

108TH CONGRESS
1ST SESSION

H. R. 2491

Entitled the “Greater Access to Affordable Pharmaceuticals Act”.

IN THE HOUSE OF REPRESENTATIVES

JUNE 17, 2003

Mrs. EMERSON (for herself, Mr. BROWN of Ohio, Mr. WAMP, Mr. WAXMAN, Mrs. BONO, Mr. EDWARDS, Mr. GUTKNECHT, Mr. EMANUEL, Mrs. NORTHUP, Mr. PALLONE, Mr. BRADLEY of New Hampshire, Mrs. LOWEY, Mr. BEREUTER, Mr. SERRANO, Mr. KINGSTON, Mr. WEXLER, Mr. JANKLOW, Ms. ROYBAL-ALLARD, Mr. OSBORNE, Mr. LANGEVIN, Mr. CALVERT, Mr. COOPER, Mr. MARKEY, Mr. ALLEN, and Mr. BURTON of Indiana) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, 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

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”.

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

2 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-
3 tion 505(j) of the Federal Food, Drug, and Cosmetic Act
4 (21 U.S.C. 355(j)) is amended—

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

10 (2) in paragraph (5)—

11 (A) in subparagraph (B)(iii)—

12 (i) by striking “paragraph (2)(B)(i)”
13 each place it appears and inserting “para-
14 graph (2)(B)”;

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

20 (iii) in subclauses (I), (II), and (III)
21 of the second sentence, by striking “the
22 court” and inserting “the United States
23 district court presiding over the matter”;

24 (B) by redesignating subparagraphs (C)
25 and (D) as subparagraphs (E) and (F), respec-
26 tively; and

1 (C) by inserting after subparagraph (B)
2 the following:

3 “(C) AVAILABILITY OF 30-MONTH PE-
4 RIOD.—

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

12 “(ii) SUBSEQUENTLY PUBLISHED
13 PATENTS.—

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

1 and for which information is required
2 to be filed under subsection (b) or (c),
3 the applicant shall amend the applica-
4 tion to include a certification de-
5 scribed in paragraph (2)(A)(vii) or a
6 statement described in paragraph
7 (2)(A)(viii) for the patent.

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

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

1 shall be available in connection with
2 the separate application.

3 “(iii) CIVIL ACTION TO OBTAIN PAT-
4 ENT CERTAINTY.—

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

21 “(II) COUNTERCLAIM TO IN-
22 FRINGEMENT ACTION.—

23 “(aa) IN GENERAL.—If the
24 owner of the patent brings a pat-
25 ent infringement action against

1 the applicant, the applicant may
2 assert a counterclaim seeking an
3 order requiring the patent owner
4 to correct or delete patent infor-
5 mation filed by the patent owner
6 under subsection (b) or (c) on
7 the ground that the patent does
8 not claim—

9 “(AA) the drug for
10 which the application was
11 approved; or

12 “(BB) an approved
13 method of using the drug.

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

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

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

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

9 (2) in subsection (c)—

10 (A) in paragraph (3)(C)—

11 (i) by striking “paragraph (3)(B)”
12 each place it appears and inserting “para-
13 graph (3)”;

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

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

24 (B) by redesignating paragraph (4) as
25 paragraph (5); and

1 (C) by inserting after paragraph (3) the
2 following:

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

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

10 “(B) SUBSEQUENTLY PUBLISHED PAT-
11 ENTS.—

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

1 “(ii) NO ADDITIONAL 30-MONTH PE-
2 RIOD.—The 30-month period described in
3 paragraph (3)(C) shall not be available
4 with respect to a certification described in
5 subsection (b)(2)(A)(iv) when the subject
6 of that certification is a subsequently pub-
7 lished patent.

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

18 “(C) CIVIL ACTION TO OBTAIN PATENT
19 CERTAINTY.—

20 “(i) DECLARATORY JUDGMENT AB-
21 SENT INFRINGEMENT ACTION.—If the
22 owner of a patent fails to bring a civil ac-
23 tion against the applicant for infringement
24 of the patent on or before the date that is
25 45 days after the date on which the notice

1 provided under paragraph (2)(B) was re-
2 ceived, the applicant may bring a civil ac-
3 tion against the owner of the patent for a
4 declaratory judgment under section 2201
5 of title 28, United States Code, that the
6 patent is invalid, is unenforceable, or will
7 not otherwise be infringed by the new drug
8 for which the person seeks approval.

9 “(ii) COUNTERCLAIM TO INFRINGE-
10 MENT ACTION.—

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

22 “(aa) the drug for which the
23 application was approved; or

24 “(bb) an approved method
25 of using the drug.

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

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

11 (c) INFRINGEMENT ACTIONS.—Section 271(e) of title
12 35, United States Code, is amended by adding at the end
13 the following:

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

1 to confer subject matter jurisdiction in the courts of
2 the United States for any action brought by the ap-
3 plicant under section 2201 of title 28 for a declara-
4 tory judgment that any patent that is the subject of
5 the certification is invalid, unenforceable, or not in-
6 fringed.”.

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

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

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

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

22 “(II) the earlier of—

23 “(aa) the date of a final de-
24 cision of a court from which no
25 appeal has or can be taken other

1 than a petition to the Supreme
2 Court for a writ of certiorari
3 holding that the patent that is
4 the subject of the certification is
5 invalid or not infringed; or

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

14 (2) by inserting after subparagraph (C) the fol-
15 lowing:

16 “(D) FORFEITURE OF 180-DAY EXCLU-
17 SIVITY PERIOD.—

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

23 “(I) FAILURE TO MARKET.—The
24 applicant fails to market the drug by
25 the later of—

1 “(aa) the date that is 60
2 days after the date on which the
3 approval of the application for
4 the drug is made effective under
5 subparagraph (B)(iii); or

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

23 “(II) WITHDRAWAL OF APPLICA-
24 TION.—The applicant withdraws the
25 application.

1 “(III) AMENDMENT OF CERTIFI-
2 CATION.—The applicant amends the
3 certification from a certification under
4 paragraph (2)(A)(vii)(IV) to a certifi-
5 cation under paragraph
6 (2)(A)(vii)(III).

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

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

1 than the date that is 60 days after the
2 date on which the Secretary publishes
3 the new patent information under
4 paragraph (7)(A)(iii)—

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

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

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

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

24 “(bb) that the Federal
25 Trade Commission determines

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

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

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

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

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

1 “(E) AVAILABILITY.—The 180-day period
2 under subparagraph (B)(iv) shall be available to
3 a first applicant submitting an application for
4 a drug with respect to any patent without re-
5 gard to whether an application has been sub-
6 mitted for the drug under this subsection con-
7 taining such a certification with respect to a
8 different patent.”.

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

22 **SEC. 4. BIOAVAILABILITY AND BIOEQUIVALENCE.**

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

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

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

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

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

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

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

1 **SEC. 5. REMEDIES FOR INFRINGEMENT.**

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

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

12 **SEC. 6. CONFORMING AMENDMENTS.**

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

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

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

21 (3) in subsections (e) and (l), by striking
22 “505(j)(5)(D)” each place it appears and inserting
23 “505(j)(5)(F)”.

○