

108TH CONGRESS
1ST SESSION

S. 1225

Entitled the “Greater Access to Affordable Pharmaceuticals Act”.

IN THE SENATE OF THE UNITED STATES

JUNE 10, 2003

Mr. GREGG (for himself, Mr. SCHUMER, Mr. MCCAIN, and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

Entitled the “Greater Access to Affordable Pharmaceuticals Act”.

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”.

6 **SEC. 2. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.**

7 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-
8 tion 505(j) of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 355(j)) is amended—

1 (1) in paragraph (2)(A)(vii), by inserting after
2 “each patent” the following: “published by the Sec-
3 retary under subsection (b)(1) or (c)(2) at least 1
4 day before the date on which the application is
5 filed”; and

6 (2) in paragraph (5)—

7 (A) in subparagraph (B)(iii)—

8 (i) by striking “paragraph (2)(B)(i)”
9 each place it appears and inserting “para-
10 graph (2)(B)”;

11 (ii) in the first sentence, by inserting
12 after “of a patent” the following: “pub-
13 lished by the Secretary under subsection
14 (b)(1) or (c)(2) at least 1 day before the
15 date on which the application is filed”; and

16 (iii) in subclauses (I), (II), and (III)
17 of the second sentence, by striking “the
18 court” and inserting “the United States
19 district court presiding over the matter”;

20 (B) by redesignating subparagraphs (C)
21 and (D) as subparagraphs (E) and (F), respec-
22 tively; and

23 (C) by inserting after subparagraph (B)
24 the following:

1 “(C) AVAILABILITY OF 30-MONTH PE-
2 RIOD.—

3 “(i) IN GENERAL.—The 30-month pe-
4 riod provided under subparagraph (B)(iii)
5 shall be available only with respect to a
6 patent published by the Secretary under
7 subsection (b)(1) or (c)(2) at least 1 day
8 before the date on which the application is
9 filed.

10 “(ii) SUBSEQUENTLY PUBLISHED
11 PATENTS.—

12 “(I) IN GENERAL.—If a patent is
13 published by the Secretary under sub-
14 section (b)(1) or (c)(2) subsequent to
15 the filing of an application described
16 in paragraph (2)(A) but before ap-
17 proval of that application (referred to
18 in this clause as a ‘subsequently pub-
19 lished patent’), and the patent claims
20 the listed drug referred to in para-
21 graph (2)(A)(i) or a use for the listed
22 drug for which the applicant is seek-
23 ing approval under this subsection
24 and for which information is required
25 to be filed under subsection (b) or (c),

1 the applicant shall amend the applica-
2 tion to include a certification de-
3 scribed in paragraph (2)(A)(vii) or a
4 statement described in paragraph
5 (2)(A)(viii) for the patent.

6 “(II) NO ADDITIONAL 30-MONTH
7 PERIOD.—The 30-month period de-
8 scribed in subparagraph (B)(iii) shall
9 not be available with respect to a cer-
10 tification described in paragraph
11 (2)(A)(vii)(IV) when the subject of
12 that certification is a subsequently
13 published patent.

14 “(III) CHALLENGE TO SUBSE-
15 QUENTLY PUBLISHED PATENT IN SEP-
16 ARATE PROCEEDING.—If the same ap-
17 plicant makes a certification described
18 in paragraph (2)(A)(vii)(IV) with re-
19 spect to the subsequently published
20 patent in a separate application under
21 this subsection, the 30-month period
22 provided under subparagraph (B)(iii)
23 shall be available in connection with
24 the separate application.

1 “(iii) CIVIL ACTION TO OBTAIN PAT-
2 ENT CERTAINTY.—

3 “(I) DECLARATORY JUDGMENT
4 ABSENT INFRINGEMENT ACTION.—If
5 the owner of a patent fails to bring a
6 civil action against the applicant for
7 infringement of the patent on or be-
8 fore the date that is 45 days after the
9 date on which the notice provided
10 under paragraph (2)(B) was received,
11 the applicant may bring a civil action
12 against the owner of the patent for a
13 declaratory judgment under section
14 2201 of title 28, United States Code,
15 that the patent is invalid, is unen-
16 forceable, or will not otherwise be in-
17 fringed by the new drug for which the
18 person seeks approval.

19 “(II) COUNTERCLAIM TO IN-
20 FRINGEMENT ACTION.—

21 “(aa) IN GENERAL.—If the
22 owner of the patent brings a pat-
23 ent infringement action against
24 the applicant, the applicant may
25 assert a counterclaim seeking an

1 order requiring the patent owner
2 to correct or delete patent infor-
3 mation filed by the patent owner
4 under subsection (b) or (c) on
5 the ground that the patent does
6 not claim—

7 “(AA) the drug for
8 which the application was
9 approved; or

10 “(BB) an approved
11 method of using the drug.

12 “(bb) NO DAMAGES.—An
13 applicant shall not be entitled to
14 damages on a counterclaim under
15 item (aa).

16 “(cc) NO INDEPENDENT
17 CAUSE OF ACTION.—Item (aa)
18 does not authorize the assertion
19 of a claim described in item (aa)
20 in any civil action or proceeding
21 other than a counterclaim de-
22 scribed in item (aa).”.

23 (b) APPLICATIONS GENERALLY.—Section 505 of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)
25 is amended—

1 (1) in subsection (b)(2)(A), by inserting after
2 “each patent” the following: “published by the Sec-
3 retary under paragraph (1) or subsection (c)(2) at
4 least 1 day before the date on which the application
5 is filed”; and

6 (2) in subsection (c)—

7 (A) in paragraph (3)(C)—

8 (i) by striking “paragraph (3)(B)”
9 each place it appears and inserting “para-
10 graph (3)”;

11 (ii) in the first sentence, by inserting
12 after “of a patent” the following: “pub-
13 lished by the Secretary under paragraph
14 (2) or subsection (b)(1) at least 1 day be-
15 fore the date on which the application is
16 filed”; and

17 (iii) in clauses (i), (ii), and (iii) of the
18 second sentence, by striking “the court”
19 and inserting “the United States district
20 court presiding over the matter”;

21 (B) by redesignating paragraph (4) as
22 paragraph (5); and

23 (C) by inserting after paragraph (3) the
24 following:

25 “(4) AVAILABILITY OF 30-MONTH PERIOD.—

1 “(A) IN GENERAL.—The 30-month period
2 provided under paragraph (3)(C) shall be avail-
3 able only with respect to a patent published by
4 the Secretary under paragraph (2) or sub-
5 section (b)(1) at least 1 day before the date on
6 which the application is filed.

7 “(B) SUBSEQUENTLY PUBLISHED PAT-
8 ENTS.—

9 “(i) IN GENERAL.—If a patent is pub-
10 lished by the Secretary under paragraph
11 (2) or subsection (b)(1) subsequent to the
12 filing of an application described in sub-
13 section (b)(2) but before approval of that
14 application (referred to in this subpara-
15 graph as a ‘subsequently published pat-
16 ent’), and the patent claims the listed drug
17 or a use for the listed drug for which the
18 applicant is seeking approval, the applicant
19 shall amend the application to include a
20 certification described in subsection
21 (b)(2)(A) or a statement described in sub-
22 section (b)(2)(B) for the patent.

23 “(ii) NO ADDITIONAL 30-MONTH PE-
24 RIOD.—The 30-month period described in
25 paragraph (3)(C) shall not be available

1 with respect to a certification described in
2 subsection (b)(2)(A)(iv) when the subject
3 of that certification is a subsequently pub-
4 lished patent.

5 “(iii) CHALLENGE TO SUBSEQUENTLY
6 PUBLISHED PATENT IN SEPARATE PRO-
7 CEEDING.—If the same applicant makes a
8 certification described in subsection
9 (b)(2)(A)(iv) with respect to the subse-
10 quently published patent in a separate ap-
11 plication under this subsection, the 30-
12 month period provided under paragraph
13 (3)(C) shall be available in connection with
14 the separate application.

15 “(C) CIVIL ACTION TO OBTAIN PATENT
16 CERTAINTY.—

17 “(i) DECLARATORY JUDGMENT AB-
18 SENT INFRINGEMENT ACTION.—If the
19 owner of a patent fails to bring a civil ac-
20 tion against the applicant for infringement
21 of the patent on or before the date that is
22 45 days after the date on which the notice
23 provided under paragraph (2)(B) was re-
24 ceived, the applicant may bring a civil ac-
25 tion against the owner of the patent for a

1 declaratory judgment under section 2201
2 of title 28, United States Code, that the
3 patent is invalid, is unenforceable, or will
4 not otherwise be infringed by the new drug
5 for which the person seeks approval.

6 “(ii) COUNTERCLAIM TO INFRINGE-
7 MENT ACTION.—

8 “(I) IN GENERAL.—If the owner
9 of the patent brings a patent infringe-
10 ment action against the applicant, the
11 applicant may assert a counterclaim
12 seeking an order requiring the patent
13 owner to correct or delete patent in-
14 formation filed by the patent owner
15 under subsection (b) or (c) on the
16 ground that the patent either does not
17 claim the drug for which the applica-
18 tion was approved or does not claim—

19 “(aa) the drug for which the
20 application was approved; or

21 “(bb) an approved method
22 of using the drug.

23 “(II) NO DAMAGES.—An appli-
24 cant shall not be entitled to damages
25 on a counterclaim under subclause (I).

1 “(III) NO INDEPENDENT CAUSE
2 OF ACTION.—Subclause (I) does not
3 authorize the assertion of a claim de-
4 scribed in subclause (I) in any civil
5 action or proceeding other than a
6 counterclaim described in subclause
7 (I).”.

8 (c) INFRINGEMENT ACTIONS.—Section 271(e) of title
9 35, United States Code, is amended by adding at the end
10 the following:

11 “(5) CASE OR CONTROVERSY.—The filing of an
12 application described in paragraph (2) that includes
13 a certification under subsection (b)(2)(A)(iv) or
14 (j)(2)(A)(vii)(IV) of section 505 of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 355), and
16 the failure of the owner of the patent to bring an
17 action for infringement of a patent that is the sub-
18 ject of the certification before the expiration of 45
19 days after the date on which the notice provided
20 under subsection (b)(3) or (j)(2)(B) of that section
21 is received, shall establish an actual controversy be-
22 tween the applicant and the patent owner sufficient
23 to confer subject matter jurisdiction in the courts of
24 the United States for any action brought by the ap-
25 plicant under section 2201 of title 28 for a declara-

1 tory judgment that any patent that is the subject of
2 the certification is invalid, unenforceable, or not in-
3 fringed.”.

4 (d) EFFECTIVE DATE.—The amendments made by
5 subsections (a) and (b) shall be effective with respect to
6 any certification under subsection (b)(2)(A)(iv) or
7 (j)(2)(A)(vii)(IV) of section 505 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 355) made after the
9 date of enactment of this Act in an application filed under
10 subsection (b)(2) or (j) of that section or in an amendment
11 to an application filed under subsection (b)(2) or (j) of
12 that section.

13 **SEC. 3. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

14 (a) IN GENERAL.—Section 505(j)(5) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as
16 amended by section 2) is amended—

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

19 “(II) the earlier of—

20 “(aa) the date of a final de-
21 cision of a court from which no
22 appeal has or can be taken other
23 than a petition to the Supreme
24 Court for a writ of certiorari
25 holding that the patent that is

1 the subject of the certification is
2 invalid or not infringed; or

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

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

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

15 “(i) DEFINITION OF FORFEITURE
16 EVENT.—In this subparagraph, the term
17 ‘forfeiture event’, with respect to an appli-
18 cation under this subsection, means the oc-
19 currence of any of the following:

20 “(I) FAILURE TO MARKET.—The
21 applicant fails to market the drug by
22 the later of—

23 “(aa) the date that is 60
24 days after the date on which the
25 approval of the application for

1 the drug is made effective under
2 subparagraph (B)(iii); or

3 “(bb) if 1 or more civil ac-
4 tions have been brought against
5 the applicant for infringement of
6 a patent subject to a certification
7 under paragraph (2)(A)(vii)(IV)
8 or 1 or more civil actions have
9 been brought by the applicant for
10 a declaratory judgment that such
11 a patent is invalid or not other-
12 wise infringed, the date that is
13 60 days after the date of a final
14 decision of a court from which no
15 appeal has been or can be taken
16 (other than a petition to the Su-
17 preme Court for a writ of certio-
18 rari) in the last of those civil ac-
19 tions to be decided.

20 “(II) WITHDRAWAL OF APPLICA-
21 TION.—The applicant withdraws the
22 application.

23 “(III) AMENDMENT OF CERTIFI-
24 CATION.—The applicant amends the
25 certification from a certification under

1 paragraph (2)(A)(vii)(IV) to a certifi-
2 cation under paragraph
3 (2)(A)(vii)(III).

4 “(IV) FAILURE TO OBTAIN TEN-
5 TATIVE APPROVAL.—The applicant
6 fails to obtain tentative approval of an
7 application within 30 months after the
8 date on which the application is filed,
9 unless the failure is caused by a
10 change in the requirements for ap-
11 proval of the application imposed after
12 the date on which the application is
13 filed.

14 “(V) FAILURE TO CHALLENGE
15 PATENT.—In a case in which, after
16 the date on which the applicant sub-
17 mitted the application, new patent in-
18 formation is submitted under sub-
19 section (e)(2) for the listed drug for a
20 patent for which certification is re-
21 quired under paragraph (2)(A), the
22 applicant fails to submit, not later
23 than the date that is 60 days after the
24 date on which the Secretary publishes

1 the new patent information under
2 paragraph (7)(A)(iii)—

3 “(aa) a certification de-
4 scribed in paragraph
5 (2)(A)(vii)(IV) with respect to
6 the patent to which the new pat-
7 ent information relates; or

8 “(bb) a statement that any
9 method of use claim of that pat-
10 ent does not claim a use for
11 which the applicant is seeking
12 approval under this subsection in
13 accordance with paragraph
14 (2)(A)(viii).

15 “(VI) AGREEMENT WITH PATENT
16 OWNER.—The applicant enters into
17 an agreement with the owner of the
18 patent—

19 “(aa) that is the subject of
20 the certification under paragraph
21 (2)(A)(vii)(IV); and

22 “(bb) that the Federal
23 Trade Commission determines
24 has violated the antitrust laws
25 (as defined in section 1 of the

1 Clayton Act (15 U.S.C. 12), ex-
2 cept that the term includes sec-
3 tion 5 of the Federal Trade Com-
4 mission Act (15 U.S.C. 45) to
5 the extent that that section ap-
6 plies to unfair methods of com-
7 petition).

8 “(ii) FORFEITURE.—The 180-day ex-
9 clusivity period described in subparagraph
10 (B)(iv) shall be forfeited by an applicant if
11 a forfeiture event occurs.

12 “(iii) SUBSEQUENT APPLICANT.—If
13 an applicant forfeits the 180-day exclu-
14 sivity period under clause (ii)—

15 “(I) a subsequent application
16 containing a certification described in
17 paragraph (2)(A)(vii)(IV) shall be-
18 come effective immediately on ap-
19 proval; and

20 “(II) the subsequent applicant
21 shall not be eligible for a 180-day ex-
22 clusivity period under subparagraph
23 (B)(iv).

24 “(E) AVAILABILITY.—The 180-day period
25 under subparagraph (B)(iv) shall be available to

1 a first applicant submitting an application for a
2 drug with respect to any patent without regard
3 to whether an application has been submitted
4 for the drug under this subsection containing
5 such a certification with respect to a different
6 patent.”.

7 (b) **APPLICABILITY.**—The amendment made by sub-
8 section (a) shall be effective only with respect to an appli-
9 cation filed under section 505(j) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 355 (j)) after the date
11 of enactment of this Act for a listed drug for which no
12 certification under section 505(j)(2)(A)(vii)(IV) of that
13 Act was made before the date of enactment of this Act,
14 except that if a forfeiture event described in section
15 505(j)(5)(D)(i)(VI) of that Act occurs in the case of an
16 applicant, the applicant shall forfeit the 180-day period
17 under section 505(j)(5)(B)(iv) of that Act without regard
18 to when the applicant made a certification under section
19 505(j)(2)(A)(vii)(IV).

20 **SEC. 4. BIOAVAILABILITY AND BIOEQUIVALENCE.**

21 (a) **IN GENERAL.**—Section 505(j)(8) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is
23 amended—

24 (1) by striking subparagraph (A) and inserting
25 the following:

1 “(A)(i) The term ‘bioavailability’ means the
2 rate and extent to which the active ingredient or
3 therapeutic ingredient is absorbed from a drug and
4 becomes available at the site of drug action.

5 “(ii) For a drug that is not intended to be ab-
6 sorbed into the bloodstream, the Secretary may as-
7 sess bioavailability by scientifically valid measure-
8 ments intended to reflect the rate and extent and ex-
9 tent to which the active ingredient or active moiety
10 becomes available at the site of drug action.”; and

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

12 “(C) For a drug that is not intended to be ab-
13 sorbed into the bloodstream, the Secretary may es-
14 tablish alternative, scientifically valid methods to
15 show bioequivalence if the alternative methods are
16 expected to detect a significant difference between
17 the drug and the listed drug in safety and thera-
18 peutic effect.”.

19 (b) EFFECT OF AMENDMENT.—The amendment
20 made by subsection (a) does not alter the standards for
21 approval of drugs under section 505(j) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

23 **SEC. 5. REMEDIES FOR INFRINGEMENT.**

24 Section 287 of title 35, United States Code, is
25 amended by adding at the end the following:

1 “(d) CONSIDERATION.—In making a determination
2 with respect to remedy brought for infringement of a pat-
3 ent that claims a drug or a method or using a drug, the
4 court shall consider whether information on the patent
5 was filed as required under 21 U.S.C. 355 (b) or (c), and,
6 if such information was required to be filed but was not,
7 the court may refuse to award treble damages under sec-
8 tion 284.”.

9 **SEC. 6. CONFORMING AMENDMENTS.**

10 Section 505A of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 355a) is amended—

12 (1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i),
13 by striking “(j)(5)(D)(ii)” each place it appears and
14 inserting “(j)(5)(F)(ii)”;

15 (2) in subsections (b)(1)(A)(ii) and
16 (c)(1)(A)(ii), by striking “(j)(5)(D)” each place it
17 appears and inserting “(j)(5)(F)”;

18 (3) in subsections (e) and (l), by striking
19 “505(j)(5)(D)” each place it appears and inserting
20 “505(j)(5)(F)”.

○