

108TH CONGRESS  
1ST SESSION

# H. R. 2491

Entitled the “Greater Access to Affordable Pharmaceuticals Act”.

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## 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

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## 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)”.

○