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S. 812

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

IN THE SENATE OF THE UNITED STATES

MAY 1, 2001

Mr. SCHUMER (for himself, Mr. MCCAIN, Mr. JOHNSON, Mrs. CLINTON, Ms. STABENOW, Mrs. CARNAHAN, Mr. KOHL, Mr. DASCHLE, Mr. DURBIN, Mr. WELLSTONE, Mr. EDWARDS, and Mr. MILLER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 11 (legislative day, JULY 10), 2002

Reported by Mr. KENNEDY, with an amendment

[Omit the part struck through and insert the part printed in italic]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

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 of 2001''.

SEC. 2. FINDINGS; PURPOSES.

(a) FINDINGS.—Congress finds that—

(1) prescription drug costs are increasing at an alarming rate and are a major worry of American families and senior citizens;

(2) enhancing competition between generic drug manufacturers and brand-name manufacturers can significantly reduce prescription drug costs for American families;

(3) the pharmaceutical market has become increasingly competitive during the last decade because of the increasing availability and accessibility of generic pharmaceuticals, but competition must be further stimulated and strengthened;

(4) the Federal Trade Commission has discovered that there are increasing opportunities for drug companies owning patents on brand-name drugs and generic drug companies to enter into private financial deals in a manner that could restrain trade and greatly reduce competition and increase prescription drug costs for consumers;

(5) generic pharmaceuticals are approved by the Food and Drug Administration on the basis of scientific testing and other information establishing that pharmaceuticals are therapeutically equivalent to brand-name pharmaceuticals, ensuring consumers

a safe, efficacious, and cost-effective alternative to brand-name innovator pharmaceuticals;

(6) the Congressional Budget Office estimates that—

(A) the use of generic pharmaceuticals for brand-name pharmaceuticals could save purchasers of pharmaceuticals between $8,000,000,000 and $10,000,000,000 each year; and

(B) generic pharmaceuticals cost between 25 percent and 60 percent less than brand-name pharmaceuticals, resulting in an estimated average savings of $15 to $30 on each prescription;

(7) generic pharmaceuticals are widely accepted by consumers and the medical profession, as the market share held by generic pharmaceuticals compared to brand-name pharmaceuticals has more than doubled during the last decade, from approximately 19 percent to 43 percent, according to the Congressional Budget Office;

(8) expanding access to generic pharmaceuticals can help consumers, especially senior citizens and the uninsured, have access to more affordable prescription drugs;

(9) Congress should ensure that measures are taken to effectuate the amendments made by the Drug Price Competition and Patent Term Restoration Act of 1984 (98 Stat. 1585) (referred to in this section as the ''Hatch-Waxman Act'') to make generic drugs more accessible, and thus reduce health care costs; and

(10) it would be in the public interest if patents on drugs for which applications are approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) were extended only through the patent extension procedure provided under the Hatch-Waxman Act rather than through the attachment of riders to bills in Congress.

(b) PURPOSES.—The purposes of this Act are—

(1) to increase competition, thereby helping all Americans, especially seniors and the uninsured, to have access to more affordable medication; and

(2) to ensure fair marketplace practices and deter pharmaceutical companies (including generic companies) from engaging in anticompetitive action or actions that tend to unfairly restrain trade.

SEC. 3. ACCELERATED GENERIC DRUG COMPETITION.

(a) IN GENERAL.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) 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 in an action described in clause (iii) (from which no appeal can or has been taken); 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 patents that are the subject of the certification are invalid or not infringed;";

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

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

"(C) FORFEITURE OF 180-DAY PERIOD.—

"(i) IN GENERAL.—The 180-day period described in subparagraph (B)(iv) shall be forfeited by the previous applicant and become available to the next applicant

submitting an application containing a certification described in paragraph (2)(A)(vii)(IV) if—

"(I) the previous applicant fails to market the drug within 90 days after the date on which the approval of the application for the drug is made effective under subparagraph (B)(iii);

"(II) the previous applicant withdraws the application;

"(III) the previous applicant amends the certification from a certification under subclause (IV) to a certification under paragraph (2)(A)(vii)(III), either voluntarily or as a result of a settlement or defeat in patent litigation;

"(IV) the previous applicant fails to get tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by—

"(aa) a change in the requirements for tentative approval

of the application imposed after the date on which the application was filed; or

"(bb) other extraordinary or unusual circumstances, as determined by the Secretary;

"(V) in a case in which, after the date on which the previous application was submitted under this subsection, new patent information is submitted for the drug under subsection (c)(2) for a patent for which certification is required under paragraph (2)(A)(vii)(IV), the previous applicant fails to challenge the patent that is the subject of the information within 60 days after the date on which the patent information is submitted; or

"(VI) the previous applicant is determined by the Secretary, after a fair and sufficient hearing and in consultation with the Federal Trade Commission, to have engaged in anti-competitive or collusive conduct, or any other conduct intended to unfairly

monopolize the commercial manufacturing of the drug of the application.

''(ii) AVAILABILITY.—The 180-day period described in subparagraph (B)(iv) shall be available only to—

''(I) the previous applicant submitting an application for a drug under this subsection containing a certification described in paragraph (2)(A)(vii)(IV) with respect to any patent; or

''(II) under clause (i), the next applicant submitting an application for a drug under this subsection containing such a certification with respect to any patent;

even if an application has been submitted for the drug under this subsection containing such a certification with respect to a different patent.

''(iii) APPLICABILITY.—The 180-day period described in subparagraph (B)(iv) shall apply only if—

''(I) the application contains a certification described in paragraph (2)(A)(vii)(IV); and

''(II) an action is brought for infringement of a patent that is the subject of the certification or the applicant brings an action (not later than 50 days after the date on which the notice provided under paragraph (2)(B)(ii) was received), against the holder of the approved application for the listed drug.''.

(b) EFFECTIVE DATE.—The amendment made by this section 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)) 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.

SEC. 4. BIOEQUIVALENCE TESTING METHODS.

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

(1) in clause (i), by striking ''or'' at the end;

(2) in clause (ii), by striking the period at the end and inserting ''; or''; and

(3) by adding at the end the following:

"(iii)(I) clauses (i) and (ii) are not applicable, as determined by the Secretary;

"(II) the effects of the drug and the listed drug do not show a significant difference based on tests (other than tests that assess rate and extent of absorption), including—

"(aa) a bioequivalence study with a pharmacodynamic endpoint;

"(bb) a bioequivalence study with a clinical endpoint;

"(cc) in vitro methods; or

"(dd) any other methodology that demonstrates that no significant differences in therapeutic effects of active ingredients are expected; and

"(III) limited confirmatory studies to supplement the bioequivalence testing are considered necessary by the Secretary.".

SEC. 5. CITIZEN PETITIONS.

Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section 3(a)) is amended by inserting after subparagraph (C) the following:

"(D) CITIZEN PETITIONS.—

"(i) IN GENERAL.—Notwithstanding any other provision of law, any petition submitted under section 10.30 of title 21, Code of Federal Regulations (or any successor regulation), shall include a statement that to the best knowledge and belief of the petitioner, the petition—

"(I) includes all information and views on which the petitioner relies;

"(II) is well grounded in fact and is warranted by law (including regulations);

"(III) is not submitted for any improper purpose, such as to harass or cause unnecessary delay;

"(IV) does not contain a materially false, misleading, or fraudulent statement that the petitioner has knowingly and willingly included; and

"(V) includes all representative data and information known to the petitioner that is favorable or unfavorable to the petition.

"(ii) APPLICABILITY OF CRIMINAL PROVISION.—Section 1001 of title 18,

United States Code, shall apply to a person that submits a petition under section 10.30 of title 21, Code of Federal Regulations (or any successor regulation).

"(iii) INVESTIGATIONS.—

"(I) IN GENERAL.—The Federal Trade Commission shall investigate, on receipt of a complaint or upon its own initiative, any petition submitted under section 10.30 of title 21, Code of Federal Regulations (or any successor regulation), that may have been submitted for an improper purpose, such as to delay competition or agency action.

"(II) REFERRAL.—If the Commission finds that a petitioner has engaged in conduct that may be illegal, the Commission shall refer the petition to the Antitrust Division of the Department of Justice for further action.

"(iv) NOTICE OF RECEIPT OF CONSIDERATION.—

''(I) IN GENERAL.—A person that submits a petition under section 10.30 of title 21, Code of Federal Regulations (or any successor regulation), shall provide a written notice to the Federal Trade Commission if the person receives any consideration for submitting the petition.

''(II) A notice under subclause (I) shall include—

''(aa) the name of the person or entity that provided the consideration;

''(bb) the dollar value of the consideration, if provided in cash, or a description of such consideration;

''(cc) the date on which the consideration was provided; and

''(dd) any other information that the Commission requires to be disclosed.''.

SEC. 6. PATENT CERTIFICATION.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 355(j)(5)) (as amended by section 3(a)(2)) is amended—

(1) in subparagraph (B), by striking clause (iii) and inserting the following:

"(iii) CERTIFICATION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

"(I) IN GENERAL.—Except as provided in subclauses (II) and (III), if the applicant made a certification described in paragraph (2)(A)(vii)(IV), the approval shall be made effective on the expiration of 45 days after the date on which the notice provided under paragraph (2)(B)(ii) was received.

"(II) ACTION FOR PATENT INFRINGEMENT.—If an action is brought for infringement of a patent that is the subject of the certification before the expiration of the 45-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received, the approval shall be made effective on the expiration of the 45-day period unless the

court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement.

"(III) PATENT INVALID OR NOT INFRINGED.—If the court decides that the patent is invalid or was not infringed, the approval shall be made effective on the date of the court decision.

"(IV) PATENT INFRINGED.—If the court decides that the patent was infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.

"(V) PROCEDURE.—In an action described in subclause (II)—

"(aa) each of the parties shall reasonably cooperate in expediting the action;

"(bb) until the expiration of 45 days after the date the notice

provided under paragraph (2)(B)(i) was received, no civil action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent, except as provided in subparagraph (H); and

''(cc) any such civil action shall be brought in the judicial district in which the defendant has its principal place of business or a regular and established place of business.''; and

(2) by adding at the end the following:

''(G) CIVIL ACTION FOR DECLARATORY JUDGMENT.—A person that files an abbreviated application for a new drug under this paragraph may bring a civil action against the holder of an approved application for a listed drug for a declaratory judgment to determine whether the patent that claims the listed drug or a method of using the drug is invalid or will not be infringed.

"(II) CIVIL ACTION TO DETERMINE LEGAL STATUS.—Notwithstanding any other provision of law, if information on a patent for a listed drug has been published under subsection (c)(2) for at least 1 year after the date on which an abbreviated application for approval of a new drug was filed under this subsection in relation to the listed drug, the person that filed the abbreviated application or the holder of the approved application for the listed drug may immediately bring a civil action to determine the legal status of the patent for the listed drug.".

(b) NEW DRUG APPLICATIONS.—Section 505(c)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)) is amended by striking subparagraph (C) and inserting the following:

"(C) CERTIFICATION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

"(i) IN GENERAL.—Except as provided in clauses (ii) and (iii), if the applicant made a certification described in subsection (b)(2)(A)(iv), the approval shall be made effective on the expiration of 45 days after the date on which the notice provided under subsection (b)(3)(B) was received.

"(ii) ACTION BROUGHT BEFORE EXPIRATION OF 45 DAYS.—If an action is brought for infringement of a patent that is the subject of the certification before the expiration of the 45-day period beginning on the date the notice provided under subsection (b)(3)(B) was received, the approval shall be made effective on the expiration of the 45-day period unless the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement.

"(iii) PATENT INVALID OR NOT INFRINGED.—If the court decides that the patent is invalid or not infringed, the approval shall be made effective on the date of the court decision.

"(iv) PATENT INFRINGED.—If the court decides that the patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.

"(v) PROCEDURE.—In an action described in clause (ii)—

"(I) each of the parties shall reasonably cooperate in expediting the action;

"(II) until the expiration of 45 days after the date the notice provided under subsection (b)(3)(B) was received, no civil action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent, except as provided in subsection (j)(5)(H); and

"(III) any such civil action shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.".

(c) EFFECTIVE DATE.—The amendments made by this section shall not apply to an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) before the date of enactment of this Act.

SEC. 7. PATENT INFORMATION.

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

(1) in subsection (b), by striking ''(b)(1) Any person'' and all that follows through paragraph (1) and inserting the following:

''(b) APPLICATIONS.—

''(1) IN GENERAL.—

''(A) FILING.—Any person may file with the Secretary an application with respect to any drug subject to subsection (a).

''(B) CONTENTS.—A person that files an application shall submit to the Secretary as a part of the application with respect to a drug—

''(i) full reports of investigations that have been made to show whether or not such drug is safe for use and whether the drug is effective in use;

''(ii) a full list of the articles used as components of the drug;

''(iii) a full statement of the composition of the drug;

''(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug;

"(v) such samples of the drug and of the articles used as components of the drug as the Secretary may require; and

"(vi) specimens of the labeling proposed to be used for the drug.

"(C) PATENT INFORMATION.—

"(i) IN GENERAL.—The applicant shall file with the application the patent number and expiration date of any patent that claims a drug or method of using a drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug for which the applicant submitted the application.

"(ii) AMENDMENT OF APPLICATION.—If an application is filed with respect to a drug and a patent as described in clause (i) is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by clause (i).

"(iii) PUBLICATION OF INFORMATION.—On approval of the application, the

Secretary shall publish information submitted under clauses (i) and (ii).

''(D) GUIDANCE.—The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by subparagraph (B)(i).''; and

(2) in paragraph (2)(A)—

(A) by striking ''which claims'' the first place it appears and all that follows through ''subsection and''; and

(B) by striking ''subsection (c)—'' and inserting ''and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug for which the investigations were conducted—'';

(3) in the first sentence of subsection (c)(2)—

(A) by inserting ''such patent information'' after ''shall file''; and

(B) by striking ''Secretary,'' and all that follows and inserting ''Secretary.'';

(4) in subsection (j)(2)(vii), by striking ''which claims the listed drug'' and all that follows through ''under this subsection and'' and inserting ''for the listed drug referred to in clause (i)''; and

(5) by adding at the end the following:

''(o) PATENT INFORMATION.—

''(1) APPLICABILITY.—This subsection applies to a holder of an approved application under subsection (c) that files a patent—

''(A) that claims, with regard to a drug of the application, a drug or method of using a drug; and

''(B) for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, after the date of approval of the application.

''(2) CERTIFICATION.—A holder of a patent described in paragraph (1) shall—

''(A) inform the Secretary of the filing of the patent; and

''(B) certify that the information is a complete and accurate listing of all such patents.

~~''(3) SECRETARY.—The Secretary shall list the information provided under paragraph (2) in accordance with subsection (j)(7).''.~~

~~SEC. 8. REPORT.~~

~~(a) IN GENERAL.—Not later than the date that is 5 years after the date of enactment of this Act, the Federal Trade Commission shall submit to Congress a report describing the extent to which implementation of the amendments made by this Act—~~

~~(1) has enabled products to come to market in a fair and expeditious manner, consistent with the rights of patent owners under intellectual property law; and~~

~~(2) has promoted lower prices of drugs and greater access to drugs through price competition.~~

~~(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000.~~

SEC. 3. FILING OF PATENT INFORMATION WITH THE FOOD AND DRUG ADMINISTRATION.

(a) FILING AFTER APPROVAL OF AN APPLICATION.—

(1) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) (as amended by section 9(a)(2)(B)(ii)) is amended in

subsection (c) by striking paragraph (2) and inserting the following:

"(2) PATENT INFORMATION.—

"(A) IN GENERAL.—Not later than the date that is 30 days after the date of an order approving an application under subsection (b) (unless the Secretary extends the date because of extraordinary or unusual circumstances), the holder of the application shall file with the Secretary the patent information described in subparagraph (C) with respect to any patent—

"(i)(I) that claims the drug for which the application was approved; or

"(II) that claims an approved method of using the drug; and

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

"(B) SUBSEQUENTLY ISSUED PATENTS.—In a case in which a patent described in subparagraph (A) is issued after the date of an order approving an application under subsection (b), the holder of the application shall file with the Sec-

retary the patent information described in subparagraph (C) not later than the date that is 30 days after the date on which the patent is issued (unless the Secretary extends the date because of extraordinary or unusual circumstances).

"(C) PATENT INFORMATION.—The patent information required to be filed under subparagraph (A) or (B) includes—

"(i) the patent number;

"(ii) the expiration date of the patent;

"(iii) with respect to each claim of the patent—

"(I) whether the patent claims the drug or claims a method of using the drug; and

"(II) whether the claim covers—

"(aa) a drug substance;

"(bb) a drug formulation;

"(cc) a drug composition; or

"(dd) a method of use;

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

"(v) the identity of the owner of the patent (including the identity of any agent of the patent owner); and

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

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

"(i) immediately publish the information described in clauses (i) through (iv) of subparagraph (C); and

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

"(E) CIVIL ACTION FOR CORRECTION OR DELETION OF PATENT INFORMATION.—

"(i) IN GENERAL.—A person that has filed an application under subsection (b)(2) or (j) for a drug may bring a civil action against the holder of the approved application for the drug seeking an order requiring that the holder of the application amend the application—

"(I) to correct patent information filed under subparagraph (A); or

"(II) to delete the patent information in its entirety for the reason that—

"(aa) the patent does not claim the drug for which the application was approved; or

"(bb) the patent does not claim an approved method of using the drug.

"(ii) LIMITATIONS.—Clause (i) does not authorize—

"(I) a civil action to correct patent information filed under subparagraph (B); or

"(II) an award of damages in a civil action under clause (i).

"(F) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to which a holder of an application fails to file information on or before the date required under subparagraph (A) or (B) shall be barred from bringing a civil action for infringement of the patent against a person that—

"(i) has filed an application under subsection (b)(2) or (j); or

"(ii) manufactures, uses, offers to sell, or sells a drug approved under an application under subsection (b)(2) or (j).".

(2) TRANSITION PROVISION.—

(A) FILING OF PATENT INFORMATION.—Each holder of an application for approval of a new drug under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) that has been approved before the date of enactment of this Act shall amend the application to include the patent information required under the amendment made by paragraph (1) not later than the date that is 30 days after the date of enactment of this Act (unless the Secretary of Health and Human Services extends the date because of extraordinary or unusual circumstances).

(B) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to which a holder of an application under subsection (b) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) fails to file information on or before the date required under subparagraph (A) shall be barred from

bringing a civil action for infringement of the patent against a person that—

(i) has filed an application under subsection (b)(2) or (j) of that section; or

(ii) manufactures, uses, offers to sell, or sells a drug approved under an application under subsection (b)(2) or (j) of that section.

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

(1) in subsection (b)(2)—

(A) in subparagraph (A), by striking "and" at the end;

(B) in subparagraph (B), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following:

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

"(i) a certification under subparagraph (A)(iv) on a claim-by-claim basis; and

"(ii) a statement under subparagraph (B) regarding the method of use claim."; and

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

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

SEC. 4. LIMITATION OF 30-MONTH STAY TO CERTAIN PATENTS.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B)—

(A) in clause (iii)—

(i) by striking "(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii)," and inserting the following:

"(iii) SUBCLAUSE (IV) CERTIFICATION WITH RESPECT TO CERTAIN PATENTS.—If the applicant made a certification described

in paragraph (2)(A)(vii)(IV) with respect to a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was filed with the Secretary under subsection (c)(2)(A),"; and

(ii) by adding at the end the following: "The 30-month period provided under the second sentence of this clause shall not apply to a certification under paragraph (2)(A)(vii)(IV) made with respect to a patent for which patent information was filed with the Secretary under subsection (c)(2)(B).";

(B) by redesignating clause (iv) as clause (v); and

(C) by inserting after clause (iii) the following:

"(iv) SUBCLAUSE (IV) CERTIFICATION WITH RESPECT TO OTHER PATENTS.—

"(I) IN GENERAL.—If the applicant made a certification described in paragraph (2)(A)(vii)(IV) with respect to a patent not described in clause (iii) for which patent information was pub-

lished by the Secretary under subsection (c)(2)(D), the approval shall be made effective on the date that is 45 days after the date on which the notice provided under paragraph (2)(B) was received, unless a civil action for infringement of the patent, accompanied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, was filed on or before the date that is 45 days after the date on which the notice was received, in which case the approval shall be made effective—

"(aa) on the date of a court action declining to grant a preliminary injunction; or

"(bb) if the court has granted a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug—

"(AA) on issuance by a court of a determination that

the patent is invalid or is not infringed;

"(BB) on issuance by a court of an order revoking the preliminary injunction or permitting the applicant to engage in the commercial manufacture or sale of the drug; or

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

"(II) COOPERATION.—Each of the parties shall reasonably cooperate in expediting a civil action under subclause (I).

"(III) EXPEDITED NOTIFICATION.—If the notice under paragraph (2)(B) contains an address for the receipt of expedited notification of a civil action under subclause (I), the plaintiff shall, on the date on which the com-

plaint is filed, simultaneously cause a notification of the civil action to be delivered to that address by the next business day.''; and

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

''(C) FAILURE TO BRING INFRINGEMENT ACTION.—If, in connection with an application under this subsection, the applicant provides an owner of a patent notice under paragraph (2)(B) with respect to the patent, and the owner of the 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 is received, the owner of the patent shall be barred from bringing a civil action for infringement of the patent in connection with the development, manufacture, use, offer to sell, or sale of the drug for which the application was filed or approved under this subsection.''.

(b) OTHER APPLICATIONS.—Section 505(c)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) (as amended by section 9(a)(3)(A)(iii)) is amended—

(1) in paragraph (3)—

(A) in subparagraph (C)—

(i) by striking "(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A)," and inserting the following:

"(C) CLAUSE (iv) CERTIFICATION WITH RESPECT TO CERTAIN PATENTS.—If the applicant made a certification described in subsection (b)(2)(A)(iv) with respect to a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was filed with the Secretary under paragraph (2)(A),"; and

(ii) by adding at the end the following: "The 30-month period provided under the second sentence of this subparagraph shall not apply to a certification under subsection (b)(2)(A)(iv) made with respect to a patent for which patent information was filed with the Secretary under paragraph (2)(B)."; and

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

"(D) CLAUSE (iv) CERTIFICATION WITH RESPECT TO OTHER PATENTS.—

"(i) IN GENERAL.—If the applicant made a certification described in subsection (b)(2)(A)(iv) with respect to a patent not described in subparagraph (C) for which patent information was published by the Secretary under paragraph (2)(D), the approval shall be made effective on the date that is 45 days after the date on which the notice provided under subsection (b)(3) was received, unless a civil action for infringement of the patent, accompanied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, was filed on or before the date that is 45 days after the date on which the notice was received, in which case the approval shall be made effective—

"(I) on the date of a court action declining to grant a preliminary injunction; or

"(II) if the court has granted a preliminary injunction prohibiting the applicant from engaging in the com-

mercial manufacture or sale of the drug—

"(aa) on issuance by a court of a determination that the patent is invalid or is not infringed;

"(bb) on issuance by a court of an order revoking the preliminary injunction or permitting the applicant to engage in the commercial manufacture or sale of the drug; or

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

"(ii) COOPERATION.—Each of the parties shall reasonably cooperate in expediting a civil action under clause (i).

"(iii) EXPEDITED NOTIFICATION.—If the notice under subsection (b)(3) contains an address for the receipt of expedited notification of a civil action under clause (i), the plaintiff shall, on the date on which the complaint is filed, simultaneously cause a

notification of the civil action to be delivered to that address by the next business day."; and

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

"(4) FAILURE TO BRING INFRINGEMENT ACTION.—If, in connection with an application under subsection (b)(2), the applicant provides an owner of a patent notice under subsection (b)(3) with respect to the patent, and the owner of the 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 is received, the owner of the patent shall be barred from bringing a civil action for infringement of the patent in connection with the development, manufacture, use, offer to sell, or sale of the drug for which the application was filed or approved under subsection (b)(2).".

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—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.

(2) TRANSITION PROVISION.—In the case of applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) filed before the date of enactment of this Act—

(A) a patent (other than a patent that claims a process for manufacturing a listed drug) for which information was submitted to the Secretary of Health and Human Services under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (as in effect on the day before the date of enactment of this Act) shall be subject to subsections (c)(3)(C) and (j)(5)(B)(iii) of section 505 of the Federal Food, Drug, and Cosmetic Act (as amended by this section); and

(B) any other patent (including a patent for which information was submitted to the Secretary under section 505(c)(2) of that Act (as in effect on the day before the date of enactment of this Act)) shall be subject to subsections (c)(3)(D) and (j)(5)(B)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act (as amended by this section).

SEC. 5. EXCLUSIVITY FOR ACCELERATED GENERIC DRUG APPLICANTS.

(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 4(a)) is amended—

(1) in subparagraph (B)(v), 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 been 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 infringed;"; and

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

"(D) FORFEITURE OF 180-DAY PERIOD.—

"(i) DEFINITIONS.—In this subparagraph:

"(I) APPLICATION.—The term 'application' means an application for approval of a drug under this subsection containing a certification under paragraph (2)(A)(vii)(IV) with respect to a patent.

"(II) FIRST APPLICATION.—The term 'first application' means the first application to be filed for approval of the drug.

"(III) FORFEITURE EVENT.—The term 'forfeiture event', with respect to an application under this subsection, means the occurrence of any of the following:

"(aa) 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 clause

(iii) or (iv) of subparagraph (B) (unless the Secretary extends the date because of extraordinary or unusual circumstances); 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 infringed, the date that is 60 days after the date of a final decision (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 (unless the Secretary extends the

date because of extraordinary or unusual circumstances).

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

"(cc) AMENDMENT OF CERTIFICATION.—The applicant, voluntarily or as a result of a settlement or defeat in patent litigation, amends the certification from a certification under paragraph (2)(A)(vii)(IV) to a certification under paragraph (2)(A)(vii)(III).

"(dd) FAILURE TO OBTAIN 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—

"(AA) a change in the requirements for approval of the application imposed after

the date on which the application is filed; or

"(BB) other extraordinary circumstances warranting an exception, as determined by the Secretary.

"(ee) 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) (unless the Secretary extends the date because of extraordinary or unusual circumstances)—

"(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).

"(ff) UNLAWFUL CONDUCT.—The Federal Trade Commission determines that the applicant engaged in unlawful conduct with respect to the application in violation of section 1 of the Sherman Act (15 U.S.C. 1).

"(IV) SUBSEQUENT APPLICATION.—The term 'subsequent application' means an application for approval of a drug that is filed subsequent to the filing of a first application for approval of that drug.

"(ii) FORFEITURE OF 180-DAY PERIOD.—

"(I) IN GENERAL.—Except as provided in subclause (II), if a forfeiture event occurs with respect to a first application—

"(aa) the 180-day period under subparagraph (B)(v) shall be forfeited by the first applicant; and

"(bb) any subsequent application shall become effective as provided under clause (i), (ii), (iii), or (iv) of subparagraph (B), and clause (v) of subparagraph (B) shall not apply to the subsequent application.

"(II) FORFEITURE TO FIRST SUBSEQUENT APPLICANT.—If the subsequent application that is the first to be made effective under subclause (I) was the first among a number of subsequent applications to be filed—

"(aa) that first subsequent application shall be treated as the

first application under this subparagraph (including subclause (I)) and as the previous application under subparagraph (B)(v); and

"(bb) any other subsequent applications shall become effective as provided under clause (i), (ii), (iii), or (iv) of subparagraph (B), but clause (v) of subparagraph (B) shall apply to any such subsequent application.

"(iii) AVAILABILITY.—The 180-day period under subparagraph (B)(v) 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.

"(iv) APPLICABILITY.—The 180-day period described in subparagraph (B)(v) shall apply to an application only if a civil action is brought against the applicant for

infringement of a patent that is the subject of the certification.".

(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)(III)(ff) of that Act occurs in the case of an applicant, the applicant shall forfeit the 180-day period under section 505(j)(5)(B)(v) of that Act without regard to when the applicant made a certification under section 505(j)(2)(A)(vii)(IV) of that Act.

SEC. 6. FAIR TREATMENT FOR INNOVATORS.

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

(1) in subsection (b)(3)(B), by striking the second sentence and inserting "The notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that, as of the date of the notice, the patent is not valid or is not infringed, and shall include, as appropriate for the relevant patent,

a description of the applicant's proposed drug substance, drug formulation, drug composition, or method of use. All information disclosed under this subparagraph shall be treated as confidential and may be used only for purposes relating to patent adjudication. Nothing in this subparagraph precludes the applicant from amending the factual or legal basis on which the applicant relies in patent litigation."; and

(2) in subsection (j)(2)(B)(ii), by striking the second sentence and inserting "The notice shall include a detailed statement of the factual and legal basis of the opinion of the applicant that, as of the date of the notice, the patent is not valid or is not infringed, and shall include, as appropriate for the relevant patent, a description of the applicant's proposed drug substance, drug formulation, drug composition, or method of use. All information disclosed under this subparagraph shall be treated as confidential and may be used only for purposes relating to patent adjudication. Nothing in this subparagraph precludes the applicant from amending the factual or legal basis on which the applicant relies in patent litigation.".

(b) INJUNCTIVE RELIEF.—Section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)) (as amended by section 4(a)(1)) is amended—

(1) in clause (iii), by adding at the end the following: "A court shall not regard the extent of the ability of an applicant to pay monetary damages as a whole or partial basis on which to deny a preliminary or permanent injunction under this clause."; and

(2) in clause (iv), by adding at the end the following:

"(IV) INJUNCTIVE RELIEF.—A court shall not regard the extent of the ability of an applicant to pay monetary damages as a whole or partial basis on which to deny a preliminary or permanent injunction under this clause.".

SEC. 7. BIOEQUIVALENCE.

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

(b) EFFECT.—Subsection (a) does not affect the authority of the Commissioner of Food and Drugs to amend part 320 of title 21, Code of Federal Regulations.

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

SEC. 8. REPORT.

(a) IN GENERAL.—Not later than the date that is 5 years after the date of enactment of this Act, the Federal Trade Commission shall submit to Congress a report describing the extent to which implementation of the amendments made by this Act—

(1) has enabled products to come to market in a fair and expeditious manner, consistent with the rights of patent owners under intellectual property law; and

(2) has promoted lower prices of drugs and greater access to drugs through price competition.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000.

SEC. 9. CONFORMING AND TECHNICAL AMENDMENTS.

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

(1) in subsection (a), by striking "(a) No person" and inserting "(a) IN GENERAL.—No person";

(2) in subsection (b)—

(A) by striking "(b)(1) Any person" and inserting the following:

"(b) APPLICATIONS.—

"(1) REQUIREMENTS.—

"(A) IN GENERAL.—Any person";

(B) in paragraph (1)—

(i) in the second sentence—

(I) by redesignating subparagraphs (A) through (F) as clauses (i) through (vi), respectively, and adjusting the margins appropriately;

(II) by striking "Such persons" and inserting the following:

"(B) INFORMATION TO BE SUBMITTED WITH APPLICATION.—A person that submits an application under subparagraph (A)"; and

(III) by striking "application" and inserting "application—";

(ii) by striking the third through fifth sentences; and

(iii) in the sixth sentence—

(I) by striking "The Secretary" and inserting the following:

"(C) GUIDANCE.—The Secretary"; and

(II) by striking "clause (A)" and inserting "subparagraph (B)(i)"; and

(C) in paragraph (2)—

(i) by striking "clause (A) of such paragraph" and inserting "paragraph (1)(B)(i)";

(ii) in subparagraphs (A) and (B), by striking "paragraph (1) or"; and

(iii) in subparagraph (B)—

(I) by striking "paragraph (1)(A)" and inserting "paragraph (1)(B)(i)"; and

(II) by striking "patent" each place it appears and inserting "claim"; and

(3) in subsection (c)—

(A) in paragraph (3)—

(i) in subparagraph (A)—

(I) by striking "(A) If the applicant" and inserting the following:

"(A) CLAUSE (i) OR (ii) CERTIFICATION.—If the applicant"; and

(II) by striking "may" and inserting "shall";

(ii) in subparagraph (B)—

(I) by striking "(B) If the applicant" and inserting the following:

"(B) CLAUSE (iii) CERTIFICATION.—If the applicant"; and

(II) by striking "may" and inserting "shall";

(iii) by redesignating subparagraph (D) as subparagraph (E); and

(iv) in subparagraph (E) (as redesignated by clause (iii)), by striking "clause (A) of subsection (b)(1)" each place it appears and inserting "subsection (b)(1)(B)(i)"; and

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

(4) in subsection (j)—

(A) in paragraph (2)(A)—

(i) in clause (vi), by striking "clauses (B) through ((F)" and inserting "subclauses (ii) through (vi) of subsection (b)(1)";

(ii) in clause (vii), by striking "(b) or"; and

(iii) in clause (viii)—

(I) by striking "(b) or"; and

(II) by striking "patent" each place it appears and inserting "claim"; and

(B) in paragraph (5)—

(i) in subparagraph (B)—

(I) in clause (i)—

(aa) by striking "(i) If the applicant" and inserting the following:

"(i) SUBCLAUSE (I) OR (II) CERTIFICATION.—If the applicant"; and

(bb) by striking "may" and inserting "shall";

(II) in clause (ii)—

(aa) by striking "(ii) If the applicant" and inserting the following:

"(i) SUBCLAUSE (III) CERTIFICATION.—If the applicant"; and

(bb) by striking "may" and inserting "shall";

(III) in clause (iii), by striking "(2)(B)(i)" each place it appears and inserting "(2)(B)"; and

(IV) in clause (v) (as redesignated by section 4(a)(1)(B)), by striking "continuing" and inserting "containing"; and

(ii) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively.

(b) SECTION 505A.—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)—

(A) by striking "(c)(3)(D)(ii)" each place it appears and inserting "(c)(3)(E)(ii)"; and

(B) 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)—

(A) by striking "(c)(3)(D)" each place it appears and inserting "(c)(3)(E)"; and

(B) by striking "(j)(5)(D)" each place it appears and inserting "(j)(5)(F)";

(3) in subsections (e) and (l)—

(A) by striking "505(c)(3)(D)" each place it appears and inserting "505(c)(3)(E)"; and

(B) by striking "505(j)(5)(D)" each place it appears and inserting "505(j)(5)(F)"; and

(4) in subsection (k), by striking "505(j)(5)(B)(iv)" and inserting "505(j)(5)(B)(v)".

(c) SECTION 527.—Section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) is amended in the second sentence by striking "505(c)(2)" and inserting "505(c)(1)(B)".

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107TH CONGRESS
2D SESSION

S. 812

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

JULY 11 (legislative day, JULY 10), 2002

Reported with an amendment