I

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

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A BILL

Entitled the ''Greater Access to Affordable Pharmaceuticals Act''.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Greater Access to Affordable Pharmaceuticals Act''.

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

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended—

(1) in paragraph (2)(A)(vii), by inserting after ''each patent'' the following: ''published by the Secretary under subsection (b)(1) or (c)(2) at least 1 day before the date on which the application is filed''; and

(2) in paragraph (5)—

(A) in subparagraph (B)(iii)—

(i) by striking ''paragraph (2)(B)(i)'' each place it appears and inserting ''paragraph (2)(B)'';

(ii) in the first sentence, by inserting after ''of a patent'' the following: ''published by the Secretary under subsection (b)(1) or (c)(2) at least 1 day before the date on which the application is filed''; and

(iii) in subclauses (I), (II), and (III) of the second sentence, by striking ''the court'' and inserting ''the United States district court presiding over the matter'';

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively; and

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

''(C) AVAILABILITY OF 30-MONTH PERIOD.—

''(i) IN GENERAL.—The 30-month period provided under subparagraph (B)(iii) shall be available only with respect to a patent published by the Secretary under subsection (b)(1) or (c)(2) at least 1 day before the date on which the application is filed.

''(ii) SUBSEQUENTLY PUBLISHED PATENTS.—

''(I) IN GENERAL.—If a patent is published by the Secretary under subsection (b)(1) or (c)(2) subsequent to the filing of an application described in paragraph (2)(A) but before approval of that application (referred to in this clause as a 'subsequently published patent'), and the patent claims the listed drug referred to in paragraph (2)(A)(i) or a use for the listed drug for which the applicant is seeking approval under this subsection

and for which information is required to be filed under subsection (b) or (c), the applicant shall amend the application to include a certification described in paragraph (2)(A)(vii) or a statement described in paragraph (2)(A)(viii) for the patent.

''(II) NO ADDITIONAL 30-MONTH PERIOD.—The 30-month period described in subparagraph (B)(iii) shall not be available with respect to a certification described in paragraph (2)(A)(vii)(IV) when the subject of that certification is a subsequently published patent.

''(III) CHALLENGE TO SUBSEQUENTLY PUBLISHED PATENT IN SEPARATE PROCEEDING.—If the same applicant makes a certification described in paragraph (2)(A)(vii)(IV) with respect to the subsequently published patent in a separate application under this subsection, the 30-month period provided under subparagraph (B)(iii)

shall be available in connection with the separate application.

"(iii) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

"(I) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—If the owner of a patent fails to bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice provided under paragraph (2)(B) was received, the applicant may bring a civil action against the owner of the patent for a declaratory judgment under section 2201 of title 28, United States Code, that the patent is invalid, is unenforceable, or will not otherwise be infringed by the new drug for which the person seeks approval.

"(II) COUNTERCLAIM TO INFRINGEMENT ACTION.—

"(aa) IN GENERAL.—If the owner of the patent brings a patent infringement action against

the applicant, the applicant may assert a counterclaim seeking an order requiring the patent owner to correct or delete patent information filed by the patent owner under subsection (b) or (c) on the ground that the patent does not claim—

"(AA) the drug for which the application was approved; or

"(BB) an approved method of using the drug.

"(bb) NO DAMAGES.—An applicant shall not be entitled to damages on a counterclaim under item (aa).

"(cc) NO INDEPENDENT CAUSE OF ACTION.—Item (aa) does not authorize the assertion of a claim described in item (aa) in any civil action or proceeding other than a counterclaim described in item (aa).".

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

(1) in subsection (b)(2)(A), by inserting after ''each patent'' the following: ''published by the Secretary under paragraph (1) or subsection (c)(2) at least 1 day before the date on which the application is filed''; and

(2) in subsection (c)—

(A) in paragraph (3)(C)—

(i) by striking ''paragraph (3)(B)'' each place it appears and inserting ''paragraph (3)'';

(ii) in the first sentence, by inserting after ''of a patent'' the following: ''published by the Secretary under paragraph (2) or subsection (b)(1) at least 1 day before the date on which the application is filed''; and

(iii) in clauses (i), (ii), and (iii) of the second sentence, by striking ''the court'' and inserting ''the United States district court presiding over the matter'';

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

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

''(4) AVAILABILITY OF 30-MONTH PERIOD.—

''(A) IN GENERAL.—The 30-month period provided under paragraph (3)(C) shall be available only with respect to a patent published by the Secretary under paragraph (2) or subsection (b)(1) at least 1 day before the date on which the application is filed.

''(B) SUBSEQUENTLY PUBLISHED PATENTS.—

''(i) IN GENERAL.—If a patent is published by the Secretary under paragraph (2) or subsection (b)(1) subsequent to the filing of an application described in subsection (b)(2) but before approval of that application (referred to in this subparagraph as a 'subsequently published patent'), and the patent claims the listed drug or a use for the listed drug for which the applicant is seeking approval, the applicant shall amend the application to include a certification described in subsection (b)(2)(A) or a statement described in subsection (b)(2)(B) for the patent.

''(ii) NO ADDITIONAL 30-MONTH PERIOD.—The 30-month period described in paragraph (3)(C) shall not be available with respect to a certification described in subsection (b)(2)(A)(iv) when the subject of that certification is a subsequently published patent.

''(iii) CHALLENGE TO SUBSEQUENTLY PUBLISHED PATENT IN SEPARATE PROCEEDING.—If the same applicant makes a certification described in subsection (b)(2)(A)(iv) with respect to the subsequently published patent in a separate application under this subsection, the 30-month period provided under paragraph (3)(C) shall be available in connection with the separate application.

''(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

''(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—If the owner of a patent fails to bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice

provided under paragraph (2)(B) was received, the applicant may bring a civil action against the owner of the patent for a declaratory judgment under section 2201 of title 28, United States Code, that the patent is invalid, is unenforceable, or will not otherwise be infringed by the new drug for which the person seeks approval.

''(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

''(I) IN GENERAL.—If the owner of the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the patent owner to correct or delete patent information filed by the patent owner under subsection (b) or (c) on the ground that the patent either does not claim the drug for which the application was approved or does not claim—

''(aa) the drug for which the application was approved; or

''(bb) an approved method of using the drug.

"(II) NO DAMAGES.—An applicant shall not be entitled to damages on a counterclaim under subclause (I).

"(III) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).".

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

"(5) CASE OR CONTROVERSY.—The filing of an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and the failure of the owner of the patent to bring an action for infringement of a patent that is the subject of the certification before the expiration of 45 days after the date on which the notice provided under subsection (b)(3) or (j)(2)(B) of that section is received, shall establish an actual controversy between the applicant and the patent owner sufficient

to confer subject matter jurisdiction in the courts of the United States for any action brought by the applicant under section 2201 of title 28 for a declaratory judgment that any patent that is the subject of the certification is invalid, unenforceable, or not infringed.''.

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

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

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

(1) in subparagraph (B)(iv), by striking subclause (II) and inserting the following:

''(II) the earlier of—

''(aa) the date of a final decision of a court from which no appeal has or can be taken other

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

"(bb) the date of a settlement order or consent decree signed by a Federal judge that enters a final judgment and includes a finding that the patent that is the subject of the certification is invalid or not otherwise infringed;"; and

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

"(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

"(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term 'forfeiture event', with respect to an application under this subsection, means the occurrence of any of the following:

"(I) FAILURE TO MARKET.—The applicant fails to market the drug by the later of—

"(aa) the date that is 60 days after the date on which the approval of the application for the drug is made effective under subparagraph (B)(iii); or

"(bb) if 1 or more civil actions have been brought against the applicant for infringement of a patent subject to a certification under paragraph (2)(A)(vii)(IV) or 1 or more civil actions have been brought by the applicant for a declaratory judgment that such a patent is invalid or not otherwise infringed, the date that is 60 days after the date of a final decision of a court from which no appeal has been or can be taken (other than a petition to the Supreme Court for a writ of certiorari) in the last of those civil actions to be decided.

"(II) WITHDRAWAL OF APPLICATION.—The applicant withdraws the application.

"(III) AMENDMENT OF CERTIFICATION.—The applicant amends the certification from a certification under paragraph (2)(A)(vii)(IV) to a certification under paragraph (2)(A)(vii)(III).

"(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The applicant fails to obtain tentative approval of an application within 30 months after the date on which the application is filed, unless the failure is caused by a change in the requirements for approval of the application imposed after the date on which the application is filed.

"(V) FAILURE TO CHALLENGE PATENT.—In a case in which, after the date on which the applicant submitted the application, new patent information is submitted under subsection (c)(2) for the listed drug for a patent for which certification is required under paragraph (2)(A), the applicant fails to submit, not later

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

"(aa) a certification described in paragraph (2)(A)(vii)(IV) with respect to the patent to which the new patent information relates; or

"(bb) a statement that any method of use claim of that patent does not claim a use for which the applicant is seeking approval under this subsection in accordance with paragraph (2)(A)(viii).

"(VI) AGREEMENT WITH PATENT OWNER.—The applicant enters into an agreement with the owner of the patent—

"(aa) that is the subject of the certification under paragraph (2)(A)(vii)(IV); and

"(bb) that the Federal Trade Commission determines

has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

''(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by an applicant if a forfeiture event occurs.

''(iii) SUBSEQUENT APPLICANT.—If an applicant forfeits the 180-day exclusivity period under clause (ii)—

''(I) a subsequent application containing a certification described in paragraph (2)(A)(vii)(IV) shall become effective immediately on approval; and

''(II) the subsequent applicant shall not be eligible for a 180-day exclusivity period under subparagraph (B)(iv).

''(E) AVAILABILITY.—The 180-day period under subparagraph (B)(iv) shall be available to a first applicant submitting an application for a drug with respect to any patent without regard to whether an application has been submitted for the drug under this subsection containing such a certification with respect to a different patent.''.

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

SEC. 4. BIOAVAILABILITY AND BIOEQUIVALENCE.

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

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

''(A)(i) The term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

''(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent and extent to which the active ingredient or active moeity becomes available at the site of drug action.''; and

(2) by adding at the end the following:

''(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.''.

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

SEC. 5. REMEDIES FOR INFRINGEMENT.

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

''(d) CONSIDERATION.—In making a determination with respect to remedy brought for infringement of a patent that claims a drug or a method or using a drug, the court shall consider whether information on the patent was filed as required under 21 U.S.C. 355 (b) or (c), and, if such information was required to be filed but was not, the court may refuse to award treble damages under section 284.''.

SEC. 6. CONFORMING AMENDMENTS.

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

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

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

(3) in subsections (e) and (l), by striking ''505(j)(5)(D)'' each place it appears and inserting ''505(j)(5)(F)''.

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