98TH CONGRESS 2d Session | HOUSE OF REPRESENTATIVES | REPT. 98-857 Part 1

# DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984

JUNE 21, 1984.—Ordered to be printed

Mr. DINGELL, from the Committee on Energy and Commerce, submitted the following

## REPORT

together with

## MINORITY VIEWS

[To accompany H.R. 3605]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3605) to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments are as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

That this Act may be cited as the "Drug Price Competition and Patent Term Restoration Act of 1984".

### TITLE I—ABBREVIATED NEW DRUG APPLICATIONS

SEC. 101. Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by redesignating subsection (j) as subsection (k) and inserting after subsection (i) the following:

"(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

"(2)(A) An abbreviated application for a new drug shall contain—

"(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a 'listed drug');

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"(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug,

"(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

"(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

"(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

"(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

"(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

"(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

"(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such 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)—

"(I) that such patent information has not been filed,

"(II) that such patent has expired,

"(III) of the date on which such patent will expire, or

"(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

"(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant has given the notice required by clause (ii) to—

"(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(II) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

"(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commerical manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

"(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients of the drug or of the route of administration, the dosage form, or strength which differ from the listed drug.

"(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds—

"(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

"(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

"(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug,

"(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

"(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

"(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

"(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

"(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

"(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

"(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

"(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

"(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

"(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are

unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

"(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

"(J) the application does not meet any other requirement of paragraph (2)(A); or

"(K) the application contains an untrue statement of material fact.

"(4)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

"(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

"(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

"(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

"(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the eighteen month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

"(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision, or

"(II) if before the expiration of such period the court decides that such patent has been 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.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of the forty-five-day period beginning on the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection containing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

"(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

"(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

"(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such

hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

"(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection and if the holder of the approved application certifies to the Secretary that no patent has ever been issued to any person for such drug or for a method of using such drug and that the holder cannot receive a patent for such drug or for a method of using such drug because in the opinion of the holder a patent may not be issued for such drug or for a method of using such drug for any known therapeutic purposes the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of four years from the date of the approval of the application under subsection (b) unless the Secretary determines that an adequate supply of such drug will not be available or the holder of the application approved under subsection (b) consents to an earlier effective date for an application under this subsection.

"(5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

"(A) for the same period as the withdrawal or suspension under subsection (e) of this paragraph, or

"(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

"(6)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

"(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;

"(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

"(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

"(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

"(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary the Secretary shall, in revisions made under clause (ii), include such information for such drug.

"(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

"(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

"(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (5), or

"(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

"(7) For purposes of this subsection:

"(A) 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.

"(B) A drug shall be considered to be bioequivalent to a listed drug if—

"(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

"(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.".

SEC. 102. (a)(1) Section 505(b) of such Act is amended by adding at the end the following: "The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such 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. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.".

(2) Section 505(c) of such Act is amended by inserting "(1)" after "(c)", by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and by adding at the end the following:

"(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such 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. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when the application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.".

(3)(A) The first sentence of section 505(d) of such Act is amended by redesignating clause (6) as clause (7) and inserting after clause (5) the following: "(6) the application failed to contain the patent information prescribed by subsection (b); or".

(B) The first sentence of section 505(e) of such Act is amended by redesignating clause (4) as clause (5) and inserting after clause (3) the following: "(4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or".

(b)(1) Section 505(a) of such Act is amended by inserting "or (j)" after "subsection (b)".

(2) Section 505(c) of such Act is amended by striking out "this subsection" and inserting in lieu thereof "subsection (b)".

(3) The second sentence of section 505(e) of such Act is amended by inserting "submitted under subsection (b) or (j)" after "an application".

(4) The second sentence of section 505(e) is amended by striking out "(j)" each place it occurs in clause (1) and inserting in lieu thereof "(k)".

(5) Section 505(k)(1) of such Act (as so redesignated) is amended by striking out "pursuant to this section" and inserting in lieu thereof "under subsection (b) or (j)".

(6) Subsections (a) and (b) of section 527 of such Act are each amended by striking out "505(b)" each place it occurs and inserting in lieu thereof "505".

SEC. 103. (a) Section 505(b) of such Act is amended by inserting "(1)" after "(b)", by redesignating clauses (1) through (6) as clauses (A) through (F), respectively, and by adding at the end the following:

"(2) An application submitted under paragraph (1) for a drug listed under subsection (j)(6) for which investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant or for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

"(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

"(i) that such patent information has not been filed,

"(ii) that such patent has expired,

"(iii) of the date on which such patent will expire, or

"(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

"(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant has given the notice required by subparagraph (B) to—

"(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(ii) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

"(B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.".

(b) Section 505(c) of such Act (as amended by section 102(a)(2)) is amended by adding at the end the following:

"(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:

"(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

"(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

"(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless an action is

brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the eighteen-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

"(i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision, or

"(ii) if before the expiration of such period the court decides that such 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.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of the forty-five-day period beginning on the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant or which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection and if the holder of the approved application certifies to the Secretary that no patent has ever been issued to any person for such drug or for a method of using such drug and that the holder cannot receive a patent for such drug or for a method of using such drug because in the opinion of the holder a patent may not be issued for such drug or for a method of using for any known therapeutic purposes such drug, the Secretary may not make the approval of another application for a drug for which investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant or which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of four years from the date of the approval of the application previously approved under subsection (b) unless the Secretary determines that an adequate supply of such drug will not be available or the holder of the application approved under subsection (b) consents to an earlier effective date for an application under this subsection.".

SEC. 104. Section 505 of such Act is amended by adding at the end the following:

"(l) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

"(1) if no work is being or will be undertaken to have the application approved,

"(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

"(3) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

"(4) if the Secretary has determined that such drug is not a new drug, or

"(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval

of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

"(m) For purposes of this section, the term 'patent' means a patent issued by the Patent and Trademark Office of the Department of Commerce.".

SEC. 105. (a) The Secretary of Health and Human Services shall promulgate, in accordance with the notice and comment requirements of section 553 of title 5, United States Code, such regulations as may be necessary for the administration of section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by sections 101, 102, and 103 of this Act; within one year of the date of enactment of this Act.

(b) During the period beginning on the date of the enactment of this Act and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new drug applications may be submitted in accordance with the provisions of section 314.2 of title 21 of the Code of Federal Regulations and shall be considered as suitable for any drug which has been approved for safety and effectiveness under section 505(c) of the Federal Food, Drug, and Cosmetic Act before the date of the enactment of this Act. If any such provision is inconsistent with the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall consider the application under the applicable requirements of such section. The Secretary of Health and Human Services may not approve such an abbreviated new drug application which is filed for a drug which is described in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act except in accordance with such section.

SEC. 106. Section 2201 of title 28, United States Code, is amended by inserting "(a)" before "In a case" and by adding at the end the following:

"(b) For limitations on actions brought with respect to drug patents see section 505 of the Federal Food, Drug, and Cosmetic Act.".

## TITLE II—PATENT EXTENSION

SEC. 201. (a) Title 35 of the United States Code is amended by adding the following new section immediately after section 155A:

**"§ 156. Extension of patent term**

"(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—

"(1) the term of the patent has not expired before an application is submitted under subsection (d) for its extension;

"(2) the term of the patent has never been extended;

"(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of subsection (d);

"(4)(A) in the case of a patent which claims the product or a method of using the product—

"(i) the product is not claimed in another patent having an earlier issuance date or which was previously extended, and

"(ii) the product and the use approved for the product in the applicable regulatory review period are not identically disclosed or described in another patent having an earlier issuance date or which was previously extended; or

"(B) in the case of a patent which claims the product, the product is also claimed in a patent which has an earlier issuance date or which was previously extended and which does not identically disclose or describe the product and—

"(i) the holder of the patent to be extended has never been and will not become the holder of the patent which has an earlier issuance date or which was previously extended, and

"(ii) the holder of the patent which has an earlier issuance date or which was previously extended has never been and will not become the holder of the patent to be extended;

"(5)(A) in the case of a patent which claims a method of manufacturing the product which does not primarily use recombinant DNA technology in the manufacture of the product—

"(i) no other patent has been issued which claims the product or a method of using the product and no other patent which claims a method of using the product may be issued for any known therapeutic purposes; and

"(ii) no other method of manufacturing the product which does not primarily use recombinant DNA technology in the manufacture of the product is claimed in a patent having an earlier issuance date;

"(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product—

"(i) the holder of the patent for the method of manufacturing the product (I) is not the holder of a patent claiming the product or a method of using the product, (II) is not owned or controlled by a holder of a patent claiming the product or a method of using the product or by a person who owns or controls a holder of such a patent, and (III) does not own or control the holder of such a patent or a person who owns or controls a holder of such a patent; and

"(ii) no other method of manufacturing the product primarily using recombinant DNA technology is claimed in a patent having an earlier issuance.

"(6) the product has been subject to a regulatory review period before its commercial marketing or use;

"(7)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; or

"(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; and

"(8) the patent does not claim another product or a method of using or manufacturing another product which product received permission for commercial marketing or use under such provision of law before the filing of an application for extension.

The product referred to in paragraphs (4), (5), (6), and (7) is hereinafter in this section referred to as the 'approved product'. For purposes of paragraphs (4)(B), (5)(B), the holder of a patent is any person who is the owner of record of the patent or is the exclusive licensee of the owner of record of the patent.

"(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

"(1) in the case of a patent which claims a product, be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

"(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred; and

"(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the approved product.

"(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—

"(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

"(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), and (3)(B)(i) of subsection (g); and

"(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years.

"(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law

under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain—

"(A) the identity of the approved product;

"(B) the identity of the patent for which an extension is being sought and the identification of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

"(C) the identity of every other patent known to the patent owner which claims or identically discloses or describes the approved product or a method of using or manufacturing the approved product;

"(D) the identity of all other products which have received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use and which are claimed in any of the patents identified in subparagraph (C);

"(E) information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);

"(F) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

"(G) such patent or other information as the Commissioner may require.

"(2)(A) Within sixty days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify—

"(i) the Secretary of Agriculture if the patent claims a drug product or a method of using or manufacturing a drug product and the drug product is subject to the Virus-Serum-Toxin Act, and

"(ii) the Secretary of Health and Human Services if the patent claims any other drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act,

of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than thirty days after the receipt of an application from the Commissioner, the Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(E) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

"(B)(i) If a petition is submitted to the Secretary making the determination under subparagraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary making the determination shall, in accordance with regulations promulgated by such Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than ninety days after the receipt of such a petition. The Secretary of Health and Human Services may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.

"(ii) The Secretary making a determination under clause (i) shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the sixty day period beginning on the publication of a determination, the Secretary making the determination to hold an informal hearing on the determination. If such a request is made within such period, such Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary who is holding the hearing shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, such Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.

"(3) For purposes of paragraph (2)(B), the term 'due diligence' means that degree of attention, continuous directed effort, and timeliness as may reasonably be expect-

ed from, and are ordinarily exercised by, a person during a regulatory review period.

"(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Commissioner.

"(e)(1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the information contained in the application for the extension. If the Commissioner determines that a patent is eligible for extension under subsection (a) and that the requirements of subsection (d) have been complied with, the Commissioner shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

"(2) If the term of a patent for which an application has been submitted under subsection (d) would expire before a determination is made under paragraph (1) respecting the application, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

"(f) For purposes of this section:

"(1) The term 'product' means:

"(A) A drug product.

"(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

"(2) The term 'drug product' means the active ingredient of a new drug, antibiotic drug, new animal drug, or human or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Virus-Serum-Toxin Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

"(3) The term 'major health or environmental effects test' means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

"(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

"(B) Any reference to section 503, 505, 507, 512, or 515 is a reference to section 503, 505, 507, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.

"(C) Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (21 U.S.C. 151–158).

"(5) The term 'informal hearing' has the meaning prescribed for such term by section 201(y) of the Federal Food, Drug, and Cosmetic Act.

"(6) The term 'patent' means a patent issued by the United States Patent and Trademark Office.

"(g) For purposes of this section, the term 'regulatory review period' has the following meanings:

"(1)(A) In the case of a product which is a drug product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a drug product is the sum of—

"(i) the period beginning on the date—

"(I) an exemption under subsection (i) of section 505, subsection (d) of section 507, or subsection (j) of section 512, or

"(II) the authority to prepare an experimental drug product under the Virus-Serum-Toxin Act,

became effective for the approved drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, 507, or 512 or the Virus-Serum-Toxin Act, and

"(ii) the period beginning on the date the application was initially submitted for the approved drug product under section 351, subsection (b) of such section 505, section 507, section 512, or the Virus-Serum-Toxin Act and ending on the date such application was approved under such section or Act.

"(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a food or color additive is the sum of—

"(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

"(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

"(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a medical device is the sum of—

"(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

"(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

"(4) A period determined under any of the preceding paragraphs is subject to the following limitations:

"(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

"(B) If the patent involved was issued before the date of the enactment of this section and—

"(i) no request for an exemption described in paragraph (1)(B) was submitted,

"(ii) no request was submitted for the preparation of an experimental drug product described in paragraph (1)(B),

"(iii) no major health or environmental effects test described in paragraph (2) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

"(iv) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted,

before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

"(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years.

"(h) The Commissioner may establish such fees as the Commissioner determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.".

(b) The analysis for chapter 14 of title 35 of the United States Code is amended by adding at the end thereof the following:

"156. Extension of patent term.".

SEC. 202. Section 271 of title 35, United States Code is amended by adding at the end the following:

"(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

"(2) It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

"(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1).

"(4) For an act of infringement described in paragraph (2)—

"(A) the court shall order the effective date of any approval of the drug involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

"(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug, and

"(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, or sale of an approved drug.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.".

SEC. 203. Section 282 of title 35, United States Code, is amended by adding at the end the following:

"Invalidity of the extension of a patent term or any portion thereof under section 156 of this title because of the material failure—

"(1) by the applicant for the extension, or

"(2) by the Commissioner,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.".

Amend the title so as to read: "A bill to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications and to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes.".

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## PURPOSE AND SUMMARY

### TITLE I

The purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962. Under current law, there is a generic drug approval procedure for pioneer drugs approved before 1962, but not for pioneer drugs approved after 1962.

Title I of the bill generally extends the procedures used to approve generic copies of pre-62 drugs to post-62 drugs. Generic copies

of any drugs may be approved if the generic is the same as the original drug or so similar that FDA has determined the differences do not require safety and effectiveness testing.

Title I also requires patent owners to submit information to FDA regarding produce and use patents that cover approved drugs. Generic copies of these drugs may be approved when the patents expire unless the generic company certifies that the patent is invalid or will not be infringed. In such cases, the generic company must notify the patent owner about its certification and approval of the generic drug may not be made effective until the court decides the suit for patent infringement or a period of 18 months, whichever occurs first. Notification must be given when the generic has submitted an ANDA with bioequivalence data.

In addition, Title I affords four years of exclusive market life to drugs which may not be patented and which are approved for the first time after enactment of the bill. Further, drugs which were approved for the first time between 1982 and the date of enactment received ten years of exclusive market life.

### TITLE II

The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval. The incentive is the restoration of some of the time lost on patent life while the product is awaiting pre-market approval. Under currrent law, a patent continues to run while the maker of the product is testing and awaiting apprc val to market it.

Title II of H.R. 3605 provides for one extension of the earliest patent on certain products subject to pre-market approval. The extension would be for a period equal to: (1) half of the time required to test the product for safety (and effectiveness in some cases); and (2) all of the time required for the agency to approve marketing of the product. These products include: human drugs, animal drugs, medical devices, and food and color additives.

Title II places several limits on the period of patent extension. First, the period of extension may not exceed two years for products either currently being tested or awaiting approval. For all other products, the period of extension may not exceed five years, Second, the period of patent extension when added to the patent time left after approval of the product may not exceed fourteen years. Third, any time that the product's manufacturer did not act with due diligence during the regulatory review period would be subtracted.

Finally, Title II provides that it is not an act of patent infringement for a generic drug maker to import or to test a patented drug in preparation for seeking FDA approval if marketing of the drug would occur after expiration of the patent.

## HEARINGS

The Committee's Subcommittee on Health and the Environment held one day of hearings on H.R. 3605, the Drug Price Competition Act, on July 15, 1983. Testimony was received from 15 witnesses,

representing nine organizations, with additional material submitted by two individuals and organizations.

## COMMITTEE CONSIDERATION

On August 2, 1983, the Committee's Subcommittee on Health and the Environment met in open session and ordered favorably reported H.R. 3605 without amendment by voice vote. On June 12, 1984, the Committee met in open session on H.R. 3605, amended the bill, and ordered it favorably reported by a voice vote. The title of the bill, as amended, is the "Drug Price Competition and Patent Term Restoration Act of 1984."

## BACKGROUND AND NEED FOR THE LEGISLATION

### TITLE I—ABBREVIATED NEW DRUG APPLICATIONS

Prior to 1962, the Federal Food, Drug and Cosmetic Act (FFDCA) required that all drugs be approved as safe before they could be marketed. The 1962 amendments required that all new drugs, generic and pioneer, must be approved as safe and effective prior to marketing.

As a result of the 1962 amendments, FDA did two things regarding pre-1962 drugs. First, the agency created the Drug Efficacy Study (DESI) to determine if all pre-1962 drugs were effective. Second, FDA established a policy permitting the approval of a generic drug equivalent to a safe and effective pre-1962 pioneer drug.

As a result of the 1962 amendments, the manufacturer of a pioneer drug must conduct tests on humans that show the product to be safe and effective and submit the results in a new drug application (NDA). A manufacturer of a generic drug must conduct tests that show the generic drug is the same as the pioneer drug and that it will be properly manufactured and labeled. This information is submitted in an abbreviated new drug application (ANDA).

The only difference between a NDA and an ANDA is that the generic manufacturer is not required to conduct human clinical trials. FDA considers such retesting to be unnecessary and wasteful because the drug has already been determined to be safe and effective. Moreover, such retesting is unethical because it requires that some sick patients take placebos and be denied treatment known to be effective.

The FDA allows this ANDA procedure only for pioneer drugs approved before 1962. There is no ANDA procedure for approving generic equivalents of pioneer drugs approved after 1962. While the FDA has been considering since 1978 an extension of the pre-1962 ANDA policy to post-1962 drugs, it has not extended the regulation. Because of the agency's failure to act, Title I of H.R. 3605 is necessary to establish a post-1962 ANDA policy.

Some have suggested that "Paper NDAs" be used to approve generic equivalents of pioneer drugs approved after 1962. Under the Paper NDA procedure, the generic manufacturer may submit scientific reports, instead of clinical trials, to support findings of safety and efficacy. This procedure is inadequate, however, because FDA estimates that satisfactory reports are not available for 85 percent of all post-1962 drugs.

Currently, there are approximately 150 drugs approved after 1962 that are off patent and for which there is no generic equivalent. All of these drugs could be approved in generic form if there was a procedure. Each year, more pioneer drugs go off patent and become available for approval as generics.

Among the drugs available or soon to be available for generic approval are five best sellers: valium, motrin, inderal, dyazide, and lasix. Dyazide, for example, is the most widely used diuretic for the treatment of high blood pressure. Its patent expired in 1981. Valium is a popular tranquilizer whose patent expires in 1985. Another drug whose patent has expired is indocin, an anti-inflammatory drug used in the treatment of arthritis that is the tenth highest selling drug in the United States.

The availability of generic versions of pioneer drugs approved after 1962 would save American consumers $920 million over the next 12 years. Older Americans, in particular, would benefit because they use almost 25 percent of all prescription drugs.

Moreover, the lack of generics for post-1962 pioneer drugs will cost Federal and State governments millions of dollars. For the drug metronidazole, purchased by the Department of Defense, the taxpayers saved approximately $1.2 million in one year as a result of the availability of a lower priced generic version. Federal and State governments will be denied comparable savings on drugs approved after 1962 because of the lack of an approval procedure.

## TITLE II—PATENT TERM RESTORATION

Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.

Although the patent term in the United States is 17 years, the period during the patent term in which products are marketed (the effective patent term) is usually less than 17 years because patents often are obtained before products are ready to be marketed.

Effective patent terms are influenced by many factors, including Federal premarketing and premanufacturing regulations. The products covered by these regulations include pharmaceuticals, medical devices, food additives, and color additives. Pharmaceuticals for instance cannot be marketed in the United States until they have been approved by the Food and Drug Administration (FDA). To obtain such approval, drugs must undergo extensive testing to prove they are both safe and effective. All these products are subject to different regulations that have had varying impacts on effective patent terms.

In testimony before several Congressional committees, representatives from the pharmaceutical firms that are heavily involved in basic research and rely upon patents, claimed that the average effective patent term of drugs has declined. They argued that a continuation of the decline would result in decreased expenditures for research and development and, eventually, in a decline in the introduction of new drugs.

As compensation for the loss of patent term due to government review, the research intensive firms argued for patent term extension legislation. They stated that the legislation would create a significant, new incentive which would result in increased expenditures for research and development, and ultimately in more innovative drugs.

### COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of Rule XI of the Rules of the House of Representatives, the Committee reports that oversight of the Food and Drug Administration and the Federal Food, Drug, and Cosmetic Act was conducted by the Subcommittee on Health and the Environment. A hearing was held on July 15, 1983. The findings of the Committee's oversight activities have been incorporated into the legislation and are discussed in those portions of this report entitled "Background and Need for the Legislation" and "Section-by-Section Analysis."

### COMMITTEE ON GOVERNMENT OPERATIONS

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Operations.

### COMMITTEE COST ESTIMATE

In compliance with clause 7(a) of rule XIII of the Rules of the House of Representatives, the Committee believes that the costs, if any, incurred in carrying out H.R. 3605 will be offset by savings to the Federal government. In testifying before the Committee's Subcommittee on Health and the Environment, officials from the Food and Drug Administration estimated that any greater workload resulting from the approval of generic drugs under Title I would be absorbed initially. Later, the officials estimated, some additional staff might be required to process generic drug applications. This additional staff could cost up to $1.1 million. The actual cost to the Federal government cannot be estimated because it is unknown how much additional staff, if any, might be hired.

Enactment of the legislation, however, will result in significant cost savings to the Federal government. Unlike the costs of H.R. 3605, these savings are certain. The Federal government spent about $2.4 billion for drugs in 1983. Many of these drugs will be available as low cost generic after enactment of H.R. 3605. For example, the Department of Defense saved approximately $1.2 million in one year when a lower priced generic version of metronidazole became available.

### CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clauses 2(l)(3) (B) and (C) of rule XI of the Rules of the House of Representatives, the Committee sets forth the following letter and cost estimate prepared by the Congressional Budget Office with respect to the reported bill:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
*Washington, DC, June 19, 1984.*

Hon. JOHN D. DINGELL,
*Chairman, Committee on Energy and Commerce,*
*House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has reviewed H.R. 3605, the Drug Price Competition and Patent Term Restoration Act of 1984, as ordered reported by the House Committee on Energy and Commerce on June 12, 1984.

Title I of this bill would allow drug manufacturers to use an abbreviated new drug application (ANDA) when seeking approval to make generic copies of drugs that were approved by the Food and Drug Administration (FDA) after 1962. An estimated 150 drug products approved after 1962 are currently off patent and would become available for generic copy using the ANDA procedure proposed in this bill.

The FDA estimates that the enactment of H.R. 3605 would at least triple the workload of the division responsible for approving ANDAs. Currently, this division reviews ANDAs for generic copies of pre-1962 approved drug products. The workload would increase as several manufacturers file an ANDA for each drug product that becomes available for generic copy. Because they would be reviewing information on new drugs, the FDA believes it would take them a year to process each of the new applications. This is about three months longer on average than it currently takes to process a pre-1962 ANDA. Dr. Marvin Seife, Director of FDA's Division of Generic Drug Monographs, testified before the Subcommittee on Health and the Environment that a greater workload could at first be absorbed, but may later require additional office space and 15 new FDA employees. Assuming an average full-time equivalent position plus overhead and fringe benefits is $70,000, the potential cost to the FDA of implementing this legislation could be about $1.1 million. The actual cost to the federal government would depend on the extent to which the FDA would expand to accomodate the increased workload.

Enactment of this legislation could also result in savings to both the federal and state and local governments. In fiscal year 1983, the federal government spent approximately $2.4 billion for drugs in the Medicaid program, and in veteran and military hospitals. Data on drug costs in the Medicare program are unavilable. If the federal government is currently purchasing these 150 copiable drug products at higher, brand name prices, savings may result if lower priced, generic copies of these drugs are substituted.

It is difficult to know in advance which of the available 150 drug products manufacturers would choose to copy. It is also difficult to estimate the price at which these generic copies would be sold. Generic versions of ten popular drug products show their price to be on average 50 percent less than their brand name equivalent. The dollar amount the federal government currently spents on these 150 brand name drug products is unknown.

Title II of this bill would extend the amount of time for which certain patents are issued to include some or all of the time re-

quired for a manufacturer to test a product for safety and efficacy and to receive marketing approval. Products affected by this legislation would be drugs, medical devices, and food and color additives. Manufacturers must show due diligence in their product testing or this amount of time will be subtracted from the total life of the patent. This provision would place an additional burden on the FDA. They would be responsible for keeping track of a manufacturer's product testing time and for determining their diligence in completing the testing. These costs, however, would be negligible.

Enactment of this bill could result in increased personnel costs to the federal government of approximately $1.1 million. The bill, however, does not specifically authorize additional appropriations for the FDA. This bill may also result in savings if cheaper, generic drugs are made available for purchase by the federal government. These savings would occur in various programs throughout the budget such as Medicare, Medicaid, and the Veterans Administration. However, the magnitude of these savings is unknown.

Please call me if I can be of additional assistance, or your staff may wish to contact Carmela Pena (226–2820) of our Budget Analysis Division for further details on this estimate.

Sincerely,

ERIC HANUSHEK
(For Rudolph G. Penner, Director).

## INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee makes the following statement with regard to the inflationary impact of the reported bill:

The Committee believes that enactment of H.R. 3605 will not have an inflationary impact upon the economy. In fact, Title I of the bill will have a deflationary effect because it makes available lower priced generic versions of drugs. Such generic drugs are three to fifteen times less costly than their brand name counterparts. The estimated $1 billion cost savings to consumers as a result of Title I's generic drug approval procedure will have a deflationary effect upon the national economy. While Title II of the bill provides for a limited extension of the patents on certain products, the Committee believes that the additional patent term will act as a spur to develop innovative and, ultimately, less costly treatments for diseases.

## SECTION-BY-SECTION ANALYSIS

### TITLE I—DRUG PRICE COMPETITION ACT

#### *Section 101*

Section 101 amends section 505 of the Federal Food, Drug and Cosmetic Act (FFDCA)[1] to establish a new subsection (J) providing for the approval of abbreviated new drug applications (ANDA). Paragraph (1) of subsection (j) sets forth the information which must be included in an ANDA.

[1] 21 U.S.C. 355.

*ANDA's for drugs which are the same*

In the case of drugs which are the same as the listed drug, the focus of the bill is to provide the Food and Drug Administration (FDA) with sufficient information to assure that the generic drug is the same as the listed drug [2] that has previously been determined to be safe and effective. Some have suggested that a generic drug must be identical in all respects to the listed drug instead of the same. The regulations that permit ANDA's for pre-1962 pioneer drugs make no such distinction.[3] In rejecting the use of the term identical, the FDA regulation comments that "identical means a product that is the same in dosage form, strength, and route of administration, contains the same active ingredient, and is recommended for use under the same conditions of use."[4] The Committee has adopted the FDA's policy of utilizing the term "same" except that the bill permits an ANDA to be approved for less than all of the indications for which the listed drug has been approved as explained below.

First, an ANDA must include sufficient information to show that the conditions of use for which the applicant is seeking approval are the same as those that have been previously approved for the listed drug. The applicant need not seek approval for all of the indications for which the listed drug has been approved. For example, if the listed drug has been approved for hypertension and angina pectoris, and if the indication for hypertension is protected by patent, then the applicant could seek approval for only the angina pectoris indication.

While the FDA's current regulations for considering ANDA's for pioneer drugs approved before 1962 permit an applicant to petition for approval for an indication other than that which has been approved for the pioneer drug, section 101 of the bill overturns that policy.[5] Thus, an ANDA may not be considered for a condition of use that has not been previously approved for the listed drug.

An ANDA must also contain sufficient information to show that the active ingredients of the generic drug are the same as those of the listed drug. If the listed drug has one active ingredient, then the active ingredient of the generic must be the same. If the listed drug has more than one active ingredient, then sufficient information must be included to show that all of the active ingredients in the generic drug are the same.

In addition, an ANDA must contain sufficient information to show that the route of administration, the dosage form and the strength of the generic drug are the same as those of the listed drug.

Further, an ANDA must include sufficient information to show that the generic drug is bioequivalent to the listed drug.

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[2] The term "listed drug" is explained in paragraph (6) of new section 505(j) of the FFDCA. Generally, a listed drug includes any drug that has been approved for safety and effectiveness or that has been approved under new subsection (j).

[3] 48 Fed. Reg. 2751 (1983).

[4] Id. at 2753.

[5] Id. at 2755.

21 C.F.R. 314.2(c) provides in part:

"A prospective applicant may seek a determination of the suitability of an abbreviated new drug application for a product that the applicant believes similar or related to a drug product that has been declared to be suitable for an abbreviated new drug application . . ."

Fifth, an ANDA must contain adequate information to show that the proposed labeling for the generic drug is the same as that of the listed drug. The Committee recognizes that the proposed labeling for the generic drug may not be exactly the same. For example, the name and address of the manufacturers would vary as might the expiration dates for the two products. Another example is that one color is used in the coating of the listed drug and another color is used in that of the generic drug. The FDA might require the listed drug maker to specify the color in its label. The generic manufacturer, which has used a different color, would have to specify a different color in its label.

Sixth, an ANDA must include a list of all the components of the generic drug, a description of the composition of the generic drug, a description of the methods and controls used in the manufacture, processing and packing of the generic drug, samples of the generic drug and its components, and specimens of the proposed labeling.

Seventh, an ANDA must include a certification by the applicant regarding the status of certain patents applicable to the listed drug if the patent information has been submitted under section 505 (b) or (c). With respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug for which the applicant is seeking approval (hereafter described as a controlling use patent), the applicant must certify, in his opinion and to the best of his knowledge, as to one of four circumstances.

The applicant may certify that the patent information required under sections 505 (b) and (c) has not been submitted if that is the case. If appropriate, the applicant may certify that one or more of the product or controlling use patents provided have expired. Third, the applicant may certify when appropriate that one or more of the product or controlling use patents will expire at some specified date in the future. When the applicant makes these certifications, it must rely upon the patent information supplied to the FDA. Last, an applicant may certify if applicable that one or more of the product or controlling use patents are invalid or will not be infringed.

The Committee recognizes that in some instances an applicant will have to make multiple certifications with respect to product or controlling use patents. For example, if the product patent has expired and a valid controlling use patent will not expire for three years, then the applicant must certify that one patent has expired and the other will expire in three years. The Committee intends that the applicant make the appropriate certification for each product and controlling use patent.

Eighth, if there are indications which are claimed by any use patent and for which the applicant is not seeking approval, then an ANDA must state that the applicant is not seeking approval for those indications which are claimed by such use patent. For example, the listed drug may be approved for two indications. If the applicant is seeking approval only for indication No. 1, and not indication No. 2 because it is protected by a use patent, then the applicant must make the appropriate certification and a statement explaining that it is not seeking approval for indication No. 2.

Finally, the Committee intends that an ANDA contain any information available to the applicant regarding reports of adverse ef-

fects not reflected in the labeling, an environmental impact analysis pursuant to FDA regulations, statements regarding the protection of human subjects in clinical investigations as required by FDA regulations, and a statement regarding compliance with good laboratory practices in non-clinical investigations as required by FDA regulations.[6]

*ANDA's for drugs which are different*

Paragraph (2)(C) prohibits any person from submitting an ANDA for a generic drug which differs from the listed drug unless the change is permitted by the statute and the FDA has granted a petition requesting the change.

If an applicant wishes to vary the route of administration, dosage form or strength of the generic drug from the listed drug, it must first petition the FDA for permission to file an ANDA for the differing generic drug. In addition, an applicant may request to vary one of the active ingredients in the generic drug from the listed drug when the listed drug is a combination product. The remaining active ingredients of the generic drug must be the same as the other active ingredients of the listed drug.

These are the only changes from the listed drug for which an applicant may petition. As is explained in the ANDA regulations for pre-1962 drugs, the Committee generally expects that approval of petitions will "ordinarily be limited to dosage forms for the same route of administration or to closely related ingredients."[7] If the FDA grants a petition for a change from the listed drug, the FDA may require such additional information in the ANDA regarding the change as it deems necessary.

The FDA must approve a petition to submit an ANDA for a differing generic drug unless clinical studies are needed to show the safety and effectiveness of the change. In reviewing a petition to change one of the active ingredients in a combination product, the Committee does not intend to change the FDA's current policy regarding the evaluation of the safety and effectiveness of combination products. If the FDA finds that safety and effectiveness testing of the active ingredients of the drug, individually or in combination, is required, then the FDA must deny the petition.

The FDA must either approve or disapprove a petition within 90 days of its submission. As is the case under the current regulations, "there is no legal requirement that the hearing opportunity provided by section 505(c) be made available to ANDA applicants who disagree with an adverse agency decision" on whether clinical studies are needed to show the safety and effectiveness of the differing generic drug.[8] "Appropriate review of such decisions may be had . . . under the applicable standard—that applicable to administrative decisionmaking generally—which is whether the agency's decision is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law (5 U.S.C. 706(2)(A)))."[9] If the FDA

[6] Id. at 2756. *See* 21 CFR 314.2(f) (4), (5). (6), (7), and (8).
[7] Id. at 2755. See 21 CFR 314.2(c).
[8] Id. at 2752.
[9] Id.

does not approve a petition, then an ANDA may not be filed for a generic drug that varies from the listed drug.

An ANDA for a drug which differs from the listed drug and for which a petition has been approved by the FDA must contain such additional information regarding the difference as the FDA may require when it granted the petition. For example, if the route of administration of the generic drug differs from that of the listed drug, then the FDA may require such additional information on that change as it deems necessary.

If the FDA approves a petition permitting an applicant to vary one of the active ingredients of a generic drug from those of the listed combination drug, the ANDA must contain sufficient information to show that the active ingredients of the generic drug (including the varying active ingredient) are of the same pharmacological or therapeutic class as those of the listed drug. In addition, the differing generic drug must be expected to have the same therapeutic effect when administered to patients for an approved condition of use.

An example of such a change in one of the active ingredients that the FDA might find acceptable is the substitution of acetaminophen for aspirin in a combination product. Another example might be the substitution of one antihistamine for another. The active ingredient, which the applicant wishes to vary and which the FDA has granted a petition, must have been approved for safety and effectiveness or must not be within the requirements of section 201(p) of FFDCA.[10]

*Certification of invalidity of noninfringement of a patent*

When an applicant certifies that any product or controlling use patent is invalid or will not be infringed, paragraph (2)(B) requires that it must give notice of such certification to either the owner of the patent or the representative of the patent owner that was designated when the patent information was submitted under section 505(b) or (c) of the FFDCA. The FDA may, by regulation, establish a procedure for designating in the NDA the representative of the patent owner. In addition, notice of the certification must be given to the holder of the approved New Drug Application (NDA) for the drug which is claimed by a product patent or the use of which is claimed by a use patent.

This notice must be given simultaneously with the submission of an ANDA. The Committee does not intend that applicants be permitted to circumvent this notice requirement by filing sham ANDA's or ANDA's which are substantially incomplete. The Committee intends that the applicant must have made a good faith effort to meet the requirements set forth in paragraph (2)(A) regarding the contents of an ANDA.

While the Committee does not intend that failure to include a minor piece of information in an ANDA vitiates the effectiveness of the notice required under paragraph (2)(B), an ANDA must in-

[10] 21 U.S.C. 321(p). For example, a drug marketed prior to 1938 and unchanged is a "grandfathered drug" and thus not within the scope of the definition of "new drug" set forth in section 201(p) of the FFDCA. Another example of a drug outside the scope of section 201(p) is a product that is generally recognized as safe and effective and that has been used to a material extent or for a material time.

clude the results of any required bioavailability or bioequivalence tests. Failure to include the results of such tests when required will void the effectiveness of any notice under paragraph (2)(B). Notice must then be given again when an ANDA with any required bioavailability or bioequivalence data is submitted to the FDA.

When the applicant gives notice of the certification of patent invalidity or non-infringement, the notice must state that an ANDA has been submitted to obtain approval of the drug to engage in the commercial manufacture, use or sale of the generic drug before the expiration of the patent which has been certified as invalid or non-infringed.

If an ANDA is amended after submission to include a certification that a product patent or controlling use patent is invalid or not infringed, then the notice of such certification must be given to the appropriate parties when the amended application is submitted.

*Grounds for disapproval of an ANDA*

Paragraph (3) provides that the FDA shall approve an ANDA except in one of the following circumstances.

First, the FDA shall not approve an ANDA if the methods used in, or the facilities and controls used for, the manufacture, processing and packing of the generic drug are inadequate to assure and preserve its identity, strength, quality and purity.

Second, an ANDA shall not be approved if it does not contain adequate information to show that each of the conditions for use for the generic drug have been previously approved for the listed drug. If an ANDA includes a condition for use for which the listed drug has not been approved, then the generic drug may not be approved.

Third, an ANDA must be disapproved if the active ingredient of the generic drug is not the same as that of the listed drug and the listed drug has only one active ingredient. An ANDA must also be disapproved if any of the active ingredients in the generic drug are not the same as those of the listed drug unless a petition regarding a change in one of the active ingredients has been granted. If the listed drug is a combination product and a petition permitting a change in one of the active ingredients in the generic drug has been granted, then the ANDA must be disapproved if the other active ingredients of the generic drug are not the same as those of the listed drug. Further, ANDA must be disapproved in such a circumstance if the different active ingredient in the generic drug is not a listed drug or if the different active ingredient is a drug within the requirements of section 201(p) of the FFDCA.

Fourth, an ANDA for a drug which is the same must be disapproved if it does not show that the route of administration, dosage form, or strength of the generic drug are all the same as those of the listed drug. If the route of administration, dosage form, or strength of the generic drug differs from that of the listed drug, an ANDA must be disapproved if no petition regarding the change was granted.

Fifth, an ANDA must be disapproved if the generic drug differs from the listed drug and a petition regarding the change has been

granted, but the ANDA does not contain all of the additional information that the FDA required in granting the petition.

A sixth ground requiring disapproval of an ANDA for a generic drug whose active ingredients are the same as those of the listed drug is that there is unsufficient information to show that the generic drug is bioequivalent to the listed drug. If a petition regarding a change in one of the active ingredients in a combination generic drug has been granted, then the ANDA must be disapproved if the application fails to show that the active ingredients of the generic drug are of the same pharmacological or therapeutic class as those of the listed drug. In addition, such an ANDA must be disapproved if it fails to show that the differing generic combination drug can be expected to have the same therapeutic effect as the listed combination product when administered to patients for an approved condition of use.

Seventh, an ANDA must also be disapproved if it fails to show that the proposed labeling for the generic drug is the same as that of the listed drug. Changes in the proposed labeling due to the fact that the generic drug is produced or distributed by a different manufacturer are not a grounds for disapproval. Similarly, changes in the proposed labeling of the generic drug because a petition regarding a change has been granted is not a grounds for disapproval.

Eighth, an ANDA must be disapproved if it or any other information before the FDA shows that the inactive ingredients of the generic drug are unsafe for use under the conditions prescribed, recommended, or suggested in the proposed labeling for the generic drug. An ANDA must also be disapproved if the composition of the generic drug is unsafe under approved conditions of use. For example, the composition of the generic drug might be unsafe because of the type or quantity of the inactive ingredient included or because of the manner in which the inactive ingredient was included.

Ninth, an ANDA may not be approved if the approval of the listed drug has been withdrawn or suspended for reasons of safety or effectiveness under section 505(e) (1)–(4) of the FFDCA.[11] The ANDA may also not be approved if the FDA determines that the listed drug has been voluntarily withdrawn from the market for safety or effectiveness reasons. The Committee recognizes that the maker of a listed drug might withdraw it from the market without specifying the reason or without articulating safety or effectiveness concerns. For this reason, the Committee authorized the FDA to examine whether safety or effectiveness concerns were one of the reasons for the voluntary withdrawal of the drug from the market. IF the FDA so finds, then an ANDA for a generic version of that drug may not be approved.

Tenth, an ANDA may not be approved if it does not meet any of the requirements set forth in paragraph (2)(A). For example, an ANDA that does not contain the certifications regarding patents required in paragraph (a)(A)(vii) cannot be approved.

Last, an ANDA may not be approved if it contains any untrue statement of material fact.[12]

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[11] 21 U.S.C. 352(e)(1)–(4).

[12] See Untrue statements in application, 21 C.F.R. 314.12 (1982).

*Approval of an ANDA*

Paragraph (4)(A) requires the FDA to approve or disapprove an ANDA within 180 days of initial receipt of the application. The Committee recognizes that extensions may be necessary so the bill permits extensions of this period for so long as the applicant and the FDA may agree upon.

*Effectiveness of an ANDA approval*

The Committee recognizes that some ANDA's will be submitted and ready for approval before the patent on the listed drug has expired. To deal with this situation and to assure that the FDA concerns itself solely with the safety and effectiveness of the generic drug, paragraph (4)(B) permits the FDA to approve an ANDA but make the approval effective at some later date when appropriate.

If the applicant certified in an ANDA that no patent information was supplied or that the relevant patents have expired, then the approval of the ANDA may be made effective immediately. If the applicant certified based upon the submitted patent information that the patent or patents would expire in one year, then an ANDA may be approved and the approval made effective in one year.

If the applicant certified that one or more of the product or controlling use patents were invalid or not infringed, then approval of the ANDA may be made effective immediately except in the following situation. If within 45 days after notice of the certification of invalidity or non-infringement is received, an action for patent infringement regarding one or more of the patents subject to the certification is brought,[13] then approval of the ANDA may not be made effective immediately. Instead, approval of the ANDA may not be made effective until 18 months after the notice of the certification was provided unless a district court has decided a case for patent infringement earlier. Once either of these events occurs and the approval of the ANDA becomes effective, then the FDA has discharged its statutory responsibility with respect to making the approval of the generic drug effective.

Each party to the action has an affirmative duty to reasonably cooperate in expediting the action. If the plaintiff breaches that duty, the court may shorten the 18 month period as it deems appropriate. If the defendant breaches that duty, the court may extend the 18 month period as it deems appropriate.

If the court decides that the patent is invalid or not infringed before the expiration of the 18 month period (or such shorter or longer period as the court decides), then the approval may be made effective on the date of the court decision. If the court decides that the patent is valid or infringed before the expiration of the 18 month period, then the approval may be made effective on such data as the court orders. The Committee wishes to emphasize that the court may not order an ANDA approved under this provision.

[13] The Committee recognizes that, in certain instances, the patent owner may agree with the certification of the applicant. For example, when the applicant certifies that patent No. 1 is invalid and patent No. 2 is not infringed, the patent owner may agree with the certification regarding patent No. 2. Then an action for patent infringement need only be brought with respect to patent No. 1.

These are times when approval of an ANDA may be made effective if the FDA has approved the ANDA.

This additional remedy permits the commencement of a legal action for patent infringement before the generic drug maker has begun marketing. The Committee believes this procedure fairly balances the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights of third parties to contest the validity of a patent or to market a product which they believe is not claimed by the patent.

The provisions of this bill relating to the litigation of disputes involving patent validity and infringement are not intended to modify existing patent law with respect to the burden of proof and the nature of the proof to be considered by the courts in determining whether a patent is valid or infringed.

Concern has been expressed that permitting an applicant to market its drug at the conclusion of the 18 month period and possibly before the resolution of the patent infringement suit overturns the statutory presumption of a patent's validity. On the contrary, the Committee intends that a patent would have the same statutory presumption of validity as is afforded under current law.

In most instances, an ANDA will contain multiple certifications. The FDA should make approval of the ANDA effective upon the last certification. For example, if an ANDA contains a certification that a product patent is expired and a controlling use patent will expire in three years, then the FDA must make approval of the ANDA effective in three years. In the case where the patent certification is amended in an ANDA to allege invalidity or non-infringement of a patent, the FDA may not make the approval effective within the 45 day period that an action for patent infringement may be brought.

No action for a declaratory judgment regarding the patent at issue may be brought before the expiration of the 45 day period commencing with the provision of notice of the certification of patent invalidity or non-infringement. Any suit for declaratory judgment after the 45 day period must be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

*Subsequent ANDA's certifying patent invalidity or noninfringement*

If an ANDA certifying patent invalidity or non-infringement is filed subsequent to an ANDA for the same listed drug that has made the same certification of invalidity or non-infringement, paragraph (4)(B)(iv) provides that the approval of the subsequent ANDA may not be made effective sooner than 180 days after the previous applicant has begun commerical marketing, or the date on which the court holds the patent invalid or not infringed, whichever occurs first. In the event of multiple ANDA's certifying patent invalidity or non-infringement, the courts should employ the existing rules for multidistrict litigation, when appropriate, to avoid hardship on the parties and witnesses and to promote the just and efficient conduct of the patent infringement actions.[14]

[14] 28 U.S.C. 1407.

*Disapproval of an ANDA*

If the FDA decides to disapprove an ANDA, paragraph (4)(C) provides that the FDA must give the applicant notice of the opportunity for a hearing on the issue of the approvability of the ANDA. To avail itself of this hearing, the applicant must submit a written request within 30 days of the notice. If a hearing is requested, it must begin not later than 120 days after the notice. However, the hearing may be held later if both the applicant and the FDA agree. The hearing shall be conducted on an expedited basis. The FDA's order regarding the hearing shall be issued within 90 days after the date for filing final briefs.

*Transition rule*

Paragraph (4)(D)(i) provides that the FDA may not make effective the approval of an ANDA for a drug including an active ingredient (including any ester or salt of the active ingredient) which was approved for the first time in an NDA between January 1, 1982 and the date of enactment of this bill until 10 years after the date of approval of the NDA. For example, if active ingredient X was approved in a drug for the first time in 1983, when the approval of an ANDA for a drug containing active ingredient X could not be made effective until 1993.

*Unpatentable drugs*

If the active ingredient (including any ester or salt of the active ingredient) of a drug is approved for the first time in an NDA after the enactment of this bill, then paragraph (4)(D)(ii) provides that the FDA may not make the approval of an ANDA for a drug which contains the same active ingredient effective until four years after the approval of the NDA if the following conditions are met.

First, the holder of the NDA must certify that no patent has ever been issued to any person for such drug or for a method of using such drug. Second, the holder must certify that it cannot receive a patent for such drug or for a method using such drug for any known therapeutic purpose. In determining whether a drug meets these two patent stipulations, the FDA may rely upon the certifications of the NDA holder.

If the FDA determines at any time during the four year period that an adequate supply of the drug will not be available, it may make the approval of an ANDA effective before the expiration of the four year period. The FDA may also make the approval of an ANDA for such drug effective before the four year period if the holder of the NDA consents.

*Withdrawal or suspension of listed drug's approval*

Paragraph (5) provides that the approval of an ANDA is withdrawn or suspended if approval of the listed version of the generic drug has been withdrawn or suspended for safety or effectiveness reasons as set forth in section 505(e) (1)–(4) of the FFDCA. The approval of an ANDA is also withdrawn or suspended if it refers to a drug whose approval is withdrawn or suspended under section 505(j)(5) of the FFDCA. In addition, the approval of an ANDA is withdrawn or suspended if the FDA determines that the listed

drug has been voluntarily withdrawn from sale due to safety or effectiveness concerns.

The Committee recognizes that the maker of a listed drug might withdraw it from the market without specifying the reason or without articulating safety or effectiveness concerns. For this reason, the Committee authorized the FDA to examine whether safety or effectiveness concerns were one of the reasons for the voluntary withdrawal of the drug from the market. If the FDA so finds, then the approval of an ANDA for a generic version of that drug must be withdrawn or suspended.

The ANDA must be withdrawn or suspended from sale for the same period as the approval of the drug to which it refers has been withdrawn or suspended. When the listed drug has been voluntarily withdrawn from the market and the FDA has determined that the listed drug was withdrawn due to safety or effectiveness reasons, then the approval of the ANDA must be withdrawn until such time as the FDA determines that the listed drug was not withdrawn from sale for safety or effectiveness reasons.

*Listings of drugs*

Within 60 days after enactment of this bill, Paragraph (6) requires the FDA to publish and to make available a list of drugs eligible for consideration in an ANDA. The list must include the official and proprietary name of each drug that has been approved for safety and effectiveness prior to the date of enactment of the bill. The list must be in alphabetical order. If the drug was approved after 1981, the list must include the date of approval of the drug and the NDA number. Third, the list must specify whether in vitro or in vivo bioequivalence studies, or both, are required for ANDA's.

At 30-day intervals, the FDA must update the list to include drugs that have been approved for safety and effectiveness after enactment of H.R. 3605 and drugs approved in ANDA's under this subsection. In addition, the FDA must integrate into the list patent information submitted under sections 505 (b) and (c) of the FFDCA as it becomes available.

A drug approved for safety and effectiveness under section 505(c) or under subsection (j) shall be considered as published and thus eligible for approval in an ANDA on the date of its approval or the date of enactment, whichever is later.

Paragraph (6)(C) provides a drug may not be listed as eligible for consideration in an ANDA if the approval of the pioneer drug is withdrawn or suspended for safety or effectiveness reasons as set forth in section 505 (e)(1)–(4) of the FFDCA or if approval of the generic drug was withdrawn or suspended under Section 505(j)(5) of the FFDCA. In addition, a drug may not be listed if the FDA determines that the drug has been voluntarily withdrawn from sale due to safety or effectiveness concerns. If such a drug has already been listed, then it must be immediately removed from the list.

The Committee recognizes that the maker of a listed drug might withdraw it from the market without specifying the reason of without articulating safety or effectiveness concerns. For this reason, the Committee authorized the FDA to examine whether safety or effectiveness concerns were one of the reasons for the voluntary withdrawal of the drugs from the market. If the FDA so finds, then

the drug may not be listed. Persons adversely affected by this decision may seek judicial review under Title 5 of the United States Code.

A drug may not be listed as long as its approval is withdrawn or suspended. If the drug has been voluntarily withdrawn from the market, then the drug may not be listed until the FDA determines that the drug was not withdrawn from sale for safety or effectiveness reasons. A notice regarding the removal of any drug from the list must be published in the Federal Register.

*Bioavailability and bioequivalence studies*

As used in this bill, 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.[15]

A drug shall be considered bioequivalent to a listed drug if the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses. A generic drug shall also be considered to be bioequivalent to a listed drug if the extent of absorption of the generic drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the generic drug is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.[16]

*Section 102*

Section 102 of the bill requires that certain patent information be filed with all new NDA's and with all NDA's previously filed but not yet approved. Pending and future NDA's may not be approved unless they contain the appropriate patent information. The FDA shall publish the patent information upon approval of the NDA.

This section also requires that any previously approved NDA be amended within 30 days of enactment of this bill to include certain patent information. The FDA shall publish the patent information upon its submission. An NDA may be revoked if the patent information available is advisable and is not filed within 30 days after receipt of a written notice from the FDA specifying the failure to provide the patent information.

The patent information to be filed includes the patent number and the expiration date of any patent which claims the drug in the NDA or which claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted

[15] See Definition of Bioavailability, 21 C.F.R. 320.1(a) (1982).
[16] See Definition of Bioequivalent Drug Products, 21 C.F.R. 320.1(e) (1982).

if a person not licensed by the owner engaged in the manufacture, sale or use of the drug. Patents which claim a method of manufacturing such drug are not required to be submitted.

Finally, section 102 makes a number of technical changes.

*Section 103*

Section 103 amends section 505(b) of the FFDCA to require an applicant filing a Paper NDA's for a listed drug under section 505(j)(6) to make the same certifications regarding patents as mandated in the filing of ANDA's under new subsection (j) of the FFDCA. In addition, the FDA must make approvals for such Paper NDA's effective under the same conditions that apply to ANDA's submitted under subsection (j). Finally, section 103 applies the 10 year transition rule and the 4 year unpatentable substances rule to Paper NDA's.

*Paper NDA's*

Paper NDA's are defined as any application submitted under section 505(b) of the FFDCA in which the investigations relied upon by the applicant to show safety and effectiveness were not conducted by or for the applicant and the applicant has not obtained a right of reference or use from the person who conducted the studies or for whom the studies were conducted.

*Patent certifications in paper NDA's for listed drugs*

When a Paper NDA's is submitted for a listed drug under section 505(j)(6), it must include a certification by the applicant regarding the status of certain patents applicable to the listed drug if such information has been provided to the FDA. With respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug for which the applicant is seeking approval (hereafter described as a controlling use patent), the applicant must certify, in his opinion and to the best of his knowledge, as to one of four circumstances.

First, the applicant may certify that the patent information required under sections 505 (b) and (c) has not been submitted if that is the case. Second, if appropriate, the applicant may certify that one or more of the product or controlling use patents provided have expired. Third, the applicant may certify when appropriate that one or more of the product or controlling use patents will expire at some specified date in the future. When the applicant makes these certifications, it must rely upon the patent information supplied to the FDA. Last, an applicant may certify if applicable that one or more of the product or controlling use patents are invalid or will not be infringed.

The Committee recognizes that in some instances an applicant will have to make multiple certifications with respect to product and controlling use patents. For example, if the product patent has expired and valid controlling use patent will not expire for three years, then the applicant must certify that one patent has expired and the other will expire in three years. The Committee intends that the applicant make the appropriate certification for each product and controlling use patent.

Every Paper NDA for a listed drug must also state, when applicable, that the applicant is not seeking approval for an indication which is claimed by any use patent for which it has not made a certification. For example, the listed drug may be approved for two indications. If the applicant is seeking approval only for indication No. 1, and not indication No. 2 because it is protected by a use patent, then the applicant must make the appropriate certifications and a statement explaining that it is not seeking approval for indication No. 2.

*Certification of invalidity or noninfringement of a patent*

When an applicant certifies that any product or controlling use patent is invalid or will not be infringed, section 505(b)(3) requires that it must give notice of such certification to either the owner of the patent or the representative of the patent owner that was so designated when the patent information was submitted under section 505 (b) or (c) of the FFDCA. The FDA may, by regulation, establish a procedure for designating in the NDA the representaitve of the patent owner. In addition, notice of the certification must be given to the holder of the approved New Drug Application (NDA) for the drug which is claimed by the product patent or the use of which is claimed by the use patent.

This notice must be given simultaneously with the submission of a Paper NDA. The Committee does not intend that applicants be permitted to circumvent this notice requriement by filing sham Paper NDA's or Paper NDA's which are substantially incomplete. The Committee intends that the applicant must have made a good faith effort to meet the requirements regarding the contents of a Paper NDA as set forth in section 505(b) of FFDCA.

When the applicant gives notice of the certification of invalidity or non-infringement, the notice must state that a Paper NDA has been submitted to obtain approval of the drug to engage in the commercial manufacture, use or sale of the generic drug before the expiration of the patent which has been certified as invalid or non-infringed.

If a Paper NDA is amended after submission to include a certification that a product patent or controlling use patent is invalid, then the notice of such certification must be given to the appropriate parties when the amended application is submitted.

*Effectiveness of approval of a paper NDA for a listed drug*

The Committee recognizes that some Paper NDA's for listed drugs will be submitted and ready for approval before the patent on the listed drug has expired. To deal with this situation and to assure that the FDA concerns itself solely with the safety and effectiveness of the generic drug, section 505(c)(3) requires the FDA to approve a Paper NDA but make the approval effective at some later date when appropriate.

If the applicant certified in the Paper NDA that no patent information was supplied or that the relevant patents have expired, then the approval of the Paper NDA may be made effective immediately. If the applicant certified based upon the submitted patent information that the patent would expire in one year, then the

Paper NDA may be approved and the approval made effective in one year.

If the applicant certified that one or more of the product of controlling use patents were invalid or not infringed, then approval of the Paper NDA may be made effective immediately except in the following situation. If within 45 days after notice of the certification of invalidity or non-infringement is received, an action for patent infringement regarding one or more of the patent subject to the certification is brought,[17] then approval of the Paper NDA may not be made effective immediately. Instead, approval of the Paper NDA may not be made effective until 18 months after the notice of the certification was provided.

Each party to the action has an affirmative duty to reasonably cooperate in expediting the action. If the plaintiff breaches that duty, the court may shorten the 18 month period as it deems appropriate. If the defendent breaches that duty, the court may extend the 18-month period as it deems appropriate.

If the court decides that the patent is invalid or not infringed before the expiration of the 18-month period (or such shorter or longer period as the court decides), then the approval may be made effective on the date of the court decision. If the court decides that the patent invalid or infringed before the expiration of the 18 month period, then the approval may be made effective on such date as the court orders. The Committee wants to emphasize that the court may not order the Paper NDA approved. These are times when the approval of a Paper NDA may be made effective if the FDA has completed its review of the Paper NDA.

No action for a declaratory judgment regarding the patent at issue may be brought before the expiration of the 45 day period commencing with the provision of notice of the certification of patent invalidity or non-infringement. After the 45 day period, any suit for declaratory judgment regarding the patent at issue must be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

*Transition rule*

Section 505(c)(3)(D)(i) provides that the FDA may not make effective the approval of a Paper NDA for a drug which contains an active ingredient (including any ester or salt of the active ingredient) which was approved for the first time in an NDA between January 1, 1982 and the date of enactment of this bill until 10 years after the date of approval of the NDA. For example, if active ingredient X was approved in a drug for the first time in 1983, then the approval of a Paper NDA for a drug containing active ingredient X could not be made effective until 1993.

*Unpatentable drugs*

If the active ingredient (including any ester or salt of the active ingredient) of a drug is approved for the first time in an NDA after

[17] The Committee recognizes that in certain instances, the patent owner may agree with the certification of the applicant. For example, when the applicant certifies that patent No. 1 is invalid and patent No. 2 is not infringed, the patent owner may agree with the certification regarding patent No. 2. Then an action for patent infringement need only be brought with respect to patent No. 1.

the enactment of this bill, then section 505(c)(3)(D)(ii) provides that the FDA may not make the approval of a Paper NDA for a drug which contains that active ingredient effective until four years after the approval of the NDA if the following conditions are met.

The holder of the NDA must certify that no patent has ever been issued to any person for such drug or for a method of using such drug. Further, the holder must certify that he cannot receive a patent for such drug or for a method using such drug for any known therapeutic purpose.

If the FDA determines at any time during the four year period that an adequate supply of the drug will not be available, it may make the approval of a Paper NDA effective before the expiration of the four year period. The FDA may also make the approval of a Paper NDA for the drug effective before the four year period if the holder of the NDA consents.

*Section 104*

Section 104 amends section 505 of the FFDCA to add a new subsection (1). This new subsection provides that safety and effectiveness information that has been submitted in an NDA and which has not been previously disclosed to the public shall be made available to the public upon request under the following circumstances unless extraordinary circumstances are shown.

First, the safety and effectiveness information and data shall be disclosed upon request if the NDA has been abandoned. Second, such information and data shall be made available upon request if the FDA has determined that the NDA is not approvable and all legal appeals have been exhausted. Third, the data and information shall be released upon request if the approval of the NDA under section 505(c) of the FFDCA has been withdrawn and all legal appeals have been exhausted. Fourth, such information and data shall be released upon request if the FDA has determined that the drug which is the subject of the NDA is not a new drug.

These conditions under which such safety and effectiveness data shall be released upon request, unless extraordinary circumstances are shown, are merely a restatement of the current regulation. The Committee intends that all terms in new section 505(1) be given the same meaning that they have in the regulation.[18] It is not the intent of the Committee to alter the rights of the public under the Freedom of Information Act.

The Committee does intend, however, to clarify the interpretation of 21 C.F.R. 314.14(f)(5).[19] In this circumstance, safety and ef-

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[18] See Confidentiality of data and information in a new drug application (NDA) file, 21 C.F.R. 314.14(f)(1)–(4) (1982).

[19] 21 C.F.R. 314.14(f)(5) provides:

"(5) A final determination has been made that the drug may be marketed without submission of such safety and/or effectiveness data and information."

The Committee was concerned that this provision of the regulation might be interpreted as permitting the disclosure of such information and data upon enactment of this bill. This is because all drugs approved for safety and effectiveness prior to enactment of this bill are deemed listed and thus eligible for consideration in an ANDA upon enactment of the bill. The Committee wished to avoid any possibility that listing of a drug under this bill would be deemed a final determination that the drug could be approved without the submission of safety and effectiveness information.

fectiveness data and information may be released upon the effective date of the first approval of an ANDA for such drug under new subsection (j) of section 505 of the FFDCA. Further, the information and data may be released on the date upon which an approval of an ANDA could be made effective if an ANDA had been submitted. The Committee recognizes that an ANDA may not be submitted for all drugs that are eligible for approval as generics. To deal with that possibility, the Committee intends to make available this data when the approval of an ANDA would have become effective.

The Committee does not intend that any safety and effectiveness data and information be released pursuant to this section during the 30 day perioid after enactment of this bill when patent information must be submitted under section 505(b) or (c). Otherwise, ANDA's filed during that period could be approved effective immediately, thus allowing for the disclosure of safety and effectiveness information and data for those drugs.

The Committee also does not intend that safety and effectiveness data and information be released under this section if an ANDA challenging the validity of a patent is approved before there has been a court decision holding the patent invalid and if the NDA holder brings an action to restrain the disclosure.

Finally, except as provided in this section, the Committee does not intend to change other regulations regarding Freedom of Information Act requests, trade secrets, and confidentiality of IND, NDA and master file safety and effectiveness information and data.

Section 104 also adds a new subsection (m) to Section 505 of the FFDCA. This provision clarifies that any reference to patent information in Section 505 applies only to patents issued by the Patent and Trademark Office of the Department of Commerce. It does not include any patents issued by foreign governments.

*Section 105*

Section 105(a) of the bill requires the FDA to promulgate such regulations as are necessary to implement new subsection (j). These regulations must be promulgated in accordance with the informal rulemaking requirements of Title 5 of the United States Code and not later than one year after enactment of this bill.

Section 105(b) of the bill establishes an interim procedure for approving ANDA's for post-1962 drugs until the final implementing regulations are promulgated. During the period after enactment of this bill and until the promulgation of regulations by the FDA, ANDA's for listed post-1962 drugs may be submitted in accordance with the current regulations applicable to pre-1962 pioneer drugs.

To the extent that there are inconsistencies between the current regulations and this Act, the FDA shall follow this Act. Under no circumstances may the FDA approve an ANDA or Paper NDA under this interim procedure for a drug that is eligible for four or ten years of market exclusivity except in accordance with those provisions.

*Section 106*

Section 106 of the bill amends section 2201 of Title 28 to insert a cross reference to explain that a suit for declaratory judgement regarding a patent may not be brought under certain circumstances set forth in section 505 of the FFDCA.

TITLE II—PATENT TERM RESTORATION ACT

*Section 201 of the Bill*

Section 201 adds a new section 156 to Title 35 of the United States Code, the Patent Law. It is entitled "Extension of Patent Term." The new section provides for the extension of the normal 17 year term of a product, use, or process patent if a product which is the subject of the patent is required by Federal law to be approved before it is commercially marketed.

*Section 156(a)*

*Conditions for extension applicable to all patents*

The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended one time from its original expiration date if the conditions described in section 156(a) are met. The term "claims" was selected because it is the term used in the patent law to describe the invention which the patent owner or its assignee may prevent others from making, using or selling during the seventeen year term of the patent. For instance, in the case of a product patent which "claims" a broad genus of compounds, the patent owner could prevent others from making, using or selling any compound which is a species of that genus.

Six of the eight conditions described in the numbered paragraphs under section 156(a) are applicable to all patents to be extended. They are found in paragraphs (1)–(3) and (6)–(8).

Paragraph (1) requires the patent to be in force at the time an application for its extension is submitted to the Commissioner of Patents and Trademarks. Paragraph (2) allows extension only if the term of the patent has not been extended previously. And paragraph (3) requires the application for extension to be submitted by the owner of record of the patent, or its agent, in accordance with the requirements of section 156(d).

Paragraphs (6) and (7) describe two conditions which must be met by the product which is claimed in the product patent to be extended, or the use or manufacture of which is claimed in the use or process patent to be extended. First, the product must have been subjected to a regulatory review period under an applicable federal law, and approved, before the product was allowed to be commercially marketed. (The product which can be the subject of a patent extension is hereafter referred to as the "approved product.") Second, with one exception, the approved product must have been approved for commercial marketing for the first time. The exception involves an approved product made under a patented process which primarily uses recombinant DNA technology. Such an approved product could have received its second approval for com-

mercial marketing, but it must be the first time a product made by the claimed process has been approved.

The Committee's bill requires extensions to be based on the first approval of a product because the only evidence available to Congress showing that patent time has been lost is data on so-called class I, new chemical entity drugs. These drugs had been approved by the Food and Drug Administration (FDA) for the first time. An exception was allowed for products made through recombinant DNA because this innovative, new technique is being employed to improve already approved drugs.

Paragraph (8) addresses the circumstances where two different approved products are the subject of the same patent. An extension would be granted only for the first approved product which has been the subject of a regulatory review period.

*Conditions of extension applicable to product and use patents*

Paragraph (4) of section 156(a) describes conditions which are applicable to product and use patents only.

Paragraph (4)(A) permits such a patent to be extended if two requirements are met. The first is that the approved product is not claimed in another product patent which has been extended or which as an earlier issuance date. The second is that the approved product and the use for which the product is approved are not identically disclosed or described in another product or use patent which has been extended or which has an earlier issuance date. The phrase "identically disclosed or described" is intended to have the same meaning which it has under current patent law.[20]

The policy which the Committee seeks to implement in paragraph (4)(A) is, in brief, that the first patent (1) which claims the approved product, in the sense that the approved product would infringe a claim of that patent, or (2) which fully discloses that product and its approved use, is the patent which should be rewarded with an extension. For example, if the approved product is the subject of several patents as a result of filing continuation, continuation-in-part, divisional or otherwise related patent applications, each of which discloses the approved product and its approved use, then only the earliest issued patent is eligible for an extension.

Paragraph (4)(B) is an exception to the rule in paragraph (4)(A) for certain product patents. If two conditions are met, a product patent can be extended even though the approved product is also claimed in another product patent which has been extended or which has an earlier issuance date. First, the product patent which was issued earlier or previously extended cannot identically disclose or describe the approved product. Second, the holder of each of the two product patents must never have been and must never become the holder of the other patent. In this paragraph, the term "holder" is any person who owns the patent or is an exclusive licensee of the owner. This exception was included to prevent an earlier issued patent which claims a broad genus of compounds from blocking the possible extension of a later issued patent claiming a

[20] The phrase "identically disclosed or described" in used in 35 U.S.C. 103 to set forth the conditions of 35 U.S.C. 102.

specific member of that genus where neither patent holder had a choice as to which patent to extend.

*Conditions of extension applicable to process patents*

Paragraph (5) of section 156(a) describes conditions which are applicable to process patents only.

Paragraph (5)(A) permits a process patent, which does not primarily utilize recombinant DNA in the manufacture of the approved product, to be extended if two conditions are met. First, there can not be any issued product patent which claims the approved product or any issued use patent which claims a method of using the approved product for any known therapeutic use. And, second, there can not be an earlier issued process patent, which does not primarily utilize recombinant DNA and which claims a method of manufacturing the approved product.

Paragraph (5)(B) permits a process patent, which primarily utilizes recombinant DNA in the manufacture of the approved product, to be extended if several conditions are met. First, the holder of the process patent can not hold a product patent claiming the approved product or a use patent claiming a method of using the approved product. Second, there can not be an ownership or control interest, either directly or indirectly, between the holder of the process patent and the holder of any product patent claiming the approved product or the holder of any use patent claiming a method of using the approved product. Third, there can not be any earlier issued process patent which claims a method of manufacturing the approved product by primarily utilizing recombinant DNA.

The Committee's bill establishes separate rules for process patents which do not use recombinant DNA because the discovery of such a new process for making an existing product does not warrant the same reward of patent extension as does the discovery of a new product. An extension for the process patent is appropriate only when there are no product or use patents. On the other hand, when recombinant DNA technology is the essential and predominant technique used in making an improved version of an existing product, the Committee believes that this new and important innovation should be rewarded.

*Section 156(b)*

*Rights to be extended*

Except for the limitations described below with respect to the scope of the patent claims, all provisions of the patent law apply to the patent during the period of extension. The limitations are as follows: (1) When a product patent claiming the approved product is extended, the holder's rights are limited to any use of the approved product which was approved before the expiration of the extended term of the patent under the provision of law under which the applicable regulatory review period occurred.

(2) When a use patent claiming a method of using the approved product is extended, the holder's rights are limited to any use of the approved product which: (a) is claimed in the use patent, and (b) was approved before the expiration of the extended term of the

patent under the provision of law under which the applicable regulatory review period occurred.

(3) When a process patent claiming a method of manufacturing the approved product is extended, the holder's rights are limited to the method of manufacturing which: (a) is claimed in the process patent, and (b) is used to make the approved product.

*Section 156(c)*

*Period of extension*

Section 156(c) specifies the rules by which the length of the period of extension is determined. The calculation made under these rules is further limited by the requirements of section 156(g)(4).

Under section 156(c), the length of the extension is based on the length of the regulatory review period in which the approved product was approved. The definition of the various regulatory review periods is in sections 156(g) (1)–(3). All regulatory review periods are divided into a testing phase and an agency approval phase.

The regulatory review period which occurs after the patent to be extended was issued is eligible to be counted towards extension in accordance with the following calculation. First, each phase of the regulatory review period is reduced by any time that the applicant for extension did not act with due diligence during that phase. (The determination of lack of due diligence is made under section 156(d).) Second, after any such reduction, one-half of the time remaining in the testing phase would be added to the time remaining in the approval phase to comprise the total period eligible for extension. Third, all of the eligible period can be counted unless to do so would result in a total remaining patent term of more than fourteen years. For example, if an approved drug product which is eligible for five years of extension had ten years of original patent term left at the end of its regulatory review period, then only four of the five years could be counted towards extension.

The additional limitation on the period of extension is found in section 156(g)(4). That section provides different maximum periods of extension depending on whether the approved product was developed before or after the date of enactment.

Under that section, the total period of regulatory review which can be counted towards extension would not exceed five years when: (1) the patent to be extended was issued after the date of enactment of this bill; or (2) the patent was issued before the date of enactment, but the approved product's regulatory review period had not begun on the date of enactment. The total period of eligible regulatory review would not exceed two years when: (1) the patent to be extended was issued before the date of enactment; and (2) the approved product's regulatory review period had begun before the date of enactment but the product had not been approved by that date. If any action was taken before the date of enactment which initiated the testing phase of the regulatory review period, then the applicant would not be eligible for the five year rule by discontinuing activity and then initiating a new regulatory review period after the date of enactment.

The Committee established different maximum periods of extension to provide greater incentive for future innovations. By extending patents for up to five years for products developed in the future, and by providing for up to fourteen years of market exclusivity, the Committee expects that research intensive companies will have the necessary incentive to increase their research and development activities.

*Section 156(d)*

*Application for extension*

To obtain an extension, the patent owner or its agent would submit an application to the Commissioner of Patents and Trademarks within 60 days of approval of the approved product. The application would contain the information described in subparagraphs (A)–(G) of section 156(d)(1). The applicant would be subject to any disclosure requirements prescribed by the Commissioner. The Committee expects that those requirements would subject the applicant to at least the same duty of disclosure, and the penalties and loss of rights for violation of the duty of disclosure, which governs all patent application proceedings before the Patents and Trademarks Office.

Within 60 days of the submission of an application, the Commissioner would notify the Secretary of Health and Human Services, or the Secretary of Agriculture, as appropriate, to review the dates contained in the application for the regulatory review period. Within 30 days, the appropriate Secretary would make a determination as to those dates, notify the Commissioner of them, and publish them in the Federal Register.

*Determination of due diligence (section 156(d)(2)(B))*

The Committee's bill provides a definition of due diligence at Section 156(d)(3). It is "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period."

A petition may be submitted by any interested person to the appropriate Secretary requesting a determination of whether the applicant for extension acted with due diligence during the regulatory review period of the approved product. The petition must be submitted within 180 days of the publication by the Secretary of a determination of the regulatory review period and must state claim that the applicant did not act with due diligence during some part of the regulatory review period. If the Secretary concludes from the information in the petition that there is reason to believe that the applicant failed to act with due diligence at some point in the regulatory review period, then the Secretary would make, within 90 days of the receipt of the petition and in accordance with regulations, a determination of whether the applicant acted with due diligence. The Secretary of HHS is prohibited from delegating the authority to make the determination to any office below that of the Commissioner of FDA.

While the bill places the burden on the petitioner to make the necessary showing, the Committee recognizes that the information

needed to make a final determination of due diligence is not available to the petitioner. To meet this burden of proof, the petitioner need not show conclusively that there was a lack of due diligence. Instead, the petitioner need only allege sufficient facts to merit an investigation by the Secretary. For example, it would be sufficient for the petitioner to demonstrate that human clinical trials did not begin for an unreasonably long period of time after the FDA granted permission to begin those trials or that the trials took an unreasonably long period of time. In those events, the Secretary would determine whether the delay was caused by a lack of due diligence on the part of the applicant.

After making the determination, the Secretary would notify the Commissioner of Patents and Trademarks and publish it in the Federal Register. Any interested person could request an informal hearing within 60 days of publication of the determination. If a timely request is made, the Secretary must hold such a hearing within 30 days, give notice of the hearing to the patent owner and any interested person, and provide such persons with an opportunity to participate. Within 30 days of the hearing, the Secretary must affirm or revise the determination, notify the Commissioner of Patents, and publish it in the Federal Register.

The Committee established a system for review of due diligence that requires the minimal amount of federal agency personnel time. The goal of the system is to assure that obvious delays during regulatory review, such as a prolonged period when human clinical trials on a drug product are not being conducted, are not counted towards patent extension. The system is not intended to cause a review of every action, but to identify significant periods of time when the loss of patent term resulted solely from the applicant's failure to pursue approval. Delays caused by the temporary unavailability of necessary testing facilities, or a scientific dispute involving tests required for approval or the interpretation of those tests, are examples of delays which can reasonably be expected to occur and would not be a basis for finding a lack of due diligence.

*Section 156(e)*

*Determination on patent extension of the Commissioner of Patents and Trademarks*

The Commissioner would make the final determination that a patent is eligible for extension under section 156(a), that the requirements of section 156(d) have been met, and that the period of extension will be the period prescribed in section 156(c). Once these findings are made, the Commissioner would be required to issue a certificate of extension to the applicant. The certificate would be recorded in the official file of the patent and be considered a part of the original patent.

The Commissioner's decision regarding a patent's eligibility for extension under the rules of section 156(a) may be based solely on the information contained in the application. The burden is on the applicant to show that all patents which are relevant to the eligibility determination have been considered and do not prevent the requested extension.

While the Commissioner would be responsible for evaluating the applicant's determination regarding the patents listed in the application, the Committee expects that most reviews would be ministerial in nature. Since the applicant is under a duty to disclose all relevant information (see section 156(d)(4)), the application should be so well documented that a substantive review by the Commissioner would usually not be necessary.

*Expiration of a patent pending extension (section 156(e)(2))*

It is possible that the original term of the patent for which extension is sought could expire before a final decision by the Commissioner to issue a certificate of extension. This might occur, for instance, because the determination of due diligence by the Secretary of HHS or Agriculture has not been completed.

In such circumstances, the Commissioner is required to determine whether the patent is eligible for extension under section 156(a), and if it is, to issue a certificate of extension for a period of up to one year. The length of this interim extension is discretionary with the Commissioner, but is intended to provide time for the completion of any outstanding requirements. If the Commissioner determined that subsequent interim extensions were necessary, and consistent with the objectives of section 156(e)(2), they could be granted as well. In no event could these interim extensions be longer than the maximum period of extension to which the applicant is thought to be eligible.

*Section 156(f)*

*Definitions*

The term "product" is defined in subsection (f)(1) to include drug products and medical devices, food additives and color additives subject to regulation under the Federal Food, Drug, and Cosmetic Act.

The term "drug product" is defined in subsection (f)(2) to mean the active ingredient of a new drug, antibiotic drug, new animal drug, or human or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and the Virus-Serum-Toxin Act), including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. The human drugs included in this definition are both prescription and over-the-counter drugs.

The term "major health or environmental effects test" is defined in subsection (f)(3) to mean a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

The term "informal hearing" is defined in subsection (f)(5) to have the same meaning as "prescribed for such term by section 201(y) of the Federal Food, Drug, and Cosmetic Act."

The term "patent" is defined in subsection (f)(6) to mean "a patent issued by the United States Patent and Trademark Office.

*Section 156(g)*

*Definition of regulatory review period*

The "regulatory review period" differs for each product that can be the subject of patent extension, but in all cases it is considered to have a testing phase and an agency approval phase.

In sections 156(g) (1)–(3) of the term "initially submitted" is used to describe the point in time when the testing phase is considered to be completed and the agency approval phase to have begun. This term is used instead of the term "filed," because an application is often not considered to be filed, even though agency review has begun, until the agency has determined that no other information is needed and a decision on the application can be made. For purposes of determining the regulatory review period and its component periods, an application for agency review is considered to be "initially submitted" if the applicant has made a deliberate effort to submit an application containing all information necessary for agency review to begin. The Committee recognizes that the agency receiving the application might decide it needs additional information or other changes in the application. As long as the application was complete enough so that agency action could be commenced, it would be considered to be "initially submitted".

*Drug products (section 156(g)(1)*

The regulatory review period for drug products is the sum of the periods: (1) beginning when an exemption under 505(i), 507(d), or 512(j) was granted or authority to prepare an experimental drug product under the Virus-Serum-Toxin Act was granted and ending when with the initial submission of an application for approval under section 351 of the Public Health Service Act, 505, 507, 512 of the Federal Food, Drug, and Cosmetic Act, or the Virus-Serum-Toxin Act; and (2) beginning when an application for approval was initially submitted under section 351 of the PHS, 505, 507, 512 of the FFDCA or the Virus-Serum-Toxin Act and ending when the application was approved.

*Food and color additives (section 156(g)(2))*

The regulatory review period for food and color additives is the sum of the periods: (1) beginning when a major health or environmental effects test for a food or color additive was initiated and ending when a petition requesting the issuance of a regulation for use of the additive was initially submitted; and (2) beginning when a petition for the issuance of a regulation was initially submitted and ending when the regulation became effective.

If permission for commercial marketing was delayed because objections were filed to the regulation, or if such permission was initially granted and later revoked before actual marketing began because objections were filed to the regulation, then the period described in (2) above would end when the objections were resolved and commercial marketing was permitted.

*Medical devices (section 156(g)(3))*

The regulatory review period for medical devices is the sum of the periods: (1) beginning when human clinical investigations are

commenced and ending when an application for approval was initially submitted; and (2) beginning when an application for approval was initially submitted and ending when the application was approved, or beginning when a notice of completion of a product development protocol was initially submitted and ending when the protocol was declared completed.

*Limitations on the regulatory review period (section 156(g)(4))*

A discussion of this section is contained in the earlier section 156(c) entitled "Period of Extension".

*Section 156(h)*

*Fees for applications*

The Commissioner of Patents and Trademarks is authorized to establish such fees as he determines appropriate to cover the entire cost of the Patents and Trademarks Office of receiving and acting upon applications for patent extensions.

*Section 202 of the Bill*

Section 202 creates a new section 271(e) in Title 35 of the United States Code, the Patent Law.

*Patent infringement (section 271(e))*

Section 271(e)(1) provides that it shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the approval of drugs. This section does not permit the commercial sale of a patented drug by the party using the drug to develop such information, but it does permit the commercial sale of research quantities of active ingredients to such party. The information which can be developed under this provision is the type which is required to obtain approval of the drug. A party which develops such information, but decides not to submit an application for approval, is protected as long as the development was done to determine whether or not an application for approval would be sought.

Section 271(e)(2) provides that it shall be an act of patent infringement to submit an ANDA for a drug (1) which is claimed in a valid product patent, or (2) a use of which is claimed in a valid use patent, if the purpose of submitting the ANDA is to get approval of the ANDA with an effective date prior to the expiration of such patents.

The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of appeals for the Federal Circuit held that this type of experimentation is infringement.

In *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.* —F.2d— (Fed. Cir., April 23, 1984), the Court of Appeals for the Federal Circuit held that the experimental use of a drug product prior to the

expiration date of a patent claiming that drug product constitutes patent infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires. It is the Committee's view that experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but prevention of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date.

Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should be a definite time and, thereafter, immediate competition should be encouraged. For that reason, Title I of the bill permits the filing of abbreviated new drug applications before a patent expires and contemplates that the effective approval date will be the expiration date of the valid patent covering the original product. Other sections of Title II permit the extension of the term of a patent for a definite time provided certain conditions are met. There should be no other direct or indirect method of extending patent term.

*Remedies for patent infringement (section 271(c) (3)–(4))*

In an infringement action pursuant to this section, no injunctive or other relief could be granted to prohibit the activity which is permitted by section 271(e)(1).

The Committee expects that infringement actions pursuant to this section will only be brought in the instance described in section 271(e)(2), where a party submitting an abbreviated new drug application under Title I of this bill certifies that a patent is invalid or non-infringed and gives the required notice of that certification to the patent owner. In the event the patent is found to be valid and infringed, so that the act of infringement described in section 271(e)(2) has occurred, the remedies available to the court are three-fold.

If the infringing party has not begun commercial marketing of the drug, injunctive relief may be granted to prevent any commercial activity with the drug and the FDA would be mandated to make the effective date of any approved ANDA not earlier than the expiration date of the infringed patent. The injunction could not prohibit the infringing party from using ther information contained in the application to support the approval of the application at the later effective date. In the case where the ANDA had not been approved, the order would mandate the effective date of any approval to be not earlier than the expiration date of the infringed patent. In the case where an ANDA had been approved, the order would mandate a change in the effective date.

If the infringing party has begun commercial marketing of the drug, damages and other monetary relief and injunctive relief may be awarded for the infringement and to prevent further infringement. In addition, the FDA would be mandated to change the effective date of the approved ANDA to the expiration date of the infringed patent.

*Section 203 of the Bill*

Section 203 adds a new provisions to section 282 of Title 35, United States Code.

*Defenses to patent infringement (section 282)*

The new provision in section 282 provides that an improper grant of patent extension, or any portion thereof, because of a material failure by the applicant or by the Commissioner of Patents and Trademarks to comply with the requirements of section 156, is a defense in any action involving the infringement of the patent during the patent extension. Any failure by the applicant to comply with the requirements of section 156 would be considered material only if the failure would have changes the decision to grant the extension or the length of the extension. Any failure by the Commissioner to comply with the requirements of section 156 would be considered material unless the Commissioner failed to meet a time deadline.

Under this provision, a court which found some portion of the extension to be improperly granted would not invalidate the entire patent extension. For example, if the Commissioner made a mathematical error that resulted in a five year extension instead of the four year extension to which the applicant was entitled, the court would invalidate only that portion of the patent extension improperly granted.

Implicit in section 156 is a directive to the Commissioner to correct any failure on his part that resulted in the funding of invalidity of a patent extension or any portion of it. The new provision does not create any cause of action under the Tort Claims Act against that Commissioner or any Patents and Trademarks Office employee involved with the extension.

In an action involving this new provision, the determination regarding due diligence made under section 156(d)(2) is not subject to review.

## Agency Views

Agency comments were submitted by the Food and Drug Administration during the July 15, 1983, hearing of the Subcommittee on Health and the Environment.

## Changes in Existing Law Made by the Bill, As Reported

In compliance with clause 3 of Rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman);

## Federal Food, Drug, and Cosmetic Act

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# CHAPTER V—DRUGS AND DEVICES

## SUBCHAPTER A—DRUGS AND DEVICES

### NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) *or (j)* is effective with respect to such drug.

(b)*(1)* Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application [(1)]*(A)* full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; [(2)]*(B)* a full list of the articles used as components of such drug; [(3)]*(C)* a full statement of the composition of such drug; [(4)]*(D)* a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; [(5)]*(E)* such samples of such drug and of the articles used as components thereof as the Secretary may require; and [(6)]*(F)* specimens of the labeling proposed to be used for such drug. *The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such 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. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.*

*(2) An application submitted under paragraph (1) for a drug listed under subsection (j)(6) for which investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant or for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—*

*(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—*

*(i) that such patent information has not been filed,*

*(ii) that such patent has expired,*

*(iii) of the date on which such patent will expire, or*

*(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and*

*(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.*

*(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant has given the notice required by subparagraph (B) to—*

*(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and*

*(ii) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.*

*(B) The notice referred to in subparagraph (A) shall state that an application, which includes data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commerical manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.*

*(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.*

(c)(*1*) Within one hundred and eighty days after the filing of an application under [this] subsection (*b*), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

[(1)](*A*) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

[(2)](*B*) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

*(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of*

*using such 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. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when the application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.*

*(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:*

*(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.*

*(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).*

*(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the eighteen-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—*

*(i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision, or*

*(ii) if before the expiration of such period the court decides that such 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.*

*In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of the forty-five day period beginning on the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.*

*(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant or which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).*

*(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection and if the holder of the approved application certifies to the Secretary that no patent has ever been issued to any person for such drug or for a method of using such drug and that the holder cannot receive a patent for such drug or for a method of using such drug because in the opinion of the holder a patent may not be issued for such drug or for a method of using for any known therapeutic purposes such drug, the Secretary may not make the approval of another application for a drug for which investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant or which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of four years from the date of the approval of the application previously approved under subsection (b) unless the Secretary determines that an adequate supply of such drug will not be available or the holder of the application approved under subsection (b) consents to an earlier effective date for an application under this subsection.*

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with

respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or *(6) the application failed to contain the patent information prescribed by subsection (b); or* [6] *(7)* based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or *(4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or* [(4)] *(5)* that the application contains any untrue statement of a material fact: *Provided,* That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hear-

ing to the applicant, withdraw the approval of an application *submitted under subsection (b) or (j)* with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection [(j)]*(k)* or to comply with the notice requirements of section 510[(j)]*(k)*(2), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

*(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.*

*(2)(A) An abbreviated application for a new drug shall contain—*

*(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a "listed drug");*

*(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug,*

*(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or*

*(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;*

*(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as*

*those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;*

*(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);*

*(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;*

*(vi) the items specified in clauses (B) through (F) of subsection (b)(1);*

*(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such 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)—*

*(I) that such patent information has not been filed,*

*(II) that such patent has expired,*

*(III) of the date on which such patent will expire, or*

*(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and*

*(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.*

*The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).*

*(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant has given the notice required by clause (ii) to—*

*(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and*

*(II) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.*

*(ii) The notice referred to in clause (i) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commerical manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.*

*(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.*

*(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients of the drug or of the route of administration, the dosage form, or strength which differ from the listed drug.*

*(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds—*

*(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;*

*(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;*

*(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug,*

*(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or*

*(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—*

*(I) that the other active ingredients are the same as the active ingredients of the listed drug, or*

*(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),*

*or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);*

*(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed*

*drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or*

*(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);*

*(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;*

*(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;*

*(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;*

*(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;*

*(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;*

*(J) the application does not meet any other requirement of paragraph (2)(A); or*

*(K) the application contains an untrue statement of material fact.*

*(4)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.*

*(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:*

*(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.*

*(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).*

*(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the eighteen month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—*

*(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision, or*

*(II) if before the expiration of such period the court decides that such patent has been 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.*

*In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of the forty-five-day period beginning on the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.*

*(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection containing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—*

*(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or*

*(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,*

*whichever is earlier.*

*(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.*

*(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).*

*(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection and if the holder of the approved application certifies to the Secretary that no patent has ever been issued to any person for such drug or for a method of using such drug and that the holder cannot receive a patent for such drug or for a method of using such drug because in the opinion of the holder a patent may not be issued for such drug or for a method of using such drug for any known therapeutic purposes the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of four years from the date of the approval of the application under subsection (b) unless the Secretary determines that an adequate supply of such drug will not be available or the holder of the application approved under subsection (b) consents to an earlier effective date for an application under this subsection.*

*(5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—*

*(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or*

*(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.*

*(6)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—*

*(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;*

*(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and*

*(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.*

*(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.*

*(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary the Secretary shall, in revisions made under clause (ii), include such information for such drug.*

*(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.*

*(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—*

*(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (5), or*

*(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.*

*A notice of the removal shall be published in the Federal Register.*

*(7) For purposes of this subsection:*

*(A) 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.*

*(B) A drug shall be considered to be bioequivalent to a listed drug if—*

*(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or*

*(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.*

[(j)(1)] *(k)(1)* In the case of any drug for which an approval of an application filed [pursuant to this section] *under subsection (b) or (j)* is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section: *Provided, however,* That regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, or similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

*(l) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—*

*(1) if no work is being or will be undertaken to have the application approved,*

*(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,*

*(3) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,*

*(4) if the Secretary has determined that such drug is not a new drug, or*

*(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.*

*(m) For purposes of this section, the term "patent" means a patent issued by the Patent and Trademark Office of the Department of Commerce.*

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SUBCHAPTER B—DRUGS FOR RARE DISEASES OR CONDITIONS

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PROTECTION FOR UNPATENTED DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 527. (a) Except as provided in subsection (b), if the Secretary—

(1) approves an application filed pursuant to section 505(b), or

(2) issues a license under section 351 of the Public Health Service Act

for a drug designated under section 526 for a rare disease or condition and for which a United States Letter of Patent may not be issued, the Secretary may not approve another application under section [505(b)] *505* or issue another license under section 351 of the Public Health Service Act for such drug for such disease or condition for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of the approval of the approved application or the issuance of the license. Section 505(c)(2) does not apply to the refusal to approve an application under the preceding sentence.

(b) If an application filed pursuant to section [505(b)] *505* is approved for a drug designated under section 526 for a rare disease or condition or a license is issued under section 351 of the Public Health Service Act for such a drug and if a United States Letter of Patent may not be issued for the drug, the Secretary may, during the seven-year period beginning on the date of the application approval or of the issuance of the license, approve another application under section [505(b),] *505,* or, if the drug is a biological product, issue a license under section 351 of the Public Health Service Act, for such drug for such disease or condition for a person who is not the holder of such approved application or of such license if—

(1) The Secretary finds, after providing the holder notice and opportunity for the submission of views, that in such period the holder of the approved application or of the license cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated; or

(2) such holder provides the Secretary in writing the consent of such holder for the approval of other applications or the issuance of other licenses before the expiration of such seven-year period.

* * * * * * *

SECTION 2201 OF TITLE 28, UNITED STATES CODE

**§ 2201. Creation of remedy**

*(a)* In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1954 or a proceeding under section 505 or 1146 of title 11, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

*"(b) For limitations on actions brought with respect to drug patents see section 505 of the Federal Food, Drug, and Cosmetic Act.*

# TITLE 35, UNITED STATES CODE

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## PART II—PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS

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### CHAPTER 14—ISSUE OF PATENT

Sec.
151. Issue of patent.

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*156. Extension of patent term.*

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***§ 156. Extension of patent term***

*(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—*

*(1) the term of the patent has not expired before an application is submitted under subsection (d) for its extension;*

*(2) the term of the patent has never been extended;*

*(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of subsection (d);*

*(4)(A) in the case of a patent which claims the product or a method of using the product—*

*(i) the product is not claimed in another patent having an earlier issuance date or which was previously extended, and*

*(ii) the product and the use approved for the product in the applicable regulatory review period are not identically disclosed or described in another patent having an earlier issuance date or which was previously extended; or*

*(B) in the case of a patent which claims the product, the product is also claimed in a patent which has an earlier issu-*

*ance date or which was previously extended and which does not identically disclose or describe the product and—*

*(i) the holder of the patent to be extended has never been and will not become the holder of the patent which has an earlier issuance date or which was previously extended, and*

*(ii) the holder of the patent which has an earlier issuance date or which was previously extended has never been and will not become the holder of the patent to be extended;*

*(5)(A) in the case of a patent which claims a method of manufacturing the product which does not primarily use recombinant DNA technology in the manufacture of the product—*

*(i) no other patent has been issued which claims the product or a method of using the product and no other patent which claims a method of using the product may be issued for any known therapeutic purposes; and*

*(ii) no other method of manufacturing the product which does not primarily use recombinant DNA technology in the manufacture of the product is claimed in a patent having an earlier issuance date;*

*(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product—*

*(i) the holder of the patent for the method of manufacturing the product (I) is not the holder of a patent claiming the product or a method of using the product, (II) is not owned or controlled by a holder of a patent claiming the product or a method of using the product or by a person who owns or controls a holder of such a patent, and (III) does not own or control the holder of such a patent or a person who owns or controls a holder of such a patent; and*

*(ii) no other method of manufacturing the product primarily using recombinant DNA technology is claimed in a patent having an earlier issuance.*

*(6) the product has been subject to a regulatory review period before its commercial marketing or use;*

*(7)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; or*

*(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; and*

*(8) the patent does not claim another product or a method of using or manufacturing another product which product received permission for commercial marketing or use under such provision of law before the filing of an application for extension.*

*The product referred to in paragraphs (4), (5), (6), and (7) is hereinafter in this section referred to as the 'approved product'. For pur-*

*poses of paragraphs (4)(B), (5)(B), the holder of a patent is any person who is the owner of record of the patent or is the exclusive licensee of the owner of record of the patent.*

*(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—*

*(1) in the case of a patent which claims a product, be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;*

*(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred; and*

*(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the approved product.*

*(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—*

*(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;*

*(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), and (3)(B)(i) of subsection (g); and*

*(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years.*

*(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain—*

*(A) the identity of the approved product;*

*(B) the identity of the patent for which an extension is being sought and the identification of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;*

*(C) the identity of every other patent known to the patent owner which claims or identically discloses or describes the approved product or a method of using or manufacturing the approved product;*

*(D) the identity of all other products which have received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use and which are claimed in any of the patents identified in subparagraph (C);*

*(E) information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);*

*(F) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and*

*(G) such patent or other information as the Commissioner may require.*

*(2)(A) Within sixty days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify—*

*(i) the Secretary of Agriculture if the patent claims a drug product or a method of using or manufacturing a drug product and the drug product is subject to the Virus-Serum-Toxin Act, and*

*(ii) the Secretary of Health and Human Services if the patent claims any other drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act,*

*of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than 30 days after the receipt of an application from the Commissioner, the Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(E) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.*

*(B)(i) If a petition is submitted to the Secretary making the determination under subparagraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary making the determination shall, in accordance with regulations promulgated by such Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than 90 days after the receipt of such a petition. The Secretary of Health and Human Services may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.*

*(ii) The Secretary making a determination under clause (i) shall notify the Commissioner of the determination and shall publish in*

*the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the sixty day period beginning on the publication of a determination, the Secretary making the determination to hold an informal hearing on the determination. If such a request is made within such period, such Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary who is holding the hearing shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, such Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.*

*(3) For purposes of paragraph (2)(B), the term "due diligence" means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.*

*(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Commissioner.*

*(e)(1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the information contained in the application for the extension. If the Commissioner determines that a patent is eligible for extension under subsection (a) and that the requirements of subsection (d) have been complied with, the Commissioner shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.*

*(2) If the term of a patent for which an application has been submitted under subsection (d) would expire before a determination is made under paragraph (1) respecting the application, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.*

*(f) For purposes of this section:*

*(1) The term "product" means:*

*(A) A drug product.*

*(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.*

*(2) The term "drug product" means the active ingredient of a new drug, antibiotic drug, new animal drug, or human or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Virus-Serum-Toxin Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.*

*"(3) The term "major health or environmental effects test" means a test which is reasonably related to the evaluation of*

*the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.*

*(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.*

*(B) Any reference to section 503, 505, 507, 512, or 515 is a reference to section 503, 505, 507, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.*

*(C) Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (21 U.S.C. 151–158).*

*(5) The term "informal hearing" has the meaning prescribed for such term by section 201(y) of the Federal Food, Drug, and Cosmetic Act.*

*(6) The term "patent" means a patent issued by the United States Patent and Trademark Office.*

*(g) For purposes of this section, the term "regulatory review period" has the following meanings:*

*(1)(A) In the case of a product which is a drug product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.*

*(B) The regulatory review period for a drug product is the sum of—*

*(i) the period beginning on the date—*

*(I) an exemption under subsection (i) of section 505, subsection (d) of section 507, or subsection (j) of section 512, or*

*(II) the authority to prepare an experimental drug product under the Virus-Serum-Toxin Act,*

*became effective for the approved drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, 507, or 512 or the Virus-Serum-Toxin Act, and*

*(ii) the period beginning on the date the application was initially submitted for the approved drug product under section 351, subsection (b) of such section 505, section 507, section 512, or the Virus-Serum-Toxin Act and ending on the date such application was approved under such section or Act.*

*(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.*

*(B) The regulatory review period for a food or color additive is the sum of—*

*(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and*

*(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.*

*(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.*

*(B) The regulatory review period for a medical device is the sum of—*

*(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and*

*(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).*

*(4) A period determined under any of the preceding paragraphs is subject to the following limitations:*

*(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.*

*(B) If the patent involved was issued before the date of the enactment of this section and—*

*(i) no request for an exemption described in paragraph (1)(B) was submitted,*

*(ii) no request was submitted for the preparation of an experimental drug product described in paragraph (1)(B),*

*(iii) no major health or environmental effects test described in paragraph (2) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or*

*(iv) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted,*

*before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.*

*(C) If the patent involved was issued before the date of the enactment of this section and if an action described in*

*subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years.*

*(h) The Commissioner may establish such fees as the Commissioner determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.*

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## PART III—PATENTS AND PROTECTION OF PATENT RIGHTS

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## CHAPTER 28—INFRINGEMENT OF PATENTS

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**§ 271. Infringement of patent**

(a) * * *

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*(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.*

*(2) It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(g)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.*

*(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1).*

*(4) For an act of infringement described in paragraph (2)—*

*(A) the court shall order the effective date of any approval of the drug involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,*

*(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug, and*

*(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, or sale of an approved drug.*

*The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of in-*

*fringement described in paragraph (2), except that a court may award attorney fees under section 285.*

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## CHAPTER 29—REMEDIES FOR INFRINGEMENT OF PATENT, AND OTHER ACTIONS

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**§ 282. Presumption of validity; defenses**

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability,

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,

(4) Any other fact or act made a defense by this title.

In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Claims Court, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires.

*Invalidity of the extension of a patent term or any portion thereof under section 156 of this title because of the material failure—*

*(1) by the applicant for the extension, or*

*(2) by the Commissioner,*

*to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.*

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# MINORITY VIEWS OF MR. BLILEY

## INTRODUCTION

H.R. 3605, as reported by the Committee, is a bill described by its proponents as having something for everyone—restoration of patent terms for products subject to elaborate premarket approval requirements to provide incentives for pharmaceutical research and facilitation of approval of generic drugs by the Food and Drug Administration under abbreviated application procedures to increase drug price competition. The objectives of this legislation are salutary and have the support of all interested parties. In my view, however, the legislation fails to achieve a proper balance between these two objectives.

Instead of providing an appropriate patent term for pharmaceuticals by restoring the time devoted to periods of "regulatory review," the bill strictly limits the types of patents eligible for term restoration and the conditions and length of the restoration period. In short, the patent term restoration provisions of this bill are largely illusory. Moreover, the bill would overrule a decision of the highest patent court in this country and thereby allow generic drug companies to use a patented product during the term of the patent. This is a substantial diminution of the rights currently held by the owner of the patent and has serious constitutional and policy implications which have not been considered by the Committee. The patent provisions of this bill also encourage patent "jumping" and litigation over the validity of patents.

The abbreviated new drug application (ANDA) provisions of this bill are equally troublesome. For example, the bill has substantial adverse effects on the resources and legal authority of the Food and Drug Administration, which has expressed some of its concerns about the bill in a document entitled "Technical Comments on June 2 Discussion Draft ANDA/Patent Term Restoration Legislation," largely to no avail. Many Members of the Congress and various prestigious academic and study groups have explored recently the need for faster approvals of innovative and medically necessary new drugs. The need to accelerate the approval of new drugs has been acknowledged by nearly everyone, including the FDA. It is astonishing, in light of the widely held view that the new drug approval process takes too long, that the Committee reported H.R. 3605, which imposes substantial new administrative and resource burdens on the FDA which will almost certainly have the effect of forcing FDA to divert resources from the review and approval of new therepeutic entities to the review and approval of copies of already-available drugs.

I am deeply concerned that in its haste to report this lengthy and complex bill, the Committee has failed to consider fully and adequately its effects—intended and unintended, desirable and un-

desirable—in either hearings or markup. H.R. 3605 is a significant piece of legislation with important implications for consumers, research-based pharmaceutical companies, generic drug companies and for the FDA. In point of fact, however, the Committee has reported a highly significant and lengthy bill without any hearings having been held on it in either the Health Subcommittee or in the full Committee. It is no answer to say that the bill is the result of lengthy negotiations between the brandname and generic drug industry trade associations. Many significant interests, including the patent bar, have never been heard from. Moreover, many of the highly innovative and research-oriented pharmaceutical firms have serious reservations about the bill as reported as apparently, does the FDA.

H.R. 3605 is an admirable beginning to the process of striking an appropriate balance among a variety of competing and important policy objectives. There is ample time for, and a compelling need to, consider, revise and improve upon the bill. In my view, the bill should be returned to the Health Subcommittee for further hearings and amendment, rather than being reported in haste by this Committee. Further, because this Committee lacks expertise in patent matters, the Committee is not qualified to evaluate the patent provisions of H.R. 3605. We do this institution a disservice by hastily reporting on the very day of introduction, a complex bill outside the expertise of the Committee after a "markup" that lasted barely thirty minutes.

In the next sections of my views, I describe in greater detail the significant areas in which this bill is deficient.

## I. TITLE I—ABBREVIATED NEW DRUG APPLICATIONS

### *A. Limits on FDA authority*

Both the research-based pharmaceutical companies which favor amendments to H.R. 3605 and the FDA itself have identified ways in which the bill unwisely restricts FDA's authority to ensure that all drugs are demonstrated to be safe and effective.

First, the bill expressly prohibits FDA from requesting data on the safety or efficacy of certain generic drugs, even where such data are needed to fulfill the FDA's public health responsibilities. Although one would not anticipate that FDA would need to resort to this authority very often, I believe it is a fundamental mistake to deprive the FDA of the authority simply because it is assumed that it will need to exercise it only rarely.

Second, it has been the longstanding policy of FDA to require that persons seeking to market drugs combining two or more active ingredients demonstrate that the combination itself, as opposed to the active ingredients individually, be shown to be safe and effective. FDA's authority to require this proof has been upheld by the courts. Without explanation or hearing, H.R. 3605 would overrule this policy and limit FDA's consideration of safety and efficacy to the individual active ingredients of combination drugs. I do not believe that the Congress should provide for the approval of new combinations of drugs without requiring the applicant to demonstrate that the combination is safe and effective. The public health should not be compromised in this fashion.

*B. Resource implications*

The review and approval by FDA of new pharmaceuticals—often innovative and highly desirable developments essential to the health of our citizens—is perhaps the most important function that the Congress has given to the FDA. The American people and the Members of the Congress rightly expect that this function be performed competently and expeditiously. New drugs are often inexpensive ways to cure life-threatening or debilitating diseases. Unnecessary delay in making these drugs available to physicians has been a continuing concern to me, many other Members of the Congress, to the FDA, to the medical community and others. The so-called "drug lag" and the need to expedite drug approvals has been widely studied and recommendations for improvements abound. Indeed, FDA is in the midst of revising its regulations and procedures for new drug approvals.

Astonishingly, then, the Committee has reported a bill which is likely to reduce FDA's ability to improve its new drug approval procedures and its timeliness in acting on new drug applications. FDA has expressed concern in its "Technical Comments" that the bill reported by the Committee will result in a "substantial increase in work load during the first few years immediately following enactment." It is obvious that this increase in workload will obligate FDA to reallocate personnel from new drug review to ANDA review. Because the bill also contains time limits on FDA's actions on ANDAs which are far more restrictive than those for NDAs,* this problem will be further exacerbated. It is apparently the Committee's view that review of ANDAs is a more important priority for FDA than NDAs. I take strong exception to that judgment.

As FDA has suggested, a phase-in of eligibility of ANDAs would ameliorate much of its workload burden while simultaneously making available immediately for ANDA treatment six of the drugs that are among the top selling prescription drug products. I urge the Members of the House to consider this idea among others as a way to greatly improve upon this bill.

*C. Disclosure of proprietary data*

The bill reported by the Committee provides for the public disclosure of all of the extensive and costly research data generated by research-oriented pharmaceutical companies, even though those safety and effectiveness data may be of significant value to foreign competitors or may retain proprietary value in the United States. These data may well retain commercial value, even when FDA no longer requires an applicant to submit them for approval of a drug (*i.e.*, when an ANDA may be filed with FDA, the full data are not needed). The data may still be valuable, for example, because in many foreign countries all or a portion of these data are needed to obtain approval. These data will be valuable particularly in those countries which do not recognize U.S. patents. By providing for the

*Under current law, the 180-day time period for acting on an NDA does not begin until the NDA is "filed," i.e., is nearly ready to be approved by FDA. Under H.R. 3605, the 180-day time period for acting on an ANDA begins when the ANDA is submitted. A substantial time may pass between "submission" and "filing" while the application is brought into conformity with FDA's criteria for approval.

release of these data, the bill hands to foreign competitors of U.S. drug firms, for the mere price of photocopying charges, data which cost many millions of dollars to obtain and which can be used to obtain approval to market drugs in competition with the owner and generator of the data. This provision of H.R. 3605 is hardly the way to protect and improve the competitiveness of America's pharmaceutical industry.

It should also be noted that this provision of H.R. 3605 has significant resource implications for FDA. Under the Freedom of Information Act, FDA is obligated to respond to requests for documents in its files, including the voluminous safety and effectiveness data made available by the bill, ordinarily within ten days. Since the enactment of the FOI Act, FDA has consistently received more requests for documents than virtually any other Federal agency. In 1983, FDA received over 39,000 FOI requests. One hundred twenty-five "full time equivalents," many highly trained scientists and doctors, were required to process these requests. Under H.R. 3605, over twenty years of safety and effectiveness data and information will, immediately upon enactment, be available for disclosure. If FDA were to receive requests for even a modest part of those data, the workload and resource burdens would be staggering. I fail to see how the public benefits by having FDA be forced to divert scarce technical personnel and resources to processing FDA requests and ANDAs, at the expense of new drug applications and other important public health functions.

## II. TITLE II—PATENT TERM RESTORATION

H.R. 3605 contains many significant revisions to our patent laws. Rather than restoring patent terms lost during extensive regulatory review periods, these revisions eliminate many of the significant rights which currently accrue to the patent owner. Moreover, the patent term restoration provisions are so restrictive that their effect may well be largely illusory. Innovation is not encouraged by these patent provisions.

### *A. Loss of patent rights*

I am advised that it has long been accepted that to use, sell or make a patented product during the life of the patent constitutes patent infringement. This aspect of the rights accruing to the patent owner was recently reaffirmed in the context of generic drugs in the so-called *Bolar* case. The United States Court of Appeals for the Federal Circuit held, consistent with prior law, that a generic drug company may not formulate and test its version of another company's patented drug until the patent term expires. The *Bolar* decision is sound law and should be retained.

H.R. 3605, however, would overrule *Bolar* and thereby permit a generic drug company to engage in acts which heretofore would have constituted patent infringement. It is extremely doubtful that it is sound policy in a bill designed to restore patent life, to dramatically cut back on existing patent rights.

I am also concerned that the constitutional implications of this provision of H.R. 3605 have not been considered. By overruling *Bolar,* the bill retrospectively deprives the patent holder of valua-

ble rights. Patent rights represent both a contractual right between the patent holder and the U.S. Government and a recognized property right. The Constitution prevents the Government from impairing the rights of contract and from "taking" or depriving one of a property right without just compensation. By overruling *Bolar* for patents already issued, H.R. 3605 violates these important protections found in our Constitution.

*B. Restrictions on patent term restoration*

Under H.R. 3605, most patents will not be eligible for restoration, even though they may cover products or methods of use, formulation or administration, of innovative drugs which required many years and great expense to research and develop and even though many years may have been devoted to securing an approval to market from the FDA. The bill thus fails to achieve one of its principal purposes: to ensure that sufficient incentives exist for innovation.

A few examples of the restrictive approach to patent term restoration will demonstrate the inadequacies of H.R. 3605.

Under present law, a patent can be obtained containing a broad claim (genus) covering many compounds. It is difficult and requires a large investment by the innovator, but is still possible subsequently to obtain a patent for specific claims (species) on a few specific compounds encompassed within the genus. Under the bill, should a patent holder obtain a patent with species claims covered by a previously-issued genus patent, the patent holder could not obtain restoration of the term of the species patent.

In addition, under present law, the Patent Office can require that the claims in a patent application be divided and prosecuted in separate patents. Under the bill, the first issued patent of the series would be the only patent term entitled to restoration, and subsequently issued patents of the series would be precluded from restoration. Accordingly, unless an FDA approved product is claimed within the first issued patent of the series, restoration of a patent term covering the product would not be available. During the patent application process, it is impossible to know which drug or drugs will ultimately be successfully tested and marketed. Therefore, a patent holder is being denied the benefit of patent term restoration due to circumstances beyond its control.

Another exception to patent term restoration encompassed by H.R. 3605 would occur where one patent covers two FDA approved drugs. Any claims in the patent covering the second FDA approved drug could not be restored. Accordingly, only one restoration is available per patent even though a company may have expended considerable resources in developing each FDA approved product.

The bill also limits availability of patent term restoration for method of manufacturing patents (not using DNA technology), including the limitation that no other type of patent has been or "may be issued for any known therapeutic purposes" claiming the method of using the product.

By excluding so many patents from eligibility for term restoration and by making the eligibility for restoration of some patents turn on circumstances beyond the control of the innovator, the bill falls well short of providing the incentives for innovation that it

purports to achieve. It is not necessary, of course, that every patent be eligible for extension in order for reasonable incentives to innovate to exist. Rather, the bill should provide for patent term restoration for all significant innovations, be they in discovering new chemical entities, new dosage forms, new uses or species of substances previously covered by broad genus patents. The restrictive eligibility provisions of H.R. 3605 make patent term restoration a haphazard and infrequent event. Innovation is not encouraged when the prospect of meaningful patent life is left to chance and happenstance and when most innovations covered by patents will not be eligible for term restoration.

H.R. 3605 also makes other significant changes to our patent laws which neither I nor this Committee have had time to learn about or consider.

### III. CONCLUSION

It is distressing and regrettable that this Committee has reported a complex, lengthy and highly significant piece of legislation without holding hearings in either the Health Subcommittee or in the full Committee and after what can only be described as a pro forma markup. It is equally distressing that this Committee reported a controversial bill which changes significantly our patent laws, an area which escapes even the broad jurisdiction of this Committee.

I share with other Members the desire to restore patent life lost during periods of regulatory review and the desire to facilitate the approval of generic drugs. I object, however, to the precipitous and superficial consideration of the bill by the Committee and to its failure to provide for and consider, the views of all parties affected by the legislation.

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