

107TH CONGRESS
2D SESSION

H. R. 5350

To provide greater access to affordable pharmaceuticals, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 9, 2002

Mr. KENNEDY of Rhode Island introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To provide greater access to affordable pharmaceuticals, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Prescription Afford-
5 ability and Medicine Safety Act of 2002”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) Although prescription drugs represent one
9 of the increasingly used medical care interventions in

1 treating common acute and chronic diseases, many
2 Americans, especially the elderly and other vulner-
3 able populations, are often unable to afford their
4 medication because of excessive and persistent drug
5 price inflation.

6 (2) In 1999, the top 5 pharmaceutical compa-
7 nies allocated a higher proportion of their revenue to
8 their income than to research and development.

9 (3) In 2000, over $\frac{1}{3}$ of the most frequently pre-
10 scribed drugs for seniors rose in price at a rate that
11 was 3 times the rate of inflation.

12 (4) Prescription drug manufacturers continue
13 to make enormous profits on the backs of Ameri-
14 cans.

15 (5) Because of the limited availability of private
16 or public prescription drug coverage for the elderly,
17 prescription drugs represent the highest out-of-pock-
18 et medical care cost for 3 of 4 elderly patients, sur-
19 passed only by the cost of long-term care services.

20 (6) Ninety percent of Americans who are 60
21 years of age or older take 1 or more medications
22 daily.

23 (7) According to a recent study, around 60 per-
24 cent of doctors say that patients somewhat often
25 talk with them about specific disease or treatment

1 they heard about from prescription drug advertise-
2 ments.

3 (8) The National Institutes of Health, the Gov-
4 ernment's most important health research arm, has
5 helped develop almost all of the 50 top-selling drugs
6 from 1992 through 1997 for a cost of over
7 \$175,000,000.

8 (9) The pharmaceutical industry makes large
9 profits off the sale of drugs produced from the ben-
10 efit of research paid for by the United States and,
11 aside from royalties, none of such profits are reim-
12 bursed to United States taxpayers.

13 (10) Only 24 percent of people over age 45 al-
14 ways ask their pharmacist about drug side effects.

15 (11) Only 31 percent of people over age 45 al-
16 ways ask their pharmacists about cost-saving generic
17 equivalents for new prescriptions.

18 **SEC. 3. GENERIC DRUG APPLICATION REVIEW.**

19 For the purpose of enabling the Food and Drug Ad-
20 ministration to employ additional staff for the Office of
21 Generic Drugs to review abbreviated applications for the
22 approval of new drugs under section 505(j) of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), and
24 for the purpose of otherwise providing for accelerated re-
25 views of such applications, there is authorized to be appro-

1 priated \$5,000,000 for each fiscal year, in addition to
 2 other authorizations of appropriations that are available
 3 for such purposes.

4 **SEC. 4. GENERIC DRUG EDUCATION.**

5 For the purpose of enabling the Food and Drug Ad-
 6 ministration, through the Office of Generic Drugs, to con-
 7 tinue the education program started in fiscal year 2001
 8 on the use and therapeutic equivalency of drugs approved
 9 under section 505(j) of the Federal Food, Drug, and Cos-
 10 metic Act (21 U.S.C. 355(j)), there is authorized to be
 11 appropriated \$1,000,000 for each fiscal year, in addition
 12 to other authorizations of appropriations that are available
 13 for such purpose.

14 **SEC. 5. PRESCRIPTION DRUG ASSISTANCE PROGRAM;**
 15 **PROFITS FROM RESEARCH.**

16 The Public Health Service Act (42 U.S.C. 201 et
 17 seq.) is amended by adding at the end the following:

18 **“TITLE XXVIII—PHARMACY**
 19 **ASSISTANCE**

20 **“SEC. 2801. GRANTS.**

21 “(a) AUTHORIZATION.—From amounts available
 22 from the revolving fund established under section 2803,
 23 the Secretary may make grants to States for the purpose
 24 of providing pharmacy assistance as described in sub-
 25 section (b).

1 “(b) USE OF FUNDS.—A grant may be made under
2 subsection (a) only if the State involved agrees that funds
3 received under the grant will be used—

4 “(1) to provide outreach services and education
5 regarding an existing State pharmacy benefit assist-
6 ance program ; or

7 “(2) to establish or expand such a program.

8 “(c) APPLICATION.—To seek a grant under this sec-
9 tion, a State shall submit an application to the Secretary
10 at such time, in such manner, and accompanied by such
11 information as the Secretary may reasonably require.

12 “(d) STATE DEFINED.—For purposes of this section,
13 the term ‘State’ means any of the several States, the Dis-
14 trict of Columbia, the Commonwealth of Puerto Rico, the
15 Commonwealth of the Northern Mariana Islands, Amer-
16 ican Samoa, Guam, the Virgin Islands, or any other terri-
17 tory or possession of the United States.

18 **“SEC. 2802. PROFITS FROM RESEARCH.**

19 “(a) IN GENERAL.—Subject to subsection (b), the
20 Secretary shall not approve any covered application for the
21 approval of a biological product under section 351 of this
22 Act or of a drug under section 505 of the Federal Food,
23 Drug, and Cosmetic Act unless the manufacturer submit-
24 ting the application enters into an agreement with the Sec-
25 retary that—

1 “(1) requires the manufacturer to pay the Sec-
2 retary 7 percent of the gross amount received by the
3 manufacturer from sales of such biological product
4 or drug; and

5 “(2) specifies the manner in which such gross
6 amount will be determined.

7 “(b) EXCEPTION.—The Secretary may waive the ap-
8 plication of subsection (a) to a manufacturer of a biologi-
9 cal product or drug when the Secretary determines that
10 it would be in the public interest to exempt such manufac-
11 turer.

12 “(c) COVERED APPLICATION.—For purposes of this
13 section, the term ‘covered application’ means an applica-
14 tion that includes the results of research carried out—

15 “(1) by an entity of the National Institutes of
16 Health; or

17 “(2) under an agreement under section 12 of
18 the Stevenson-Wydler Technology Innovation Act of
19 1980.

20 **“SEC. 2803. REVOLVING FUND.**

21 “(a) ESTABLISHMENT.—There is hereby established
22 in the Treasury a revolving fund which shall consist of
23 the amounts deposited by the Secretary under subsection
24 (b).

1 “(b) DEPOSIT OF FUNDS.—The Secretary shall de-
 2 posit in the fund established under this section all pay-
 3 ments made to the Secretary under an agreement pursu-
 4 ant to section 2802(a)(1).

5 “(c) USE OF AMOUNTS IN FUND.—To the extent or
 6 in the amounts made available in advance in appropria-
 7 tions Acts, amounts in the fund established under this sec-
 8 tion shall be available to the Secretary to make grants
 9 under section 2801.”.

10 **SEC. 6. LIMITATION ON DEDUCTIONS FOR ADVERTISING BY**
 11 **PRESCRIPTION DRUG MANUFACTURERS.**

12 (a) IN GENERAL.—Part IX of subchapter B of chap-
 13 ter 1 of subtitle A of the Internal Revenue Code of 1986
 14 (relating to items not deductible) is amended by adding
 15 at the end the following:

16 **“SEC. 280I. LIMITATION ON DEDUCTIONS FOR ADVER-**
 17 **TISING BY PRESCRIPTION DRUG MANUFAC-**
 18 **TURERS.**

19 “(a) IN GENERAL.—No deduction shall be allowed
 20 under this chapter for any taxable year for any expendi-
 21 ture relating to the advertising, promoting, or marketing
 22 (in any medium) of any prescription drug manufactured
 23 by the taxpayer to the extent the aggregate amount of
 24 such expenditures exceeds 50 percent of the taxpayer’s ag-

1 gregate research and development expenditures for such
2 taxable year.

3 “(b) DEFINITIONS AND SPECIAL RULES.—For pur-
4 poses of this section—

5 “(1) PRESCRIPTION DRUGS.—The term ‘pre-
6 scription drug’ means any drug subject to subsection
7 (b)(1) of the Federal Food, Drug, and Cosmetic Act.

8 “(2) RESEARCH AND DEVELOPMENT EXPENDI-
9 TURES.—The term ‘research and development ex-
10 penditures’ means any expenditures that may be
11 treated as expenses under section 174.

12 “(3) AGGREGATION RULES.—All members of
13 the same controlled group of corporations (within
14 the meaning of section 52(a)) and all persons under
15 common control (within the meaning of section
16 52(b)) shall be treated as 1 person.”.

17 (b) CLERICAL AMENDMENT.—The table of sections
18 for such part IX is amended by adding after the item re-
19 lating to section 280H the following:

“Sec. 280I. Limitation on deductions for advertising by pre-
scription drug manufacturers.”.

20 (c) EFFECTIVE DATE.—The amendments made by
21 this section shall apply to taxable years beginning after
22 December 31, 2001.

23 (d) TRANSFER TO THE FEDERAL HOSPITAL INSUR-
24 ANCE TRUST FUND OF RESULTING BUDGETARY SAV-

INGS.—There are authorized to be appropriated to the Federal Hospital Insurance Trust Fund established under section 1817 of the Social Security Act amounts equal to the increase in Federal revenues resulting from the amendment made by subsection (a). Such appropriated amounts may be transferred from the general fund of the Treasury on the basis of estimates of such revenues made by the Secretary of the Treasury.

SEC. 7. LIMITATION OF 30-MONTH STAY TO CERTAIN PATENTS.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—

(1) IN GENERAL.—Clause (iii) of section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)) is amended to read as follows:

“(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii):

“(I) If such certification concerns a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was submitted under subsection (b), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of 45 days from

1 the date the notice provided under paragraph
2 (2)(B)(i) is received. If such an action is
3 brought before the expiration of such days, the
4 approval shall be made effective upon the expi-
5 ration of the 30-month period beginning on the
6 date of the receipt of the notice provided under
7 paragraph (2)(B)(i) or such shorter or longer
8 period as the court may order because either
9 party to the action failed to reasonably cooper-
10 ate in expediting the action, except that—

11 “(aa) if before the expiration of such
12 period the court decides that such patent is
13 invalid or not infringed, the approval shall
14 be made effective on the date of the court
15 decision;

16 “(bb) if before the expiration of such
17 period the court decides that such patent
18 has been infringed, the approval shall be
19 made effective on such date as the court
20 orders under section 271(e)(4)(A) of title
21 35, United States Code; or

22 “(cc) if before the expiration of such
23 period the court grants a preliminary in-
24 junction prohibiting the applicant from en-
25 gaging in the commercial manufacture or

1 sale of the drug until the court decides the
2 issues of patent validity and infringement
3 and if the court decides that such patent
4 is invalid or not infringed, the approval
5 shall be made effective on the date of such
6 court decision.

7 “In such an action, each of the parties shall
8 reasonably cooperate in expediting the action.
9 Until the expiration of 45 days from the date
10 the notice made under paragraph (2)(B)(i) is
11 received, no action may be brought under sec-
12 tion 2201 of title 28, United States Code, for
13 a declaratory judgment with respect to the pat-
14 ent. Any action brought under such section
15 2201 shall be brought in the judicial district
16 where the defendant has its principal place of
17 business or a regular and established place of
18 business. The 30-month period provided under
19 the second sentence of this clause shall not
20 apply to a certification under paragraph
21 (2)(A)(vii)(IV) made with respect to a patent
22 for which patent information was submitted
23 under subsection (c)(2).

24 “(II) If the certification referred to at the
25 beginning of this clause concerns a patent

1 (other than a patent that claims a process for
2 manufacturing the listed drug) for which patent
3 information was submitted under subsection
4 (c)(2), the approval shall be made effective on
5 the date that is 45 days after the date on which
6 the notice provided under paragraph (2)(B) is
7 received, unless a civil action for infringement
8 of the patent, accompanied by a motion for pre-
9 liminary injunction to enjoin the applicant from
10 engaging in the commercial manufacture or sale
11 of the drug, is filed on or before such date, in
12 which case the approval shall be made
13 effective—

14 “(aa) on the date of a court action de-
15 clining to grant a preliminary injunction;
16 or

17 “(bb) if the court has granted a pre-
18 liminary injunction prohibiting the appli-
19 cant from engaging in the commercial
20 manufacture or sale of the drug—

21 “(AA) on issuance by a court of
22 a determination that the patent is in-
23 valid or is not infringed;

24 “(BB) on issuance by a court of
25 an order revoking the preliminary in-

1 junction or permitting the applicant to
2 engage in the commercial manufac-
3 ture or sale of the drug; or

4 “(CC) on the date specified in a
5 court order under section
6 271(e)(4)(A) of title 35, United
7 States Code, if the court determines
8 that the patent is infringed.

9 “Each of the parties shall reasonably cooperate
10 in expediting a civil action under this subclause.
11 If the notice under paragraph (2)(B) contains
12 an address for the receipt of expedited notifica-
13 tion of a civil action under this subclause, the
14 plaintiff shall, on the date on which the com-
15 plaint is filed, simultaneously cause a notifica-
16 tion of the civil action to be delivered to that
17 address by the next business day.”.

18 (2) FAILURE TO BRING INFRINGEMENT AC-
19 TION.—Paragraph (5) of section 505(j) of the Fed-
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.
21 355(j)) is amended by adding at the end the fol-
22 lowing:

23 “(E) If, in connection with an application under this
24 subsection, the applicant provides an owner of a patent
25 notice under paragraph (2)(B) with respect to the patent,

1 and the owner of the patent fails to bring a civil action
2 against the applicant for infringement of the patent on
3 or before the date that is 45 days after the date on which
4 the notice is received, the owner of the patent shall be
5 barred from bringing a civil action for infringement of the
6 patent in connection with the development, manufacture,
7 use, offer to sell, or sale of the drug for which the applica-
8 tion was filed or approved under this subsection.”.

9 (b) OTHER APPLICATIONS.—

10 (1) IN GENERAL.—Subparagraph (C) of section
11 505(c)(3) of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 355(c)(3)) is amended to read as fol-
13 lows:

14 “(C) If the applicant made a certification de-
15 scribed in subsection (b)(2)(A)(iv):

16 “(i) If such certification concerns a patent
17 (other than a patent that claims a process for
18 manufacturing the listed drug) for which patent
19 information was submitted under subsection
20 (b), the approval shall be made effective imme-
21 diately unless an action is brought for infringe-
22 ment of a patent which is the subject of the cer-
23 tification before the expiration of 45 days from
24 the date the notice provided under subsection
25 (b)(3)(A) is received. If such an action is

1 brought before the expiration of such days, the
2 approval may be made effective upon the expi-
3 ration of the 30-month period beginning on the
4 date of the receipt of the notice provided under
5 subsection (b)(3)(A) or such shorter or longer
6 period as the court may order because either
7 party to the action failed to reasonably cooper-
8 ate in expediting the action, except that—

9 “(I) if before the expiration of such
10 period the court decides that such patent is
11 invalid or not infringed, the approval shall
12 be made effective on the date of the court
13 decision;

14 “(II) if, before the expiration of such
15 period, the court decides that such patent
16 has been infringed, the approval shall be
17 made effective on such date as the court
18 orders under section 271(e)(4)(A) of title
19 35, United States Code; or

20 “(III) if before the expiration of such
21 period the court grants a preliminary in-
22 junction prohibiting the applicant from en-
23 gaging in the commercial manufacture or
24 sale of the drug until the court decides the
25 issues of patent validity and infringement

1 and if the court decides that such patent
2 is invalid or not infringed, the approval
3 shall be made effective on the date of such
4 court decision.

5 “In such an action, each of the parties shall
6 reasonably cooperate in expediting the action.
7 Until the expiration of 45 days from the date
8 the notice made under subsection (b)(3)(A) is
9 received, no action may be brought under sec-
10 tion 2201 of title 28, United States Code, for
11 a declaratory judgment with respect to the pat-
12 ent. Any action brought under such section
13 2201 shall be brought in the judicial district
14 where the defendant has its principal place of
15 business or a regular and established place of
16 business. The 30-month period provided under
17 the second sentence of this subparagraph shall
18 not apply to a certification under subsection
19 (b)(2)(A)(iv) made with respect to a patent for
20 which patent information was submitted under
21 subsection (c)(2).

22 “(ii) If the certification referred to at the
23 beginning of this subparagraph concerns a pat-
24 ent (other than a patent that claims a process
25 for manufacturing the listed drug) for which

1 patent information was submitted under sub-
2 section (c)(2), the approval shall be made effec-
3 tive on the date that is 45 days after the date
4 on which the notice provided under subsection
5 (b)(3) is received, unless a civil action for in-
6 fringement of the patent, accompanied by a mo-
7 tion for preliminary injunction to enjoin the ap-
8 plicant from engaging in the commercial manu-
9 facture or sale of the drug, is filed on or before
10 such date, in which case the approval shall be
11 made effective—

12 “(I) on the date of a court action de-
13 clining to grant a preliminary injunction;
14 or

15 “(II) if the court has granted a pre-
16 liminary injunction prohibiting the appli-
17 cant from engaging in the commercial
18 manufacture or sale of the drug—

19 “(aa) on issuance by a court of a
20 determination that the patent is in-
21 valid or is not infringed;

22 “(bb) on issuance by a court of
23 an order revoking the preliminary in-
24 junction or permitting the applicant to

1 engage in the commercial manufac-
2 ture or sale of the drug; or

3 “(cc) on the date specified in a
4 court order under section
5 271(e)(4)(A) of title 35, United
6 States Code, if the court determines
7 that the patent is infringed.

8 “Each of the parties shall reasonably cooperate
9 in expediting a civil action under this clause. If
10 the notice under subsection (b)(3) contains an
11 address for the receipt of expedited notification
12 of a civil action under this clause, the plaintiff
13 shall, on the date on which the complaint is
14 filed, simultaneously cause a notification of the
15 civil action to be delivered to that address by
16 the next business day.”.

17 (2) FAILURE TO BRING INFRINGEMENT AC-
18 TION.—Subsection (c) of section 505 of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C.
20 355(c)(3)) is amended by adding at the end the fol-
21 lowing:

22 “(5) If, in connection with an application under sub-
23 section (b)(2), the applicant provides an owner of a patent
24 notice under subsection (b)(3) with respect to the patent,
25 and the owner of the patent fails to bring a civil action

1 against the applicant for infringement of the patent on
2 or before the date that is 45 days after the date on which
3 the notice is received, the owner of the patent shall be
4 barred from bringing a civil action for infringement of the
5 patent in connection with the development, manufacture,
6 use, offer to sell, or sale of the drug for which the applica-
7 tion was filed or approved under subsection (b)(2).”.

8 (c) EFFECTIVE DATE.—The amendments made by
9 subsections (a) and (b) shall be effective with respect to
10 any certification under subsection (b)(2)(A)(iv) or
11 (j)(2)(A)(vii)(IV) of section 505 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 355) made after the
13 date of enactment of this Act in an application filed under
14 subsection (b)(2) or (j) of that section, including with re-
15 spect to patent information that was submitted to the Sec-
16 retary before such date under subsection (c)(2) of such
17 Act.

18 **SEC. 8. EXCLUSIVITY FOR ACCELERATED GENERIC DRUG**
19 **APPLICANTS.**

20 (a) IN GENERAL.—Section 505(j)(5) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is
22 amended—

23 (1) in subparagraph (B)(iv)—

1 (A) in the text preceding subclause (I), by
2 inserting “the earlier of—” after “not earlier
3 than one hundred and eighty days after”;

4 (B) by striking “or” at the end of sub-
5 clause (I);

6 (C) by striking subclause (II) and all that
7 follows through the end; and

8 (D) by adding after subclause (I) the fol-
9 lowing:

10 “(II) the date of a final decision of a court
11 (from which no appeal has been or can be
12 taken, other than a petition to the Supreme
13 Court for a writ of certiorari) holding that the
14 patent that is the subject of the certification is
15 invalid or not infringed, or

16 “(III) the date of a settlement order or
17 consent decree signed by a Federal judge that
18 enters a final judgment and includes a finding
19 that the patent that is the subject of the certifi-
20 cation is invalid or not infringed.”; and

21 (2) by inserting after subparagraph (D) the fol-
22 lowing:

23 “(E) FORFEITURE OF 180-DAY PERIOD.—

1 “(i) IN GENERAL.—Except as provided in
2 clause (ii), if a forfeiture event occurs with respect
3 to a first application—

4 “(I) the 180-day period under subpara-
5 graph (B)(iv) shall be forfeited by the first ap-
6 plicant; and

7 “(II) any subsequent application shall be-
8 come effective as provided under clause (i), (ii),
9 or (iii) of subparagraph (B), and clause (iv) of
10 subparagraph (B) shall not apply to the subse-
11 quent application.

12 “(ii) FORFEITURE TO FIRST SUBSEQUENT AP-
13 PLICANT.—If the subsequent application that is the
14 first to be made effective under clause (i) was the
15 first among a number of subsequent applications to
16 be filed—

17 “(I) that first subsequent application shall
18 be treated as the first application under this
19 subparagraph (including clause (i)) and as the
20 previous application under subparagraph
21 (B)(iv); and

22 “(II) any other subsequent applications
23 shall become effective as provided under clause
24 (i), (ii), or (iii) of subparagraph (B), but clause

1 (iv) of subparagraph (B) shall apply to any
2 such subsequent application.

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

10 “(iv) APPLICABILITY.—The 180-day period de-
11 scribed in subparagraph (B)(iv) shall apply to an ap-
12 plication only if a civil action is brought against the
13 applicant for infringement of a patent that is the
14 subject of the certification.

15 “(v) DEFINITIONS.—In this subparagraph:

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

21 “(II) FIRST APPLICATION.—The term
22 ‘first application’ means the first application to
23 be filed for approval of the drug.

24 “(III) FORFEITURE EVENT.—The term
25 ‘forfeiture event’, with respect to an application

1 under this subsection, means the occurrence of
2 any of the following:

3 “(aa) FAILURE TO MARKET.—The ap-
4 plicant fails to market the drug by the
5 later of—

6 “(AA) the date that is 60 days
7 after the date on which the approval
8 of the application for the drug is
9 made effective under clause (iii) of
10 subparagraph (B) (unless the Sec-
11 retary extends the date because of ex-
12 traordinary or unusual cir-
13 cumstances); or

14 “(BB) if 1 or more civil actions
15 have been brought against the appli-
16 cant for infringement of a patent sub-
17 ject to a certification under paragraph
18 (2)(A)(vii)(IV) or 1 or more civil ac-
19 tions have been brought by the appli-
20 cant for a declaratory judgment that
21 such a patent is invalid or not in-
22 fringed, the date that is 60 days after
23 the date of a final decision (from
24 which no appeal has been or can be
25 taken, other than a petition to the Su-

1 preme Court for a writ of certiorari)
2 in the last of those civil actions to be
3 decided (unless the Secretary extends
4 the date because of extraordinary or
5 unusual circumstances).

6 “(bb) WITHDRAWAL OF APPLICA-
7 TION.—The applicant withdraws the appli-
8 cation.

9 “(cc) AMENDMENT OF CERTIFI-
10 CATION.—The applicant, voluntarily or as
11 a result of a settlement or defeat in patent
12 litigation, amends the certification from a
13 certification under paragraph
14 (2)(A)(vii)(IV) to a certification under
15 paragraph (2)(A)(vii)(III).

16 “(dd) FAILURE TO OBTAIN AP-
17 PROVAL.—The applicant fails to obtain
18 tentative approval of an application within
19 30 months after the date on which the ap-
20 plication is filed, unless the failure is
21 caused by—

22 “(AA) a change in the require-
23 ments for approval of the application
24 imposed after the date on which the
25 application is filed; or

1 “(BB) other extraordinary cir-
2 cumstances warranting an exception,
3 as determined by the Secretary.

4 “(ee) FAILURE TO CHALLENGE PAT-
5 ENT.—In a case in which, after the date
6 on which the applicant submitted the ap-
7 plication, new patent information is sub-
8 mitted under subsection (c)(2) for the list-
9 ed drug for a patent for which certification
10 is required under paragraph (2)(A), the
11 applicant fails to submit, not later than the
12 date that is 60 days after the date on
13 which the Secretary publishes the new pat-
14 ent information under paragraph
15 (7)(A)(iii) (unless the Secretary extends
16 the date because of extraordinary or un-
17 usual circumstances)—

18 “(AA) a certification described in
19 paragraph (2)(A)(vii)(IV) with respect
20 to the patent to which the new patent
21 information relates; or

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

1 subsection in accordance with para-
2 graph (2)(A)(viii).

3 “(ff) UNLAWFUL CONDUCT.—The
4 Federal Trade Commission determines
5 that the applicant engaged in unlawful
6 conduct with respect to the application in
7 violation of section 1 of the Sherman Act.

8 “(IV) SUBSEQUENT APPLICATION.—The
9 term ‘subsequent application’ means an applica-
10 tion for approval of a drug that is filed subse-
11 quent to the filing of a first application for ap-
12 proval of that drug.”.

13 (b) APPLICABILITY.—The amendment made by sub-
14 section (a) shall apply only with respect to an application
15 filed under section 505(j) of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 355(j)) after the date of enact-
17 ment of this Act for a listed drug for which no certification
18 under section 505(j)(2)(A)(vii)(IV) of that Act was made
19 before the date of enactment of this Act, except that if
20 a forfeiture event described in section
21 505(j)(5)(E)(v)(III)(ff) of that Act (as amended by this
22 section) occurs in the case of an applicant, the applicant
23 shall forfeit the 180-day period under section
24 505(j)(5)(B)(iv) of that Act without regard to when the

1 applicant made a certification under section
2 505(j)(2)(A)(vii)(IV) of that Act.

3 **SEC. 9. BIOEQUIVALENCE.**

4 (a) IN GENERAL.—The amendments to part 320 of
5 title 21, Code of Federal Regulations, promulgated by the
6 Commissioner of Food and Drugs on July 17, 1991 (57
7 Fed. Reg. 17997 (April 28, 1992)), shall continue in effect
8 as an exercise of authorities under sections 501, 502, 505,
9 and 701 of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 351, 352, 355, 371).

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

14 (c) EFFECT OF SECTION.—This section shall not be
15 construed to alter the authority of the Secretary of Health
16 and Human Services to regulate biological products under
17 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
18 et seq.). Any such authority shall be exercised under that
19 Act as in effect on the day before the date of enactment
20 of this Act.

21 **SEC. 10. FILING OF PATENT INFORMATION WITH THE FOOD**
22 **AND DRUG ADMINISTRATION.**

23 (a) FILING AFTER APPROVAL OF AN APPLICA-
24 TION.—

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

6 “(2) PATENT INFORMATION.—

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

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

17 “(II) that claims an approved method
18 of using the drug; and

19 “(ii) with respect to which a claim of
20 patent infringement could reasonably be
21 asserted if a person not licensed by the
22 owner engaged in the manufacture, use, or
23 sale of the drug.

24 “(B) SUBSEQUENTLY ISSUED PATENTS.—

25 In a case in which a patent described in sub-

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

10 “(C) PATENT INFORMATION.—The patent
11 information required to be filed under subpara-
12 graph (A) or (B) includes—

13 “(i) the patent number;

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

15 “(iii) with respect to each claim of the
16 patent—

17 “(I) whether the patent claims
18 the drug or claims a method of using
19 the drug; and

20 “(II) whether the claim covers—

21 “(aa) a drug substance;

22 “(bb) a drug formulation;

23 “(cc) a drug composition; or

24 “(dd) a method of use;

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

3 “(v) the identity of the owner of the
4 patent (including the identity of any agent
5 of the patent owner); and

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

11 “(D) PUBLICATION.—On filing of patent
12 information required under subparagraph (A)
13 or (B), the Secretary shall—

14 “(i) immediately publish the informa-
15 tion described in clauses (i) through (iv) of
16 subparagraph (C); and

17 “(ii) make the information described
18 in clauses (v) and (vi) of subparagraph (C)
19 available to the public on request.

20 “(E) CIVIL ACTION FOR CORRECTION OR
21 DELETION OF PATENT INFORMATION.—

22 “(i) IN GENERAL.—A person that has
23 filed an application under subsection (b)(2)
24 or (j) for a drug may bring a civil action
25 against the holder of the approved applica-

1 tion for the drug seeking an order requir-
2 ing that the holder of the application
3 amend the application—

4 “(I) to correct patent information
5 filed under subparagraph (A); or

6 “(II) to delete the patent infor-
7 mation in its entirety for the reason
8 that—

9 “(aa) the patent does not
10 claim the drug for which the ap-
11 plication was approved; or

12 “(bb) the patent does not
13 claim an approved method of
14 using the drug.

15 “(ii) LIMITATIONS.—Clause (i) does
16 not authorize—

17 “(I) a civil action to correct pat-
18 ent information filed under subpara-
19 graph (B); or

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

22 “(F) NO CLAIM FOR PATENT INFRINGE-
23 MENT.—An owner of a patent with respect to
24 which a holder of an application fails to file in-
25 formation on or before the date required under

1 subparagraph (A) or (B) shall be barred from
2 bringing a civil action for infringement of the
3 patent against a person that—

4 “(i) has filed an application under
5 subsection (b)(2) or (j); or

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

9 (2) TRANSITION PROVISION.—

10 (A) FILING OF PATENT INFORMATION.—

11 Each holder of an application for approval of a
12 new drug under section 505(b) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C.
14 355(b)) that has been approved before the date
15 of enactment of this Act shall amend the appli-
16 cation to include the patent information re-
17 quired under the amendment made by para-
18 graph (1) not later than the date that is 30
19 days after the date of enactment of this Act
20 (unless the Secretary of Health and Human
21 Services extends the date because of extraor-
22 dinary or unusual circumstances).

23 (B) NO CLAIM FOR PATENT INFRINGE-
24 MENT.—An owner of a patent with respect to
25 which a holder of an application under sub-

1 section (b) of section 505 of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 355) fails
3 to file information on or before the date re-
4 quired under subparagraph (A) shall be barred
5 from bringing a civil action for infringement of
6 the patent against a person that—

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

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

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

16 (1) in subsection (b)(2)—

17 (A) in subparagraph (A), by striking
18 “and” at the end;

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

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

22 “(C) with respect to a patent that claims
23 both the drug and a method of using the drug
24 or claims more than 1 method of using the drug
25 for which the application is filed—

1 “(i) a certification under subpara-
2 graph (A)(iv) on a claim-by-claim basis;
3 and

4 “(ii) a statement under subparagraph
5 (B) regarding the method of use claim.”;
6 and

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

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

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