “(B) TREATMENT OF FINDINGS.—In a re-
23 view of an order issued by the Commission con-
24 ducted by a court of appeals of the United
25 States under subparagraph (A), the factual

1 findings of the Commission shall be conclusive
2 if those facts are supported by the evidence.

3 “(3) EQUITABLE REMEDIES.—

4 “(A) DISGORGEMENT.—

5 “(i) IN GENERAL.—In a suit brought
6 under paragraph (1)(C), the Commission
7 may seek, and the court may order,
8 disgorgement of any unjust enrichment
9 that a person obtained as a result of the
10 violation that gives rise to the suit.

11 “(ii) CALCULATION.—Any
12 disgorgement that is ordered with respect
13 to a person under clause (i) shall be offset
14 by any amount of restitution ordered
15 under subparagraph (B).

16 “(iii) LIMITATIONS PERIOD.—The
17 Commission may seek disgorgement under
18 this subparagraph not later than 5 years
19 after the latest date on which the person
20 from which the disgorgement is sought re-
21 ceives any unjust enrichment from the ef-
22 fects of the violation that gives rise to the
23 suit in which the Commission seeks the
24 disgorgement.

25 “(B) RESTITUTION.—

1 “(i) IN GENERAL.—In a suit brought
2 under paragraph (1)(C), the Commission
3 may seek, and the court may order, res-
4 titution with respect to the violation that
5 gives rise to the suit.

6 “(ii) LIMITATIONS PERIOD.—The
7 Commission may seek restitution under
8 this subparagraph not later than 5 years
9 after the latest date on which the person
10 from which the restitution is sought re-
11 ceives any unjust enrichment from the ef-
12 fects of the violation that gives rise to the
13 suit in which the Commission seeks the
14 restitution.

15 “(4) RULES OF CONSTRUCTION.—Nothing in
16 this subsection may be construed as—

17 “(A) requiring the Commission to bring a
18 suit seeking a temporary injunction under para-
19 graph (1)(B) before bringing a suit seeking a
20 permanent injunction under paragraph (1)(C);
21 or

22 “(B) affecting any other authority of the
23 Commission under this Act to seek relief or ob-
24 tain a remedy with respect to a violation of this
25 Act.”.

1 (b) APPLICABILITY.—Section 27 of the Federal
2 Trade Commission Act, as added by subsection (a), shall
3 apply with respect to any—

4 (1) conduct that occurs on or after the date of
5 enactment of this Act; and

6 (2) action or proceeding that is commenced on
7 or after the date of enactment of this Act.

8 (c) ANTITRUST LAWS.—Nothing in this section, or
9 the amendments made by this section, shall modify, im-
10 pair, limit, or supersede the applicability of the antitrust
11 laws as defined in subsection (a) of the first section of
12 the Clayton Act (15 U.S.C. 12(a)), and of section 5 of
13 the Federal Trade Commission Act (15 U.S.C. 45) to the
14 extent that it applies to unfair methods of competition.

15 (d) RULEMAKING.—The Federal Trade Commission
16 may issue rules under section 553 of title 5, United States
17 Code, to carry out section 27 of the Federal Trade Com-
18 mission Act, as added by subsection (a), including by de-
19 fining any terms used in such section 27 (other than terms
20 that are defined in subsection (a) of such section 27).

21 (e) CONFIRMATION.—Upon the request of the Com-
22 mission, the Secretary shall provide confirmation of—

23 (1) any request made by the Secretary to the
24 manufacturer for an application or supplement to an

1 application for a change, modification, or reformula-
2 tion of a drug or biological product;

3 (2) any withdrawal by the manufacturer of an
4 application for a drug or reference product; or

5 (3) any request made by a manufacturer to the
6 Secretary for withdrawal of an approval of the appli-
7 cation for a drug or reference product or a request
8 for placement of a drug or reference product on the
9 discontinued products list.

10 **SEC. 203. TITLE 35 AMENDMENTS.**

11 (a) IN GENERAL.—Section 271(e) of title 35, United
12 States Code, is amended—

13 (1) in paragraph (2)(C), in the flush text fol-
14 lowing clause (ii), by adding at the end the fol-
15 lowing: “With respect to a submission described in
16 clause (ii), the act of infringement shall extend to
17 any patent that claims the biological product, a
18 method of using the biological product, or a method
19 or product used to manufacture the biological prod-
20 uct.”; and

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

22 “(7)(A) Subject to subparagraphs (C), (D), and (E),
23 if the sponsor of an approved application for a reference
24 product, as defined in section 351(i) of the Public Health
25 Service Act (42 U.S.C. 262(i)) (referred to in this para-

1 graph as the ‘reference product sponsor’), brings an action
2 for infringement under this section against an applicant
3 for approval of a biological product under section 351(k)
4 of such Act that references that reference product (re-
5 ferred to in this paragraph as the ‘subsection (k) appli-
6 cant’), the reference product sponsor may assert in the
7 action a total of not more than 20 patents of the type
8 described in subparagraph (B), not more than 10 of which
9 shall have issued after the date specified in section
10 351(l)(7)(A) of such Act.

11 “(B) The patents described in this subparagraph are
12 patents that satisfy each of the following requirements:

13 “(i) Patents that claim the biological product
14 that is the subject of an application under section
15 351(k) of the Public Health Service Act (42 U.S.C.
16 262(k)) (or a use of that product) or a method or
17 product used in the manufacture of such biological
18 product.

19 “(ii) Patents that are included on the list of
20 patents described in section 351(l)(3)(A) of the Pub-
21 lic Health Service Act (42 U.S.C. 262(l)(3)(A)), in-
22 cluding as provided under section 351(l)(7) of such
23 Act.

24 “(iii) Patents that—

1 “(I) have an actual filing date of more
2 than 4 years after the date on which the ref-
3 erence product is approved; or

4 “(II) include a claim to a method in a
5 manufacturing process that is not used by the
6 reference product sponsor.

7 “(C) The court in which an action described in sub-
8 paragraph (A) is brought may increase the number of pat-
9 ents limited under that subparagraph—

10 “(i) if the request to increase that number is
11 made without undue delay; and

12 “(ii)(I) if the interest of justice so requires; or

13 “(II) for good cause shown, which—

14 “(aa) shall be established if the subsection
15 (k) applicant fails to provide information re-
16 quired under section 351(l)(2)(A) of the Public
17 Health Service Act (42 U.S.C. 262(l)(2)(A))
18 that would enable the reference product sponsor
19 to form a reasonable belief with respect to
20 whether a claim of infringement under this sec-
21 tion could reasonably be asserted; and

22 “(bb) may be established—

23 “(AA) if there is a material change to
24 the biological product (or process with re-
25 spect to the biological product) of the sub-

1 section (k) applicant that is the subject of
2 the application;

3 “(BB) if, with respect to a patent on
4 the supplemental list described in section
5 351(l)(7)(A) of Public Health Service Act
6 (42 U.S.C. 262(l)(7)(A)), the patent would
7 have issued before the date specified in
8 such section 351(l)(7)(A) but for the fail-
9 ure of the Office to issue the patent or a
10 delay in the issuance of the patent, as de-
11 scribed in paragraph (1) of section 154(b)
12 and subject to the limitations under para-
13 graph (2) of such section 154(b); or

14 “(CC) for another reason that shows
15 good cause, as determined appropriate by
16 the court.

17 “(D) In determining whether good cause has been
18 shown for the purposes of subparagraph (C)(ii)(II), a
19 court may consider whether the reference product sponsor
20 has provided a reasonable description of the identity and
21 relevance of any information beyond the subsection (k) ap-
22 plication that the court believes is necessary to enable the
23 court to form a belief with respect to whether a claim of
24 infringement under this section could reasonably be as-
25 sserted.

1 “(E) The limitation imposed under subparagraph
2 (A)—

3 “(i) shall apply only if the subsection (k) appli-
4 cant completes all actions required under paragraphs
5 (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of
6 section 351(l) of the Public Health Service Act (42
7 U.S.C. 262(l)); and

8 “(ii) shall not apply with respect to any patent
9 that claims, with respect to a biological product, a
10 method for using that product in therapy, diagnosis,
11 or prophylaxis, such as an indication or method of
12 treatment or other condition of use.”.

13 (b) APPLICABILITY.—The amendments made by sub-
14 section (a) shall apply with respect to an application sub-
15 mitted under section 351(k) of the Public Health Service
16 Act (42 U.S.C. 262(k)) on or after the date of enactment
17 of this Act.

