

In the House of Representatives, U. S.,

July 22, 2020.

Resolved, That the House agree to the amendment of the Senate to the bill (H.R. 2486) entitled “An Act to reauthorize mandatory funding programs for historically Black colleges and universities and other minority-serving institutions.”, with the following

HOUSE AMENDMENTS TO SENATE AMENDMENT:

(1)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”;

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

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

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

9 Section 212(f) of the Immigration and Nationality Act
10 (8 U.S.C. 1182(f)) is amended to read as follows:

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

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

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

1 “(B) impose any restrictions on the entry of
2 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 Sec-
6 retary 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 re-
17 striction 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 restriction*
2 *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 para-*
10 *graph (1) and the specified objective of such*
11 *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 com-*
19 *plies with paragraph (2), as well as any in-*
20 *telligence informing such actions.*

21 “(C) *TERMINATION.*—*If the briefing and re-*
22 *port described in subparagraph (B) are not pro-*
23 *vided to Congress during the 48 hours that begin*
24 *when the President exercises the authority under*
25 *paragraph (1), the suspension or restriction shall*

1 *immediately terminate absent intervening con-*
2 *gressional action.*

3 “(D) CONGRESSIONAL COMMITTEES.—The
4 term ‘Congress’, as used in this paragraph, refers
5 to the Select Committee on Intelligence of the
6 Senate, the Committee on Foreign Relations of
7 the Senate, the Committee on the Judiciary of
8 the Senate, the Committee on Homeland Secu-
9 rity and Governmental Affairs of the Senate, the
10 Permanent Select Committee on Intelligence of
11 the House of Representatives, the Committee on
12 Foreign Affairs of the House of Representatives,
13 the Committee on the Judiciary of the House of
14 Representatives, and the Committee on Home-
15 land Security of the House of Representatives.

16 “(4) PUBLICATION.—The Secretary of State and
17 the Secretary of Homeland Security shall publicly an-
18 nounce and publish an unclassified version of the re-
19 port described in paragraph (3)(B) in the Federal
20 Register.

21 “(5) JUDICIAL REVIEW.—

22 “(A) IN GENERAL.—Notwithstanding any
23 other provision of law, an individual or entity
24 who is present in the United States and has been
25 harmed by a violation of this subsection may file

1 *an action in an appropriate district court of the*
2 *United States to seek declaratory or injunctive*
3 *relief.*

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

8 “(6) *TREATMENT OF COMMERCIAL AIRLINES.*—
9 *Whenever the Secretary of Homeland Security finds*
10 *that a commercial airline has failed to comply with*
11 *regulations of the Secretary of Homeland Security re-*
12 *lating to requirements of airlines for the detection of*
13 *fraudulent documents used by passengers traveling to*
14 *the United States (including the training of personnel*
15 *in such detection), the Secretary of Homeland Secu-*
16 *rity may suspend the entry of some or all aliens*
17 *transported to the United States by such airline.*

18 “(7) *RULE OF CONSTRUCTION.*—*Nothing in this*
19 *section may be construed as authorizing the Presi-*
20 *dent, the Secretary of State, or the Secretary of*
21 *Homeland Security to act in a manner inconsistent*
22 *with the policy decisions expressed in the immigra-*
23 *tion laws.*

24 “(8) *CLARIFICATION.*—*For purposes of para-*
25 *graph (1), the term ‘public safety of the United*

1 *States' includes efforts necessary to contain a commu-*
2 *nicable disease of public health significance (as de-*
3 *finied in section 34.2(b) of title 42, Code of Federal*
4 *Regulations (or any successor regulation)).”.*

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

6 *(a) TERMINATION.—Presidential Proclamations 9645,*
7 *9822, and 9983 and Executive Orders 13769, 13780, and*
8 *13815 shall be void beginning on the date of the enactment*
9 *of this Act.*

10 *(b) EFFECT.—All actions taken pursuant to any proc-*
11 *lamation or executive order terminated under subsection (a)*
12 *shall cease on the date of the enactment of this Act.*

13 **SEC. 105. VISA APPLICANTS REPORT.**

14 *(a) INITIAL REPORTS.—*

15 *(1) IN GENERAL.—Not later than 90 days after*
16 *the date of the enactment of this Act, the Secretary of*
17 *State, in coordination with the Secretary of Home-*
18 *land Security and the heads of other relevant Federal*
19 *agencies, shall submit a report to the congressional*
20 *committees referred to in section 212(f)(3)(D) of the*
21 *Immigration and Nationality Act, as amended by sec-*
22 *tion 103 of this title, that describes the implementa-*
23 *tion of each of the presidential proclamations and ex-*
24 *ecutive orders referred to in section 104.*

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

8 *(A) the total number of individuals who ap-*
9 *plied for a visa during the time period the proc-*
10 *lamation was in effect, disaggregated by country*
11 *and visa category;*

12 *(B) the total number of visa applicants de-*
13 *scribed in subparagraph (A) who were approved,*
14 *disaggregated by country and visa category;*

15 *(C) the total number of visa applicants de-*
16 *scribed in subparagraph (A) who were refused,*
17 *disaggregated by country and visa category, and*
18 *the reasons they were refused;*

19 *(D) the total number of visa applicants de-*
20 *scribed in subparagraph (A) whose applications*
21 *remain pending, disaggregated by country and*
22 *visa category;*

23 *(E) the total number of visa applicants de-*
24 *scribed in subparagraph (A) who were granted a*

1 *waiver, disaggregated by country and visa cat-*
2 *egory;*

3 *(F) the total number of visa applicants de-*
4 *scribed in subparagraph (A) who were denied a*
5 *waiver, disaggregated by country and visa cat-*
6 *egory, and the reasons such waiver requests were*
7 *denied;*

8 *(G) the total number of refugees admitted,*
9 *disaggregated by country; and*

10 *(H) the complete reports that have been sub-*
11 *mitted to the President every 180 days in ac-*
12 *cordance with section 4 of Presidential Procla-*
13 *mation 9645 in its original form, and as amend-*
14 *ed by Presidential Proclamation 9983.*

15 **(b) ADDITIONAL REPORTS.**—*Not later than 30 days*
16 *after the date on which the President exercises the authority*
17 *under section 212(f) of the Immigration and Nationality*
18 *Act (8 U.S.C. 1182(f)), as amended by section 103 of this*
19 *title, and every 30 days thereafter, the Secretary of State,*
20 *in coordination with the Secretary of Homeland Security*
21 *and heads of other relevant Federal agencies, shall submit*
22 *a report to the congressional committees referred to in para-*
23 *graph (3)(D) of such section 212(f) that identifies, with re-*
24 *spect to countries affected by a suspension or restriction,*
25 *the information described in subparagraphs (A) through*

1 *(H) of subsection (a)(2) of this section and specific evidence*
 2 *supporting the need for the continued exercise of presi-*
 3 *dential authority under such section 212(f), including the*
 4 *information described in paragraph (3)(B) of such section*
 5 *212(f). If the report described in this subsection is not pro-*
 6 *vided to Congress in the time specified, the suspension or*
 7 *restriction shall immediately terminate absent intervening*
 8 *congressional action. A final report with such information*
 9 *shall be prepared and submitted to such congressional com-*
 10 *mittees not later than 30 days after the suspension or re-*
 11 *striction is lifted.*

12 *(c) FORM; AVAILABILITY.—The reports required under*
 13 *subsections (a) and (b) shall be made publicly available on-*
 14 *line in unclassified form.*

15 **TITLE II—AFFORDABLE PRE-**
 16 **SCRIPTIONS FOR PATIENTS**
 17 **ACT OF 2020**

18 **SEC. 201. SHORT TITLE.**

19 *This title may be cited as the “Affordable Prescriptions*
 20 *for Patients Act of 2020”.*

21 **SEC. 202. PRODUCT HOPPING.**

22 *(a) IN GENERAL.—The Federal Trade Commission Act*
 23 *(15 U.S.C. 41 et seq.) is amended by inserting after section*
 24 *26 (15 U.S.C. 57c–2) the following:*

1 **“SEC. 27. PRODUCT HOPPING.**

2 “(a) *DEFINITIONS.—In this section:*

3 “(1) *ABBREVIATED NEW DRUG APPLICATION.—*

4 *The term ‘abbreviated new drug application’ means*
5 *an application under subsection (b)(2) or (j) of sec-*
6 *tion 505 of the Federal Food, Drug, and Cosmetic Act*
7 *(21 U.S.C. 355).*

8 “(2) *BIOSIMILAR BIOLOGICAL PRODUCT.—The*

9 *term ‘biosimilar biological product’ means a biologi-*
10 *cal product licensed under section 351(k) of the Public*
11 *Health Service Act (42 U.S.C. 262(k)).*

12 “(3) *BIOSIMILAR BIOLOGICAL PRODUCT LICENSE*

13 *APPLICATION.—The term ‘biosimilar biological prod-*
14 *uct license application’ means an application sub-*
15 *mitted under section 351(k) of the Public Health*
16 *Service Act (42 U.S.C. 262(k)).*

17 “(4) *FOLLOW-ON PRODUCT.—The term ‘follow-on*
18 *product’—*

19 “(A) *means a drug approved through an*
20 *application or supplement to an application sub-*
21 *mitted under section 505(b) of the Federal Food,*
22 *Drug, and Cosmetic Act (21 U.S.C. 355(b)) or a*
23 *biological product licensed through an applica-*
24 *tion or supplement to an application submitted*
25 *under section 351(a) of the Public Health Service*
26 *Act (42 U.S.C. 262(a)) for a change, modifica-*

tion, or reformulation to the same manufacturer's previously approved drug or biological product that treats the same medical condition; and

“(B) excludes such an application or supplement to an application for a change, modification, or reformulation of a drug or biological product that is requested by the Secretary or necessary to comply with law, including sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c).

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

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

“(7) *MANUFACTURER*.—The term ‘manufacturer’ means the holder, licensee, or assignee of—

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

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

4 “(8) *REFERENCE PRODUCT*.—The term ‘reference
 5 product’ has the meaning given the term in section
 6 351(i) of the Public Health Service Act (42 U.S.C.
 7 262(i)).

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

10 “(10) *ULTIMATE PARENT ENTITY*.—The term ‘ul-
 11 timate parent entity’ has the meaning given the term
 12 in section 801.1 of title 16, Code of Federal Regula-
 13 tions, or any successor regulation.

14 “(b) *PROHIBITION ON PRODUCT HOPPING*.—

15 “(1) *PRIMA FACIE*.—Except as provided in para-
 16 graph (2), a manufacturer of a reference product or
 17 listed drug shall be considered to have engaged in an
 18 unfair method of competition in or affecting com-
 19 merce in violation of section 5(a) if the Commission
 20 demonstrates by a preponderance of the evidence in a
 21 proceeding initiated by the Commission under sub-
 22 section (c)(1)(A), or in a suit brought under subpara-
 23 graph (B) or (C) of subsection (c)(1), that, during the
 24 period beginning on the date on which the manufac-
 25 turer of the reference product or listed drug first re-

1 *ceives notice that an applicant has submitted to the*
2 *Commissioner of Food and Drugs an abbreviated new*
3 *drug application or biosimilar biological product li-*
4 *cense application and ending on the date that is 180*
5 *days after the date on which that generic drug or bio-*
6 *similar biological product is first marketed, the man-*
7 *ufacturer engaged in either of the following actions:*

8 *“(A) The manufacturer engaged in a hard*
9 *switch, which shall be established by dem-*
10 *onstrating that the manufacturer engaged in ei-*
11 *ther of the following actions:*

12 *“(i) Upon the request of the manufac-*
13 *turer of the listed drug or reference product,*
14 *the Commissioner of Food and Drugs with-*
15 *drew the approval of the application for the*
16 *listed drug or reference product or placed*
17 *the listed drug or reference product on the*
18 *discontinued products list and the manufac-*
19 *turer marketed or sold a follow-on product.*

20 *“(ii) The manufacturer of the listed*
21 *drug or reference product—*

22 *“(I)(aa) announced withdrawal*
23 *of, discontinuance of the manufacture*
24 *of, or intent to withdraw the applica-*
25 *tion with respect to the drug or ref-*

1 *erence product in a manner that im-*
2 *pedes competition from a generic drug*
3 *or a biosimilar biological product, as*
4 *established by objective circumstances;*
5 *or*

6 *“(bb) destroyed the inventory of*
7 *the listed drug or reference product in*
8 *a manner that impedes competition*
9 *from a generic drug or a biosimilar bi-*
10 *ological product, which may be estab-*
11 *lished by objective circumstances; and*

12 *“(II) marketed or sold a follow-on*
13 *product.*

14 *“(B) The manufacturer engaged in a soft*
15 *switch, which shall be established by dem-*
16 *onstrating that the manufacturer engaged in*
17 *both of the following actions:*

18 *“(i) The manufacturer took actions*
19 *with respect to the listed drug or reference*
20 *product other than those described in sub-*
21 *paragraph (A) that unfairly disadvantage*
22 *the listed drug or reference product relative*
23 *to the follow-on product described in clause*
24 *(ii) in a manner that impedes competition*
25 *from a generic drug or a biosimilar biologi-*

1 *cal product that is highly similar to, and*
2 *has no clinically meaningful difference with*
3 *respect to safety, purity, and potency from,*
4 *the reference product, which may be estab-*
5 *lished by objective circumstances.*

6 “(ii) *The manufacturer marketed or*
7 *sold a follow-on product.*

8 “(2) *JUSTIFICATION.—*

9 “(A) *IN GENERAL.—Subject to paragraph*
10 *(3), the actions described in paragraph (1) by a*
11 *manufacturer of a listed drug or reference prod-*
12 *uct shall not be considered to be an unfair meth-*
13 *od of competition in or affecting commerce if—*

14 “(i) *the manufacturer demonstrates to*
15 *the Commission or a district court of the*
16 *United States, as applicable, by a prepon-*
17 *derance of the evidence in a proceeding ini-*
18 *tiated by the Commission under subsection*
19 *(c)(1)(A), or in a suit brought under sub-*
20 *paragraph (B) or (C) of subsection (c)(1),*
21 *that—*

22 “(I) *the manufacturer would have*
23 *taken the actions regardless of whether*
24 *a generic drug that references the listed*
25 *drug or biosimilar biological product*

1 *that references the reference product*
2 *had already entered the market; and*

3 “(II)(aa) *with respect to a hard*
4 *switch under paragraph (1)(A), the*
5 *manufacturer took the action for rea-*
6 *sons relating to the safety risk to pa-*
7 *tients of the listed drug or reference*
8 *product;*

9 “(bb) *with respect to an action de-*
10 *scribed in item (aa) or (bb) of para-*
11 *graph (1)(A)(ii)(I), there is a supply*
12 *disruption that—*

13 “(AA) *is outside of the con-*
14 *trol of the manufacturer;*

15 “(BB) *prevents the produc-*
16 *tion or distribution of the appli-*
17 *cable listed drug or reference*
18 *product; and*

19 “(CC) *cannot be remedied by*
20 *reasonable efforts; or*

21 “(cc) *with respect to a soft switch*
22 *under paragraph (1)(B), the manufac-*
23 *turer had legitimate pro-competitive*
24 *reasons, apart from the financial ef-*

1 *fects of reduced competition, to take the*
 2 *action.*

3 “(B) *RULE OF CONSTRUCTION.*—*Nothing in*
 4 *subparagraph (A) may be construed to limit the*
 5 *information that the Commission may otherwise*
 6 *obtain in any proceeding or action instituted*
 7 *with respect to a violation of this section.*

8 “(3) *RESPONSE.*—*With respect to a justification*
 9 *offered by a manufacturer under paragraph (2), the*
 10 *Commission may—*

11 “(A) *rebut any evidence presented by a*
 12 *manufacturer during that justification; or*

13 “(B) *establish by a preponderance of the*
 14 *evidence that, on balance, the pro-competitive*
 15 *benefits from the conduct described in subpara-*
 16 *graph (A) or (B) of paragraph (1), as applica-*
 17 *ble, do not outweigh any anticompetitive effects*
 18 *of the conduct, even in consideration of the jus-*
 19 *tification so offered.*

20 “(c) *ENFORCEMENT.*—

21 “(1) *IN GENERAL.*—*If the Commission has rea-*
 22 *son to believe that any manufacturer has violated, is*
 23 *violating, or is about to violate this section, the Com-*
 24 *mission may take any of the following actions:*

25 “(A) *Institute a proceeding—*

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

4 “(ii) in which the Commission may
5 impose on the manufacturer any penalty
6 that the Commission may impose for a vio-
7 lation of section 5.

8 “(B) In the same manner and to the same
9 extent as provided in section 13(b), bring suit in
10 a district court of the United States to tempo-
11 rarily enjoin the action of the manufacturer.

12 “(C) Bring suit in a district court of the
13 United States, in which the Commission may
14 seek—

15 “(i) to permanently enjoin the action
16 of the manufacturer;

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

19 “(iii) any other equitable remedy, in-
20 cluding ancillary equitable relief.

21 “(2) JUDICIAL REVIEW.—

22 “(A) IN GENERAL.—Notwithstanding any
23 provision of section 5, any manufacturer that is
24 subject to a final order of the Commission that
25 is issued in a proceeding instituted under para-

graph (1)(A) may, not later than 30 days after the date on which the Commission issues the order, petition for review of the order in—

“(i) the United States Court of Appeals for the District of Columbia Circuit; or

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

“(B) *TREATMENT OF FINDINGS.*—In a review of an order issued by the Commission conducted by a court of appeals of the United States under subparagraph (A), the factual findings of the Commission shall be conclusive if those facts are supported by the evidence.

“(3) *EQUITABLE REMEDIES.*—

“(A) *DISGORGEMENT.*—

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

“(ii) *CALCULATION.*—Any disgorgement that is ordered with respect to

1 a person under clause (i) shall be offset by
2 any amount of restitution ordered under
3 subparagraph (B).

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

13 “(B) *RESTITUTION.*—

14 “(i) *IN GENERAL.*—In a suit brought
15 under paragraph (1)(C), the Commission
16 may seek, and the court may order, restitu-
17 tion with respect to the violation that gives
18 rise to the suit.

19 “(ii) *LIMITATIONS PERIOD.*—The Com-
20 mission may seek restitution under this sub-
21 paragraph not later than 5 years after the
22 latest date on which the person from which
23 the restitution is sought receives any unjust
24 enrichment from the effects of the violation

1 that gives rise to the suit in which the Com-
 2 mission seeks the restitution.

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

5 “(A) requiring the Commission to bring a
 6 suit seeking a temporary injunction under para-
 7 graph (1)(B) before bringing a suit seeking a
 8 permanent injunction under paragraph (1)(C);
 9 or

10 “(B) affecting any other authority of the
 11 Commission under this Act to seek relief or ob-
 12 tain a remedy with respect to a violation of this
 13 Act.”.

14 (b) *APPLICABILITY.*—Section 27 of the Federal Trade
 15 Commission Act, as added by subsection (a), shall apply
 16 with respect to any—

17 (1) conduct that occurs on or after the date of en-
 18 actment of this Act; and

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

21 (c) *ANTITRUST LAWS.*—Nothing in this section, or the
 22 amendments made by this section, shall modify, impair,
 23 limit, or supersede the applicability of the antitrust laws
 24 as defined in subsection (a) of the first section of the Clay-
 25 ton Act (15 U.S.C. 12(a)), and of section 5 of the Federal

1 *Trade Commission Act (15 U.S.C. 45) to the extent that*
 2 *it applies to unfair methods of competition.*

3 (d) *RULEMAKING.—The Federal Trade Commission*
 4 *may issue rules under section 553 of title 5, United States*
 5 *Code, to carry out section 27 of the Federal Trade Commis-*
 6 *sion Act, as added by subsection (a), including by defining*
 7 *any terms used in such section 27 (other than terms that*
 8 *are defined in subsection (a) of such section 27).*

9 (e) *CONFIRMATION.—Upon the request of the Commis-*
 10 *sion, the Secretary shall provide confirmation of—*

11 (1) *any request made by the Secretary to the*
 12 *manufacturer for an application or supplement to an*
 13 *application for a change, modification, or reformula-*
 14 *tion of a drug or biological product;*

15 (2) *any withdrawal by the manufacturer of an*
 16 *application for a drug or reference product; or*

17 (3) *any request made by a manufacturer to the*
 18 *Secretary for withdrawal of an approval of the appli-*
 19 *cation for a drug or reference product or a request for*
 20 *placement of a drug or reference product on the dis-*
 21 *continued products list.*

22 **SEC. 203. TITLE 35 AMENDMENTS.**

23 (a) *IN GENERAL.—Section 271(e) of title 35, United*
 24 *States Code, is amended—*

1 (1) in paragraph (2)(C), in the flush text fol-
 2 lowing clause (ii), by adding at the end the following:
 3 “With respect to a submission described in clause (ii),
 4 the act of infringement shall extend to any patent
 5 that claims the biological product, a method of using
 6 the biological product, or a method or product used
 7 to manufacture the biological product.”; and

8 (2) by adding at the end the following:
 9 “(7)(A) Subject to subparagraphs (C), (D), and (E),
 10 if the sponsor of an approved application for a reference
 11 product, as defined in section 351(i) of the Public Health
 12 Service Act (42 U.S.C. 262(i)) (referred to in this para-
 13 graph as the ‘reference product sponsor’), brings an action
 14 for infringement under this section against an applicant
 15 for approval of a biological product under section 351(k)
 16 of such Act that references that reference product (referred
 17 to in this paragraph as the ‘subsection (k) applicant’), the
 18 reference product sponsor may assert in the action a total
 19 of not more than 20 patents of the type described in sub-
 20 paragraph (B), not more than 10 of which shall have issued
 21 after the date specified in section 351(l)(7)(A) of such Act.

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

24 “(i) Patents that claim the biological product
 25 that is the subject of an application under section

1 *351(k) of the Public Health Service Act (42 U.S.C.*
 2 *262(k)) (or a use of that product) or a method or*
 3 *product used in the manufacture of such biological*
 4 *product.*

5 *“(ii) Patents that are included on the list of pat-*
 6 *ents described in section 351(l)(3)(A) of the Public*
 7 *Health Service Act (42 U.S.C. 262(l)(3)(A)), includ-*
 8 *ing as provided under section 351(l)(7) of such Act.*

9 *“(iii) Patents that—*

10 *“(I) have an actual filing date of more than*
 11 *4 years after the date on which the reference*
 12 *product is approved; or*

13 *“(II) include a claim to a method in a*
 14 *manufacturing process that is not used by the*
 15 *reference product sponsor.*

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

19 *“(i) if the request to increase that number is*
 20 *made without undue delay; and*

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

22 *“(II) for good cause shown, which—*

23 *“(aa) shall be established if the subsection*
 24 *(k) applicant fails to provide information re-*
 25 *quired under section 351(l)(2)(A) of the Public*

1 *Health Service Act (42 U.S.C. 262(l)(2)(A)) that*
2 *would enable the reference product sponsor to*
3 *form a reasonable belief with respect to whether*
4 *a claim of infringement under this section could*
5 *reasonably be asserted; and*

6 *“(bb) may be established—*

7 *“(AA) if there is a material change to*
8 *the biological product (or process with re-*
9 *spect to the biological product) of the sub-*
10 *section (k) applicant that is the subject of*
11 *the application;*

12 *“(BB) if, with respect to a patent on*
13 *the supplemental list described in section*
14 *351(l)(7)(A) of Public Health Service Act*
15 *(42 U.S.C. 262(l)(7)(A)), the patent would*
16 *have issued before the date specified in such*
17 *section 351(l)(7)(A) but for the failure of the*
18 *Office to issue the patent or a delay in the*
19 *issuance of the patent, as described in para-*
20 *graph (1) of section 154(b) and subject to*
21 *the limitations under paragraph (2) of such*
22 *section 154(b); or*

23 *“(CC) for another reason that shows*
24 *good cause, as determined appropriate by*
25 *the court.*

1 “(D) In determining whether good cause has been
 2 shown for the purposes of subparagraph (C)(ii)(II), a court
 3 may consider whether the reference product sponsor has pro-
 4 vided a reasonable description of the identity and relevance
 5 of any information beyond the subsection (k) application
 6 that the court believes is necessary to enable the court to
 7 form a belief with respect to whether a claim of infringe-
 8 ment under this section could reasonably be asserted.

9 “(E) The limitation imposed under subparagraph
 10 (A)—

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

16 “(ii) shall not apply with respect to any patent
 17 that claims, with respect to a biological product, a
 18 method for using that product in therapy, diagnosis,
 19 or prophylaxis, such as an indication or method of
 20 treatment or other condition of use.”.

21 (b) *APPLICABILITY.*—The amendments made by sub-
 22 section (a) shall apply with respect to an application sub-
 23 mitted under section 351(k) of the Public Health Service
 24 Act (42 U.S.C. 262(k)) on or after the date of enactment
 25 of this Act.

(2) In the matter proposed to be inserted by the amendment of the Senate, strike sections 4, 5, and 6 and insert the following:

1 *TITLE III—ACCESS TO COUNSEL*
2 *ACT OF 2020*

3 *SEC. 301. SHORT TITLE.*

4 *This title may be cited as the “Access to Counsel Act*
5 *of 2020”.*

6 *SEC. 302. ACCESS TO COUNSEL AND OTHER ASSISTANCE AT*
7 *PORTS OF ENTRY AND DEFERRED INSPEC-*
8 *TION.*

9 *(a) ACCESS TO COUNSEL AND OTHER ASSISTANCE*
10 *DURING INSPECTION.—Section 235 of the Immigration and*
11 *Nationality Act (8 U.S.C. 1225) is amended by adding at*
12 *the end the following:*

13 *“(e) ACCESS TO COUNSEL AND OTHER ASSISTANCE*
14 *DURING INSPECTION.—*

15 *“(1) IN GENERAL.—The Secretary of Homeland*
16 *Security shall ensure that a covered individual has a*
17 *meaningful opportunity to consult with counsel and*
18 *an interested party during the inspection process.*

19 *“(2) SCOPE OF ASSISTANCE.—The Secretary of*
20 *Homeland Security shall—*

21 *“(A) provide the covered individual a*
22 *meaningful opportunity to consult with counsel*

1 *and an interested party not later than one hour*
2 *after the secondary inspection process commences*
3 *and as necessary throughout the inspection proc-*
4 *ess, including, as applicable, during deferred in-*
5 *spection;*

6 *“(B) allow counsel and an interested party*
7 *to advocate on behalf of the covered individual,*
8 *including by providing to the examining immi-*
9 *gration officer information, documentation, and*
10 *other evidence in support of the covered indi-*
11 *vidual; and*

12 *“(C) to the greatest extent practicable, ac-*
13 *commodate a request by the covered individual*
14 *for counsel or an interested party to appear in-*
15 *person at the secondary or deferred inspection*
16 *site.*

17 *“(3) SPECIAL RULE FOR LAWFUL PERMANENT*
18 *RESIDENTS.—*

19 *“(A) IN GENERAL.—The Secretary of Home-*
20 *land Security may not accept Form I-407*
21 *Record of Abandonment of Lawful Permanent*
22 *Resident Status (or a successor form) from a*
23 *lawful permanent resident subject to secondary*
24 *or deferred inspection without providing such*
25 *lawful permanent resident a reasonable oppor-*

1 *tunity to seek advice from counsel prior to the*
2 *submission of the form.*

3 “(B) *EXCEPTION.*—*The Secretary of Home-*
4 *land Security may accept Form I-407 Record of*
5 *Abandonment of Lawful Permanent Resident*
6 *Status (or a successor form) from a lawful per-*
7 *manent resident subject to secondary or deferred*
8 *inspection if such lawful permanent resident*
9 *knowingly, intelligently, and voluntarily waives,*
10 *in writing, the opportunity to seek advice from*
11 *counsel.*

12 “(4) *DEFINITIONS.*—*In this section:*

13 “(A) *COUNSEL.*—*The term ‘counsel’*
14 *means—*

15 “(i) *an attorney who is a member in*
16 *good standing of the bar of any State, the*
17 *District of Columbia, or a territory or a*
18 *possession of the United States and is not*
19 *under an order suspending, enjoining, re-*
20 *straining, disbarring, or otherwise restrict-*
21 *ing the attorney in the practice of law; or*

22 “(ii) *an individual accredited by the*
23 *Attorney General, acting as a representative*
24 *of an organization recognized by the Execu-*
25 *tive Office for Immigration Review, to rep-*

1 *resent a covered individual in immigration*
2 *matters.*

3 “(B) COVERED INDIVIDUAL.—The term ‘cov-
4 *ered individual’ means an individual subject to*
5 *secondary or deferred inspection who is—*

6 “(i) *a national of the United States;*

7 “(ii) *an immigrant, lawfully admitted*
8 *for permanent residence, who is returning*
9 *from a temporary visit abroad;*

10 “(iii) *an alien seeking admission as an*
11 *immigrant in possession of a valid unex-*
12 *pired immigrant visa;*

13 “(iv) *an alien seeking admission as a*
14 *non-immigrant in possession of a valid un-*
15 *expired non-immigrant visa;*

16 “(v) *a refugee;*

17 “(vi) *a returning asylee; or*

18 “(vii) *an alien who has been approved*
19 *for parole under section 212(d)(5)(A), in-*
20 *cluding an alien who is returning to the*
21 *United States in possession of a valid ad-*
22 *vance parole document.*

23 “(C) INTERESTED PARTY.—The term ‘inter-
24 *ested party’ means—*

1 “(i) a relative of the covered indi-
2 vidual;

3 “(ii) in the case of a covered indi-
4 vidual to whom an immigrant or non-im-
5 migrant visa has been issued, the petitioner
6 or sponsor thereof (including an agent of
7 such petitioner or sponsor); or

8 “(iii) a person, organization, or entity
9 in the United States with a bona fide con-
10 nection to the covered individual.”.

11 (b) *EFFECTIVE DATE.*—The amendment made by sub-
12 section (a) shall take effect 180 days after the date of the
13 enactment of this Act.

14 (c) *SAVINGS PROVISION.*—Nothing in this title, or in
15 any amendment made by this title, may be construed to
16 limit a right to counsel or any right to appointed counsel
17 under—

18 (1) section 240(b)(4)(A) (8 U.S.C.
19 1229a(b)(4)(A)),

20 (2) section 292 of the Immigration and Nation-
21 ality Act (8 U.S.C. 1362), or

22 (3) any other provision of law, including any
23 final court order securing such rights,

- 1 *as in effect on the day before the date of the enactment of*
- 2 *this Act.*

Attest:

Clerk.

116TH CONGRESS
2^D SESSION

H.R. 2486

**HOUSE AMENDMENTS TO
SENATE AMENDMENT**