

108TH CONGRESS
1ST SESSION

S. 54

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

IN THE SENATE OF THE UNITED STATES

JANUARY 7, 2003

Mr. SCHUMER (for himself, Mr. MCCAIN, Mr. EDWARDS, Ms. COLLINS, Mr. KENNEDY, Mr. MILLER, Mr. JOHNSON, Mrs. CLINTON, Mr. KOHL, Mr. FEINGOLD, Ms. STABENOW, Mr. DASCHLE, Mr. NELSON of Florida, Mr. ROCKEFELLER, Mr. LEAHY, Mr. REED, Mr. PRYOR, Mr. DURBIN, and Mr. DORGAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Greater Access to Af-
5 fordable Pharmaceuticals Act of 2003”.

6 **SEC. 2. FINDINGS; PURPOSES.**

7 (a) FINDINGS.—Congress finds that—

1 (1) prescription drug costs are increasing at an
2 alarming rate and are a major worry of American
3 families and senior citizens;

4 (2) enhancing competition between generic drug
5 manufacturers and brand-name manufacturers can
6 significantly reduce prescription drug costs for
7 American families;

8 (3) the pharmaceutical market has become in-
9 creasingly competitive during the last decade be-
10 cause of the increasing availability and accessibility
11 of generic pharmaceuticals, but competition must be
12 further stimulated and strengthened;

13 (4) the Federal Trade Commission has discov-
14 ered that there are increasing opportunities for drug
15 companies owning patents on brand-name drugs and
16 generic drug companies to enter into private finan-
17 cial deals in a manner that could restrain trade and
18 greatly reduce competition and increase prescription
19 drug costs for consumers;

20 (5) generic pharmaceuticals are approved by the
21 Food and Drug Administration on the basis of sci-
22 entific testing and other information establishing
23 that pharmaceuticals are therapeutically equivalent
24 to brand-name pharmaceuticals, ensuring consumers

1 a safe, efficacious, and cost-effective alternative to
2 brand-name innovator pharmaceuticals;

3 (6) the Congressional Budget Office estimates
4 that—

5 (A) the use of generic pharmaceuticals for
6 brand-name pharmaceuticals could save pur-
7 chasers of pharmaceuticals between
8 \$8,000,000,000 and \$10,000,000,000 each
9 year; and

10 (B) generic pharmaceuticals cost between
11 25 percent and 60 percent less than brand-
12 name pharmaceuticals, resulting in an esti-
13 mated average savings of \$15 to \$30 on each
14 prescription;

15 (7) generic pharmaceuticals are widely accepted
16 by consumers and the medical profession, as the
17 market share held by generic pharmaceuticals com-
18 pared to brand-name pharmaceuticals has more than
19 doubled during the last decade, from approximately
20 19 percent to 43 percent, according to the Congres-
21 sional Budget Office;

22 (8) expanding access to generic pharmaceuticals
23 can help consumers, especially senior citizens and
24 the uninsured, have access to more affordable pre-
25 scription drugs;

1 (9) Congress should ensure that measures are
2 taken to effectuate the amendments made by the
3 Drug Price Competition and Patent Term Restora-
4 tion Act of 1984 (98 Stat. 1585) (referred to in this
5 section as the “Hatch-Waxman Act”) to make ge-
6 neric drugs more accessible, and thus reduce health
7 care costs; and

8 (10) it would be in the public interest if patents
9 on drugs for which applications are approved under
10 section 505(c) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 355(c)) were extended only
12 through the patent extension procedure provided
13 under the Hatch-Waxman Act rather than through
14 the attachment of riders to bills in Congress.

15 (b) PURPOSES.—The purposes of this Act are—

16 (1) to increase competition, thereby helping all
17 Americans, especially seniors and the uninsured, to
18 have access to more affordable medication; and

19 (2) to ensure fair marketplace practices and
20 deter pharmaceutical companies (including generic
21 companies) from engaging in anticompetitive action
22 or actions that tend to unfairly restrain trade.

1 **SEC. 3. FILING OF PATENT INFORMATION WITH THE FOOD**
2 **AND DRUG ADMINISTRATION.**

3 (a) FILING AFTER APPROVAL OF AN APPLICA-
4 TION.—

5 (1) IN GENERAL.—Section 505 of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 355) (as
7 amended by section 9(a)(2)(B)(ii)) is amended in
8 subsection (c) by striking paragraph (2) and insert-
9 ing the following:

10 “(2) PATENT INFORMATION.—

11 “(A) IN GENERAL.—Not later than the
12 date that is 30 days after the date of an order
13 approving an application under subsection (b)
14 (unless the Secretary extends the date because
15 of extraordinary or unusual circumstances), the
16 holder of the application shall file with the Sec-
17 retary the patent information described in sub-
18 paragraph (C) with respect to any patent—

19 “(i)(I) that claims the drug for which
20 the application was approved; or

21 “(II) that claims an approved method
22 of using the drug; and

23 “(ii) with respect to which a claim of
24 patent infringement could reasonably be
25 asserted if a person not licensed by the

1 owner engaged in the manufacture, use, or
2 sale of the drug.

3 “(B) SUBSEQUENTLY ISSUED PATENTS.—

4 In a case in which a patent described in sub-
5 paragraph (A) is issued after the date of an
6 order approving an application under subsection
7 (b), the holder of the application shall file with
8 the Secretary the patent information described
9 in subparagraph (C) not later than the date
10 that is 30 days after the date on which the pat-
11 ent is issued (unless the Secretary extends the
12 date because of extraordinary or unusual cir-
13 cumstances).

14 “(C) PATENT INFORMATION.—The patent
15 information required to be filed under subpara-
16 graph (A) or (B) includes—

17 “(i) the patent number;

18 “(ii) the expiration date of the patent;

19 “(iii) with respect to each claim of the
20 patent—

21 “(I) whether the patent claims
22 the drug or claims a method of using
23 the drug; and

24 “(II) whether the claim covers—

25 “(aa) a drug substance;

1 “(bb) a drug formulation;

2 “(cc) a drug composition; or

3 “(dd) a method of use;

4 “(iv) if the patent claims a method of
5 use, the approved use covered by the claim;

6 “(v) the identity of the owner of the
7 patent (including the identity of any agent
8 of the patent owner); and

9 “(vi) a declaration that the applicant,
10 as of the date of the filing, has provided
11 complete and accurate patent information
12 for all patents described in subparagraph
13 (A).

14 “(D) PUBLICATION.—On filing of patent
15 information required under subparagraph (A)
16 or (B), the Secretary shall—

17 “(i) immediately publish the informa-
18 tion described in clauses (i) through (iv) of
19 subparagraph (C); and

20 “(ii) make the information described
21 in clauses (v) and (vi) of subparagraph (C)
22 available to the public on request.

23 “(E) CIVIL ACTION FOR CORRECTION OR
24 DELETION OF PATENT INFORMATION.—

1 “(i) IN GENERAL.—A person that has
2 filed an application under subsection (b)(2)
3 or (j) for a drug may bring a civil action
4 against the holder of the approved applica-
5 tion for the drug seeking an order requir-
6 ing that the holder of the application
7 amend the application—

8 “(I) to correct patent information
9 filed under subparagraph (A); or

10 “(II) to delete the patent infor-
11 mation in its entirety for the reason
12 that—

13 “(aa) the patent does not
14 claim the drug for which the ap-
15 plication was approved; or

16 “(bb) the patent does not
17 claim an approved method of
18 using the drug.

19 “(ii) LIMITATIONS.—Clause (i) does
20 not authorize—

21 “(I) a civil action to correct pat-
22 ent information filed under subpara-
23 graph (B); or

24 “(II) an award of damages in a
25 civil action under clause (i).

1 “(F) NO CLAIM FOR PATENT INFRINGE-
2 MENT.—An owner of a patent with respect to
3 which a holder of an application fails to file in-
4 formation on or before the date required under
5 subparagraph (A) or (B) shall be barred from
6 bringing a civil action for infringement of the
7 patent against a person that—

8 “(i) has filed an application under
9 subsection (b)(2) or (j); or

10 “(ii) manufactures, uses, offers to sell,
11 or sells a drug approved under an applica-
12 tion under subsection (b)(2) or (j).”.

13 (2) TRANSITION PROVISION.—

14 (A) FILING OF PATENT INFORMATION.—

15 Each holder of an application for approval of a
16 new drug under section 505(b) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C.
18 355(b)) that has been approved before the date
19 of enactment of this Act shall amend the appli-
20 cation to include the patent information re-
21 quired under the amendment made by para-
22 graph (1) not later than the date that is 30
23 days after the date of enactment of this Act
24 (unless the Secretary of Health and Human

1 Services extends the date because of extraor-
2 dinary or unusual circumstances).

3 (B) NO CLAIM FOR PATENT INFRINGE-
4 MENT.—An owner of a patent with respect to
5 which a holder of an application under sub-
6 section (b) of section 505 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355) fails
8 to file information on or before the date re-
9 quired under subparagraph (A) shall be barred
10 from bringing a civil action for infringement of
11 the patent against a person that—

12 (i) has filed an application under sub-
13 section (b)(2) or (j) of that section; or

14 (ii) manufactures, uses, offers to sell,
15 or sells a drug approved under an applica-
16 tion under subsection (b)(2) or (j) of that
17 section.

18 (b) FILING WITH AN APPLICATION.—Section 505 of
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 355) is amended—

21 (1) in subsection (b)(2)—

22 (A) in subparagraph (A), by striking
23 “and” at the end;

24 (B) in subparagraph (B), by striking the
25 period at the end and inserting “; and”; and

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

2 “(C) with respect to a patent that claims
3 both the drug and a method of using the drug
4 or claims more than 1 method of using the drug
5 for which the application is filed—

6 “(i) a certification under subpara-
7 graph (A)(iv) on a claim-by-claim basis;
8 and

9 “(ii) a statement under subparagraph
10 (B) regarding the method of use claim.”;
11 and

12 (2) in subsection (j)(2)(A), by inserting after
13 clause (viii) the following:

14 “With respect to a patent that claims both the drug and
15 a method of using the drug or claims more than 1 method
16 of using the drug for which the application is filed, the
17 application shall contain a certification under clause
18 (vii)(IV) on a claim-by-claim basis and a statement under
19 clause (viii) regarding the method of use claim.”.

20 **SEC. 4. LIMITATION OF 30-MONTH STAY TO CERTAIN PAT-**
21 **ENTS.**

22 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-
23 tion 505(j)(5) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 355(j)(5)) is amended—

25 (1) in subparagraph (B)—

1 (A) in clause (iii)—

2 (i) by striking “(iii) If the applicant
3 made a certification described in subclause
4 (IV) of paragraph (2)(A)(vii),” and insert-
5 ing the following:

6 “(iii) SUBCLAUSE (IV) CERTIFICATION
7 WITH RESPECT TO CERTAIN PATENTS.—If
8 the applicant made a certification de-
9 scribed in paragraph (2)(A)(vii)(IV) with
10 respect to a patent (other than a patent
11 that claims a process for manufacturing
12 the listed drug) for which patent informa-
13 tion was filed with the Secretary under
14 subsection (c)(2)(A),”; and

15 (ii) by adding at the end the fol-
16 lowing: “The 30-month period provided
17 under the second sentence of this clause
18 shall not apply to a certification under
19 paragraph (2)(A)(vii)(IV) made with re-
20 spect to a patent for which patent informa-
21 tion was filed with the Secretary under
22 subsection (c)(2)(B).”;

23 (B) by redesignating clause (iv) as clause
24 (v); and

1 (C) by inserting after clause (iii) the fol-
2 lowing:

3 “(iv) SUBCLAUSE (IV) CERTIFICATION
4 WITH RESPECT TO OTHER PATENTS.—

5 “(I) IN GENERAL.—If the appli-
6 cant made a certification described in
7 paragraph (2)(A)(vii)(IV) with respect
8 to a patent not described in clause
9 (iii) for which patent information was
10 published by the Secretary under sub-
11 section (c)(2)(D), the approval shall
12 be made effective on the date that is
13 45 days after the date on which the
14 notice provided under paragraph
15 (2)(B) was received, unless a civil ac-
16 tion for infringement of the patent,
17 accompanied by a motion for prelimi-
18 nary injunction to enjoin the applicant
19 from engaging in the commercial
20 manufacture or sale of the drug, was
21 filed on or before the date that is 45
22 days after the date on which the no-
23 tice was received, in which case the
24 approval shall be made effective—

1 “(aa) on the date of a court
2 action declining to grant a pre-
3 liminary injunction; or

4 “(bb) if the court has grant-
5 ed a preliminary injunction pro-
6 hibiting the applicant from en-
7 gaging in the commercial manu-
8 facture or sale of the drug—

9 “(AA) on issuance by a
10 court of a determination
11 that the patent is invalid or
12 is not infringed;

13 “(BB) on issuance by a
14 court of an order revoking
15 the preliminary injunction or
16 permitting the applicant to
17 engage in the commercial
18 manufacture or sale of the
19 drug; or

20 “(CC) on the date spec-
21 ified in a court order under
22 section 271(e)(4)(A) of title
23 35, United States Code, if
24 the court determines that
25 the patent is infringed.

1 “(II) COOPERATION.—Each of
2 the parties shall reasonably cooperate
3 in expediting a civil action under sub-
4 clause (I).

5 “(III) EXPEDITED NOTIFICA-
6 TION.—If the notice under paragraph
7 (2)(B) contains an address for the re-
8 ceipt of expedited notification of a
9 civil action under subclause (I), the
10 plaintiff shall, on the date on which
11 the complaint is filed, simultaneously
12 cause a notification of the civil action
13 to be delivered to that address by the
14 next business day.”; and

15 (2) by inserting after subparagraph (B) the fol-
16 lowing:

17 “(C) FAILURE TO BRING INFRINGEMENT
18 ACTION.—If, in connection with an application
19 under this subsection, the applicant provides an
20 owner of a patent notice under paragraph
21 (2)(B) with respect to the patent, and the
22 owner of the patent fails to bring a civil action
23 against the applicant for infringement of the
24 patent on or before the date that is 45 days
25 after the date on which the notice is received,

1 the owner of the patent shall be barred from
2 bringing a civil action for infringement of the
3 patent in connection with the development,
4 manufacture, use, offer to sell, or sale of the
5 drug for which the application was filed or ap-
6 proved under this subsection.”.

7 (b) OTHER APPLICATIONS.—Section 505(e) of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e))
9 (as amended by section 9(a)(3)(A)(iii)) is amended—

10 (1) in paragraph (3)—

11 (A) in subparagraph (C)—

12 (i) by striking “(C) If the applicant
13 made a certification described in clause
14 (iv) of subsection (b)(2)(A),” and inserting
15 the following:

16 “(C) CLAUSE (iv) CERTIFICATION WITH
17 RESPECT TO CERTAIN PATENTS.—If the appli-
18 cant made a certification described in sub-
19 section (b)(2)(A)(iv) with respect to a patent
20 (other than a patent that claims a process for
21 manufacturing the listed drug) for which patent
22 information was filed with the Secretary under
23 paragraph (2)(A),”; and

24 (ii) by adding at the end the fol-
25 lowing: “The 30-month period provided

1 under the second sentence of this subpara-
2 graph shall not apply to a certification
3 under subsection (b)(2)(A)(iv) made with
4 respect to a patent for which patent infor-
5 mation was filed with the Secretary under
6 paragraph (2)(B).”; and

7 (B) by inserting after subparagraph (C)
8 the following:

9 “(D) CLAUSE (iv) CERTIFICATION WITH
10 RESPECT TO OTHER PATENTS.—

11 “(i) IN GENERAL.—If the applicant
12 made a certification described in sub-
13 section (b)(2)(A)(iv) with respect to a pat-
14 ent not described in subparagraph (C) for
15 which patent information was published by
16 the Secretary under paragraph (2)(D), the
17 approval shall be made effective on the
18 date that is 45 days after the date on
19 which the notice provided under subsection
20 (b)(3) was received, unless a civil action
21 for infringement of the patent, accom-
22 panied by a motion for preliminary injunc-
23 tion to enjoin the applicant from engaging
24 in the commercial manufacture or sale of
25 the drug, was filed on or before the date

1 that is 45 days after the date on which the
2 notice was received, in which case the ap-
3 proval shall be made effective—

4 “(I) on the date of a court action
5 declining to grant a preliminary in-
6 junction; or

7 “(II) if the court has granted a
8 preliminary injunction prohibiting the
9 applicant from engaging in the com-
10 mercial manufacture or sale of the
11 drug—

12 “(aa) on issuance by a court
13 of a determination that the pat-
14 ent is invalid or is not infringed;

15 “(bb) on issuance by a court
16 of an order revoking the prelimi-
17 nary injunction or permitting the
18 applicant to engage in the com-
19 mercial manufacture or sale of
20 the drug; or

21 “(cc) on the date specified
22 in a court order under section
23 271(e)(4)(A) of title 35, United
24 States Code, if the court deter-

1 mines that the patent is in-
2 fringed.

3 “(ii) COOPERATION.—Each of the
4 parties shall reasonably cooperate in expe-
5 diting a civil action under clause (i).

6 “(iii) EXPEDITED NOTIFICATION.—If
7 the notice under subsection (b)(3) contains
8 an address for the receipt of expedited no-
9 tification of a civil action under clause (i),
10 the plaintiff shall, on the date on which the
11 complaint is filed, simultaneously cause a
12 notification of the civil action to be deliv-
13 ered to that address by the next business
14 day.”; and

15 (2) by inserting after paragraph (3) the fol-
16 lowing:

17 “(4) FAILURE TO BRING INFRINGEMENT AC-
18 TION.—If, in connection with an application under
19 subsection (b)(2), the applicant provides an owner of
20 a patent notice under subsection (b)(3) with respect
21 to the patent, and the owner of the patent fails to
22 bring a civil action against the applicant for in-
23 fringement of the patent on or before the date that
24 is 45 days after the date on which the notice is re-
25 ceived, the owner of the patent shall be barred from

1 bringing a civil action for infringement of the patent
2 in connection with the development, manufacture,
3 use, offer to sell, or sale of the drug for which the
4 application was filed or approved under subsection
5 (b)(2).”.

6 (c) EFFECTIVE DATE.—

7 (1) IN GENERAL.—The amendments made by
8 subsections (a) and (b) shall be effective with re-
9 spect to any certification under subsection
10 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 355) made after the date of enactment of
13 this Act in an application filed under subsection
14 (b)(2) or (j) of that section.

15 (2) TRANSITION PROVISION.—In the case of ap-
16 plications under section 505(b) of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 355(b)) filed be-
18 fore the date of enactment of this Act—

19 (A) a patent (other than a patent that
20 claims a process for manufacturing a listed
21 drug) for which information was submitted to
22 the Secretary of Health and Human Services
23 under section 505(b)(1) of the Federal Food,
24 Drug, and Cosmetic Act (as in effect on the day
25 before the date of enactment of this Act) shall

1 be subject to subsections (c)(3)(C) and
2 (j)(5)(B)(iii) of section 505 of the Federal
3 Food, Drug, and Cosmetic Act (as amended by
4 this section); and

5 (B) any other patent (including a patent
6 for which information was submitted to the
7 Secretary under section 505(c)(2) of that Act
8 (as in effect on the day before the date of en-
9 actment of this Act)) shall be subject to sub-
10 sections (c)(3)(D) and (j)(5)(B)(iv) of section
11 505 of the Federal Food, Drug, and Cosmetic
12 Act (as amended by this section).

13 **SEC. 5. EXCLUSIVITY FOR ACCELERATED GENERIC DRUG**
14 **APPLICANTS.**

15 (a) IN GENERAL.—Section 505(j)(5) of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as
17 amended by section 4(a)) is amended—

18 (1) in subparagraph (B)(v), by striking sub-
19 clause (II) and inserting the following:

20 “(II) the earlier of—

21 “(aa) the date of a final de-
22 cision of a court (from which no
23 appeal has been or can be taken,
24 other than a petition to the Su-
25 preme Court for a writ of certio-

1 rari) holding that the patent that
2 is the subject of the certification
3 is invalid or not infringed; or

4 “(bb) the date of a settle-
5 ment order or consent decree
6 signed by a Federal judge that
7 enters a final judgment and in-
8 cludes a finding that the patent
9 that is the subject of the certifi-
10 cation is invalid or not in-
11 fringed;”; and

12 (2) by inserting after subparagraph (C) the fol-
13 lowing:

14 “(D) FORFEITURE OF 180-DAY PERIOD.—

15 “(i) DEFINITIONS.—In this subpara-
16 graph:

17 “(I) APPLICATION.—The term
18 ‘application’ means an application for
19 approval of a drug under this sub-
20 section containing a certification
21 under paragraph (2)(A)(vii)(IV) with
22 respect to a patent.

23 “(II) FIRST APPLICATION.—The
24 term ‘first application’ means the first

1 application to be filed for approval of
2 the drug.

3 “(III) FORFEITURE EVENT.—

4 The term ‘forfeiture event’, with re-
5 spect to an application under this sub-
6 section, means the occurrence of any
7 of the following:

8 “(aa) FAILURE TO MAR-
9 KET.—The applicant fails to
10 market the drug by the later of—

11 “(AA) the date that is
12 60 days after the date on
13 which the approval of the
14 application for the drug is
15 made effective under clause
16 (iii) or (iv) of subparagraph
17 (B) (unless the Secretary ex-
18 tends the date because of ex-
19 traordinary or unusual cir-
20 cumstances); or

21 “(BB) if 1 or more civil
22 actions have been brought
23 against the applicant for in-
24 fringement of a patent sub-
25 ject to a certification under

1 paragraph (2)(A)(vii)(IV) or
2 1 or more civil actions have
3 been brought by the appli-
4 cant for a declaratory judg-
5 ment that such a patent is
6 invalid or not infringed, the
7 date that is 60 days after
8 the date of a final decision
9 (from which no appeal has
10 been or can be taken, other
11 than a petition to the Su-
12 preme Court for a writ of
13 certiorari) in the last of
14 those civil actions to be de-
15 cided (unless the Secretary
16 extends the date because of
17 extraordinary or unusual
18 circumstances).

19 “(bb) WITHDRAWAL OF AP-
20 PPLICATION.—The applicant with-
21 draws the application.

22 “(cc) AMENDMENT OF CER-
23 TIFICATION.—The applicant, vol-
24 untarily or as a result of a settle-
25 ment or defeat in patent litiga-

1 tion, amends the certification
2 from a certification under para-
3 graph (2)(A)(vii)(IV) to a certifi-
4 cation under paragraph
5 (2)(A)(vii)(III).

6 “(dd) FAILURE TO OBTAIN
7 APPROVAL.—The applicant fails
8 to obtain tentative approval of an
9 application within 30 months
10 after the date on which the appli-
11 cation is filed, unless the failure
12 is caused by—

13 “(AA) a change in the
14 requirements for approval of
15 the application imposed
16 after the date on which the
17 application is filed; or

18 “(BB) other extraor-
19 dinary circumstances war-
20 ranting an exception, as de-
21 termined by the Secretary.

22 “(ee) FAILURE TO CHAL-
23 LENGE PATENT.—In a case in
24 which, after the date on which
25 the applicant submitted the ap-

1 plication, new patent information
2 is submitted under subsection
3 (c)(2) for the listed drug for a
4 patent for which certification is
5 required under paragraph (2)(A),
6 the applicant fails to submit, not
7 later than the date that is 60
8 days after the date on which the
9 Secretary publishes the new pat-
10 ent information under paragraph
11 (7)(A)(iii) (unless the Secretary
12 extends the date because of ex-
13 traordinary or unusual cir-
14 cumstances)—

15 “(AA) a certification
16 described in paragraph
17 (2)(A)(vii)(IV) with respect
18 to the patent to which the
19 new patent information re-
20 lates; or

21 “(BB) a statement that
22 any method of use claim of
23 that patent does not claim a
24 use for which the applicant
25 is seeking approval under

1 this subsection in accord-
2 ance with paragraph
3 (2)(A)(viii).

4 “(ff) UNLAWFUL CON-
5 DUCT.—The Federal Trade Com-
6 mission determines that the ap-
7 plicant engaged in unlawful con-
8 duct with respect to the applica-
9 tion in violation of section 1 of
10 the Sherman Act (15 U.S.C. 1).

11 “(IV) SUBSEQUENT APPLICA-
12 TION.—The term ‘subsequent applica-
13 tion’ means an application for ap-
14 proval of a drug that is filed subse-
15 quent to the filing of a first applica-
16 tion for approval of that drug.

17 “(ii) FORFEITURE OF 180-DAY PE-
18 RIOD.—

19 “(I) IN GENERAL.—Except as
20 provided in subclause (II), if a for-
21 feiture event occurs with respect to a
22 first application—

23 “(aa) the 180-day period
24 under subparagraph (B)(v) shall

1 be forfeited by the first applicant;
2 and

3 “(bb) any subsequent appli-
4 cation shall become effective as
5 provided under clause (i), (ii),
6 (iii), or (iv) of subparagraph (B),
7 and clause (v) of subparagraph
8 (B) shall not apply to the subse-
9 quent application.

10 “(II) FORFEITURE TO FIRST
11 SUBSEQUENT APPLICANT.—If the sub-
12 sequent application that is the first to
13 be made effective under subclause (I)
14 was the first among a number of sub-
15 sequent applications to be filed—

16 “(aa) that first subsequent
17 application shall be treated as
18 the first application under this
19 subparagraph (including sub-
20 clause (I)) and as the previous
21 application under subparagraph
22 (B)(v); and

23 “(bb) any other subsequent
24 applications shall become effec-
25 tive as provided under clause (i),

1 (ii), (iii), or (iv) of subparagraph
2 (B), but clause (v) of subpara-
3 graph (B) shall apply to any such
4 subsequent application.

5 “(iii) AVAILABILITY.—The 180-day
6 period under subparagraph (B)(v) shall be
7 available to a first applicant submitting an
8 application for a drug with respect to any
9 patent without regard to whether an appli-
10 cation has been submitted for the drug
11 under this subsection containing such a
12 certification with respect to a different pat-
13 ent.

14 “(iv) APPLICABILITY.—The 180-day
15 period described in subparagraph (B)(v)
16 shall apply to an application only if a civil
17 action is brought against the applicant for
18 infringement of a patent that is the subject
19 of the certification.”.

20 (b) APPLICABILITY.—The amendment made by sub-
21 section (a) shall be effective only with respect to an appli-
22 cation filed under section 505(j) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date
24 of enactment of this Act for a listed drug for which no
25 certification under section 505(j)(2)(A)(vii)(IV) of that

1 Act was made before the date of enactment of this Act,
2 except that if a forfeiture event described in section
3 505(j)(5)(D)(i)(III)(ff) of that Act occurs in the case of
4 an applicant, the applicant shall forfeit the 180-day period
5 under section 505(j)(5)(B)(v) of that Act without regard
6 to when the applicant made a certification under section
7 505(j)(2)(A)(vii)(IV) of that Act.

8 **SEC. 6. FAIR TREATMENT FOR INNOVATORS.**

9 (a) BASIS FOR APPLICATION.—Section 505 of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)
11 is amended—

12 (1) in subsection (b)(3)(B), by striking the sec-
13 ond sentence and inserting “The notice shall include
14 a detailed statement of the factual and legal basis of
15 the applicant’s opinion that, as of the date of the no-
16 tice, the patent is not valid or is not infringed, and
17 shall include, as appropriate for the relevant patent,
18 a description of the applicant’s proposed drug sub-
19 stance, drug formulation, drug composition, or meth-
20 od of use. All information disclosed under this sub-
21 paragraph shall be treated as confidential and may
22 be used only for purposes relating to patent adju-
23 dication. Nothing in this subparagraph precludes the
24 applicant from amending the factual or legal basis

1 on which the applicant relies in patent litigation.”;
2 and

3 (2) in subsection (j)(2)(B)(ii), by striking the
4 second sentence and inserting “The notice shall in-
5 clude a detailed statement of the factual and legal
6 basis of the opinion of the applicant that, as of the
7 date of the notice, the patent is not valid or is not
8 infringed, and shall include, as appropriate for the
9 relevant patent, a description of the applicant’s pro-
10 posed drug substance, drug formulation, drug com-
11 position, or method of use. All information disclosed
12 under this subparagraph shall be treated as con-
13 fidential and may be used only for purposes relating
14 to patent adjudication. Nothing in this subparagraph
15 precludes the applicant from amending the factual
16 or legal basis on which the applicant relies in patent
17 litigation.”.

18 (b) INJUNCTIVE RELIEF.—Section 505(j)(5)(B) of
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 355(j)(5)(B)) (as amended by section 4(a)(1)) is amend-
21 ed—

22 (1) in clause (iii), by adding at the end the fol-
23 lowing: “A court shall not regard the extent of the
24 ability of an applicant to pay monetary damages as
25 a whole or partial basis on which to deny a prelimi-

1 nary or permanent injunction under this clause.”;
2 and

3 (2) in clause (iv), by adding at the end the fol-
4 lowing:

5 “(IV) INJUNCTIVE RELIEF.—A court shall
6 not regard the extent of the ability of an appli-
7 cant to pay monetary damages as a whole or
8 partial basis on which to deny a preliminary or
9 permanent injunction under this clause.”.

10 **SEC. 7. BIOEQUIVALENCE.**

11 (a) IN GENERAL.—The amendments to part 320 of
12 title 21, Code of Federal Regulations, promulgated by the
13 Commissioner of Food and Drugs on July 17, 1991 (57
14 Fed. Reg. 17997 (April 28, 1992)), shall continue in effect
15 as an exercise of authorities under sections 501, 502, 505,
16 and 701 of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 351, 352, 355, 371).

18 (b) EFFECT.—Subsection (a) does not affect the au-
19 thority of the Commissioner of Food and Drugs to amend
20 part 320 of title 21, Code of Federal Regulations.

21 (c) EFFECT OF SECTION.—This section shall not be
22 construed to alter the authority of the Secretary of Health
23 and Human Services to regulate biological products under
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
25 et seq.). Any such authority shall be exercised under that

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

3 **SEC. 8. REPORT.**

4 (a) IN GENERAL.—Not later than the date that is
5 5 years after the date of enactment of this Act, the Fed-
6 eral Trade Commission shall submit to Congress a report
7 describing the extent to which implementation of the
8 amendments made by this Act—

9 (1) has enabled products to come to market in
10 a fair and expeditious manner, consistent with the
11 rights of patent owners under intellectual property
12 law; and

13 (2) has promoted lower prices of drugs and
14 greater access to drugs through price competition.

15 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
16 authorized to be appropriated to carry out this section
17 \$5,000,000.

18 **SEC. 9. CONFORMING AND TECHNICAL AMENDMENTS.**

19 (a) SECTION 505.—Section 505 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

21 (1) in subsection (a), by striking “(a) No per-
22 son” and inserting “(a) IN GENERAL.—No person”;

23 (2) in subsection (b)—

24 (A) by striking “(b)(1) Any person” and
25 inserting the following:

1 “(b) APPLICATIONS.—

2 “(1) REQUIREMENTS.—

3 “(A) IN GENERAL.—Any person”;

4 (B) in paragraph (1)—

5 (i) in the second sentence—

6 (I) by redesignating subpara-
7 graphs (A) through (F) as clauses (i)
8 through (vi), respectively, and adjust-
9 ing the margins appropriately;

10 (II) by striking “Such persons”
11 and inserting the following:

12 “(B) INFORMATION TO BE SUBMITTED
13 WITH APPLICATION.—A person that submits an
14 application under subparagraph (A)”;

15 (III) by striking “application”
16 and inserting “application—”;

17 (ii) by striking the third through fifth
18 sentences; and

19 (iii) in the sixth sentence—

20 (I) by striking “The Secretary”
21 and inserting the following:

22 “(C) GUIDANCE.—The Secretary”; and

23 (II) by striking “clause (A)” and
24 inserting “subparagraph (B)(i)”; and

25 (C) in paragraph (2)—

- 1 (i) by striking “clause (A) of such
2 paragraph” and inserting “paragraph
3 (1)(B)(i)”;
- 4 (ii) in subparagraphs (A) and (B), by
5 striking “paragraph (1) or”; and
- 6 (iii) in subparagraph (B)—
- 7 (I) by striking “paragraph
8 (1)(A)” and inserting “paragraph
9 (1)(B)(i)”;
- 10 (II) by striking “patent” each
11 place it appears and inserting
12 “claim”; and
- 13 (3) in subsection (c)—
- 14 (A) in paragraph (3)—
- 15 (i) in subparagraph (A)—
- 16 (I) by striking “(A) If the appli-
17 cant” and inserting the following:
18 “(A) CLAUSE (i) OR (ii) CERTIFICATION.—
19 If the applicant”; and
- 20 (II) by striking “may” and in-
21 serting “shall”;
- 22 (ii) in subparagraph (B)—
- 23 (I) by striking “(B) If the appli-
24 cant” and inserting the following:

- 1 “(B) CLAUSE (iii) CERTIFICATION.—If the
2 applicant”; and
- 3 (II) by striking “may” and in-
4 sserting “shall”;
- 5 (iii) by redesignating subparagraph
6 (D) as subparagraph (E); and
- 7 (iv) in subparagraph (E) (as redesignig-
8 nated by clause (iii)), by striking “clause
9 (A) of subsection (b)(1)” each place it ap-
10 pears and inserting “subsection
11 (b)(1)(B)(i)”; and
- 12 (B) by redesignating paragraph (4) as
13 paragraph (5); and
- 14 (4) in subsection (j)—
- 15 (A) in paragraph (2)(A)—
- 16 (i) in clause (vi), by striking “clauses
17 (B) through ((F)” and inserting “sub-
18 clauses (ii) through (vi) of subsection
19 (b)(1)”; and
- 20 (ii) in clause (vii), by striking “(b)
21 or”; and
- 22 (iii) in clause (viii)—
- 23 (I) by striking “(b) or”; and

- 1 (II) by striking “patent” each
2 place it appears and inserting
3 “claim”; and
- 4 (B) in paragraph (5)—
- 5 (i) in subparagraph (B)—
- 6 (I) in clause (i)—
- 7 (aa) by striking “(i) If the
8 applicant” and inserting the fol-
9 lowing:
- 10 “(i) SUBCLAUSE (I) OR (II) CERTIFI-
11 CATION.—If the applicant”; and
- 12 (bb) by striking “may” and
13 inserting “shall”;
- 14 (II) in clause (ii)—
- 15 (aa) by striking “(ii) If the
16 applicant” and inserting the fol-
17 lowing:
- 18 “(i) SUBCLAUSE (III) CERTIFI-
19 CATION.—If the applicant”; and
- 20 (bb) by striking “may” and
21 inserting “shall”;
- 22 (III) in clause (iii), by striking
23 “(2)(B)(i)” each place it appears and
24 inserting “(2)(B)”; and

1 (IV) in clause (v) (as redesignated by section 4(a)(1)(B)), by striking “continuing” and inserting “containing”; and

2
3
4
5 (ii) by redesignating subparagraphs
6 (C) and (D) as subparagraphs (E) and
7 (F), respectively.

8 (b) SECTION 505A.—Section 505A of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is
10 amended—

11 (1) in subsections (b)(1)(A)(i) and
12 (c)(1)(A)(i)—

13 (A) by striking “(c)(3)(D)(ii)” each place
14 it appears and inserting “(c)(3)(E)(ii)”; and

15 (B) by striking “(j)(5)(D)(ii)” each place
16 it appears and inserting “(j)(5)(F)(ii)”; and

17 (2) in subsections (b)(1)(A)(ii) and
18 (c)(1)(A)(ii)—

19 (A) by striking “(c)(3)(D)” each place it
20 appears and inserting “(c)(3)(E)”; and

21 (B) by striking “(j)(5)(D)” each place it
22 appears and inserting “(j)(5)(F)”; and

23 (3) in subsections (e) and (l)—

24 (A) by striking “505(c)(3)(D)” each place
25 it appears and inserting “505(c)(3)(E)”; and

1 (B) by striking “505(j)(5)(D)” each place
2 it appears and inserting “505(j)(5)(F)”; and
3 (4) in subsection (k), by striking
4 “505(j)(5)(B)(iv)” and inserting “505(j)(5)(B)(v)”.

5 (c) SECTION 527.—Section 527(a) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) is
7 amended in the second sentence by striking “505(c)(2)”
8 and inserting “505(c)(1)(B)”.

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