

98TH CONGRESS
2D SESSION

S. 2748

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.

IN THE SENATE OF THE UNITED STATES

JUNE 12 (legislative day, JUNE 11), 1984

Mr. HATCH (for himself, Mr. MATHIAS, Mr. KENNEDY, and Mr. DECONCINI) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the “Drug Price Competition
4 and Patent Term Restoration Act of 1984”.

1 **TITLE I—ABBREVIATED NEW DRUG**
2 **APPLICATIONS**

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

7 “(j)(1) Any person may file with the Secretary an abbrevi-
8 ated application for the approval of a new drug.

9 “(2)(A) An abbreviated application for a new drug shall
10 contain—

11 “(i) information to show that the conditions of use
12 prescribed, recommended, or suggested in the labeling
13 proposed for the new drug have been previously ap-
14 proved for a drug listed under paragraph (6) (herein-
15 after in this subsection referred to as a ‘listed drug’);

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

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

24 “(III) if the listed drug referred to in clause (i)
25 has more than one active ingredient and if one of the

1 active ingredients of the new drug is different and the
2 application is filed pursuant to the approval of a peti-
3 tion filed under subparagraph (C), information to show
4 that the other active ingredients of the new drug are
5 the same as the active ingredients of the listed drug,
6 information to show that the different active ingredient
7 is an active ingredient of a listed drug or of a drug
8 which does not meet the requirements of section
9 201(p), and such other information respecting the dif-
10 ferent active ingredient with respect to which the peti-
11 tion was filed as the Secretary may require;

12 “(iii) information to show that the route of admin-
13 istration, the dosage form, and the strength of the new
14 drug are the same as those of the listed drug referred
15 to in clause (i) or, if the route of administration, the
16 dosage form, or the strength of the new drug is differ-
17 ent and the application is filed pursuant to the approval
18 of a petition filed under subparagraph (C), such infor-
19 mation respecting the route of administration, dosage
20 form, or strength with respect to which the petition
21 was filed as the Secretary may require;

22 “(iv) information to show that the new drug is
23 bioequivalent to the listed drug referred to in clause (i),
24 except that if the application is filed pursuant to the
25 approval of a petition filed under subparagraph (C), in-

1 formation to show that the active ingredients of the
2 new drug are of the same pharmacological or therapeu-
3 tic class as those of the listed drug referred to in clause
4 (i) and the new drug can be expected to have the same
5 therapeutic effect as the listed drug when administered
6 to patients for a condition of use referred to in clause
7 (i);

8 “(v) information to show that the labeling pro-
9 posed for the new drug is the same as the labeling ap-
10 proved for the listed drug referred to in clause (i)
11 except for changes required because of differences ap-
12 proved under a petition filed under subparagraph (C) or
13 because the new drug and the listed drug are produced
14 or distributed by different manufacturers;

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

17 “(vii) a certification, in the opinion of the appli-
18 cant and to the best of his knowledge, with respect to
19 each patent which claims the listed drug referred to in
20 clause (i) or which claims a use for such listed drug for
21 which the applicant is seeking approval under this sub-
22 section and for which information is required to be filed
23 under subsection (b) or (c)—

24 “(I) that such patent information has not
25 been filed,

1 “(II) that such patent has expired,

2 “(III) of the date on which such patent will
3 expire, or

4 “(IV) that such patent is invalid or will not
5 be infringed by the manufacture, use, or sale of
6 the new drug for which the application is submit-
7 ted; and

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

14 The Secretary may not require that an abbreviated applica-
15 tion contain information in addition to that required by
16 clauses (i) through (viii).

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

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

24 “(II) the holder of the approved application under
25 subsection (b) for the drug which is claimed by the

1 patent or a use of which is claimed by the patent or
2 the representative of such holder designated to receive
3 such notice.

4 “(ii) The notice referred to in clause (i) shall state that
5 an application has been submitted under this subsection for
6 the drug with respect to which the certification is made to
7 obtain approval to engage in the commercial manufacture,
8 use, or sale of such drug before the expiration of the patent
9 referred to in the certification. Such notice shall include a
10 detailed statement of the factual and legal basis of the appli-
11 cant’s opinion that the patent is not valid or will not be in-
12 fringed.

13 “(iii) If an application is amended to include a certifica-
14 tion described in subparagraph (A)(vii)(IV), the notice re-
15 quired by clause (ii) shall be given when the amended appli-
16 cation is submitted.

17 “(C) If a person wants to submit an abbreviated applica-
18 tion for a new drug which has a different active ingredient or
19 whose route of administration, dosage form, or strength differ
20 from that of a listed drug, such person shall submit a petition
21 to the Secretary seeking permission to file such an applica-
22 tion. The Secretary shall approve or disapprove a petition
23 submitted under this subparagraph within ninety days of the
24 date the petition is submitted. The Secretary shall approve
25 such a petition unless the Secretary finds that investigations

1 must be conducted to show the safety and effectiveness of the
2 active ingredients of the drug or of the route of administra-
3 tion, the dosage form, or strength which differ from the listed
4 drug.

5 “(3) Subject to paragraph (4), the Secretary shall ap-
6 prove an application for a drug unless the Secretary finds—

7 “(A) the methods used in, or the facilities and
8 controls used for, the manufacture, processing, and
9 packing of the drug are inadequate to assure and pre-
10 serve its identity, strength, quality, and purity;

11 “(B) information submitted with the application is
12 insufficient to show that each of the proposed condi-
13 tions of use have been previously approved for the
14 listed drug referred to in the application;

15 “(C)(i) if the listed drug has only one active ingre-
16 dient, information submitted with the application is in-
17 sufficient to show that the active ingredient is the same
18 as that of the listed drug,

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

23 “(iii) if the listed drug has more than one active
24 ingredient and if the application is for a drug which
25 has an active ingredient different from the listed drug,

1 information submitted with the application is insuffi-
2 cient to show—

3 “(I) that the other active ingredients are the
4 same as the active ingredients of the listed drug,
5 or

6 “(II) that the different active ingredient is an
7 active ingredient of a listed drug or a drug which
8 does not meet the requirements of section 201(p),
9 or no petition to file an application for the drug with
10 the different ingredient was approved under paragraph
11 (2)(C);

12 “(D)(i) if the application is for a drug whose route
13 of administration, dosage form, or strength of the drug
14 is the same as the route of administration, dosage
15 form, or strength of the listed drug referred to in the
16 application, information submitted in the application is
17 insufficient to show that the route of administration,
18 dosage form, or strength is the same as that of the
19 listed drug, or

20 “(ii) if the application is for a drug whose route of
21 administration, dosage form, or strength of the drug is
22 different from that of the listed drug referred to in the
23 application, no petition to file an application for the
24 drug with the different route of administration, dosage

1 form, or strength was approved under paragraph
2 (2)(C);

3 “(E) if the application was filed pursuant to the
4 approval of a petition under paragraph (2)(C), the ap-
5 plication did not contain the information required by
6 the Secretary respecting the active ingredient, route of
7 administration, dosage form, or strength which is not
8 the same;

9 “(F) information submitted in the application is in-
10 sufficient to show that the drug is bioequivalent to the
11 listed drug referred to in the application or, if the ap-
12 plication was filed pursuant to a petition approved
13 under paragraph (2)(C), information submitted in the
14 application is insufficient to show that the active ingre-
15 dients of the new drug are of the same pharmacological
16 or therapeutic class as those of the listed drug referred
17 to in paragraph (2)(A)(i) and that the new drug can be
18 expected to have the same therapeutic effect as the
19 listed drug when administered to patients for a condi-
20 tion of use referred to in such paragraph;

21 “(G) information submitted in the application is
22 insufficient to show that the labeling proposed for the
23 drug is the same as the labeling approved for the listed
24 drug referred to in the application except for changes
25 required because of differences approved under a peti-

1 tion filed under paragraph (2)(C) or because the drug
2 and the listed drug are produced or distributed by dif-
3 ferent manufacturers;

4 “(H) information submitted in the application or
5 any other information available to the Secretary shows
6 that (i) the inactive ingredients of the drug are unsafe
7 for use under the conditions prescribed, recommended,
8 or suggested in the labeling proposed for the drug, or
9 (ii) the composition of the drug is unsafe under such
10 conditions because of the type or quantity of inactive
11 ingredients included or the manner in which the inac-
12 tive ingredients are included;

13 “(I) the approval under subsection (c) of the listed
14 drug referred to in the application under this subsection
15 has been withdrawn or suspended for grounds de-
16 scribed in the first sentence of subsection (e), the ap-
17 proval under this subsection of the listed drug referred
18 to in the application under this subsection has been
19 withdrawn or suspended under paragraph (5), or the
20 Secretary has determined that the listed drug has been
21 withdrawn from sale for safety or effectiveness reasons;

22 “(J) the application does not meet any other re-
23 quirement of paragraph (2)(A); or

24 “(K) the application contains an untrue statement
25 of material fact.

1 “(4)(A) Within one hundred and eighty days of the ini-
2 tial receipt of an application under paragraph (2) or within
3 such additional period as may be agreed upon by the Secre-
4 tary and the applicant, the Secretary shall approve or disap-
5 prove the application.

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

9 “(i) If the applicant only made a certification de-
10 scribed in subclause (I) or (II) of paragraph (2)(A)(vii)
11 or in both such subclauses, the approval may be made
12 effective immediately.

13 “(ii) If the applicant made a certification described
14 in subclause (III) of paragraph (2)(A)(vii), the approval
15 may be made effective on the date certified under sub-
16 clause (III).

17 “(iii) If the applicant made a certification de-
18 scribed in subclause (IV) of paragraph (2)(A)(vii), the
19 approval shall be made effective immediately unless an
20 action is brought for infringement of each patent which
21 is the subject of the certification before the expiration
22 of forty-five days from the date the notice provided
23 under paragraph (2)(B)(i) is received. If such an action
24 is brought before the expiration of such days, the ap-
25 proval shall be made effective upon the expiration of

1 the eighteen-month period beginning on the date of the
2 receipt of the notice provided under paragraph (2)(B)(i)
3 or such shorter or longer period as the court may order
4 because either party to the action failed to reasonably
5 cooperate in expediting the action, except that—

6 “(I) if before the expiration of such period
7 the court decides that each such patent is invalid
8 or not infringed, the approval shall be made effec-
9 tive on the date of the court decision, or

10 “(II) if before the expiration of such period
11 the court decides that any such patent has been
12 infringed, the approval shall be made effective on
13 such date as the court orders under section
14 271(e)(4)(A) of title 35, United States Code.

15 In such an action, each of the parties shall reasonably
16 cooperate in expediting the action. Until the expiration
17 of the forty-five-day period beginning on the date the
18 notice made under paragraph (2)(B)(i) is received, no
19 action may be brought under section 2201 of title 28,
20 United States Code, for a declaratory judgment with
21 respect to the patent. Any action brought under section
22 2201 shall be brought in the judicial district where the
23 defendant has its principal place of business or a regu-
24 lar and established place of business.

1 “(iv) If the application contains a certification de-
2 scribed in subclause (IV) of paragraph (2)(A)(vii) and is
3 for a drug for which a previous application has been
4 submitted under this subsection containing such a certi-
5 fication, the application shall be made effective not ear-
6 lier than one hundred and eighty days after—

7 “(I) the date the Secretary receives notice
8 from the applicant under the previous application
9 of the first commercial marketing of the drug
10 under the previous application, or

11 “(II) the date of a decision of a court in an
12 action described in clause (iii) holding the patent
13 which is the subject of the certification to be in-
14 valid or not infringed,

15 which ever is earlier.

16 “(C) If the Secretary decides to disapprove an applica-
17 tion, the Secretary shall give the applicant notice of an op-
18 portunity for a hearing before the Secretary on the question
19 of whether such application is approvable. If the applicant
20 elects to accept the opportunity for hearing by written re-
21 quest within thirty days after such notice, such hearing shall
22 commence not more than ninety days after the expiration of
23 such thirty days unless the Secretary and the applicant other-
24 wise agree. Any such hearing shall thereafter be conducted
25 on an expedited basis and the Secretary’s order thereon shall

1 be issued within ninety days after the date fixed by the Sec-
2 retary for filing final briefs.

3 “(D)(i) If an application (other than an abbreviated new
4 drug application) submitted under subsection (b) for a drug,
5 no active ingredient (including any ester or salt of the active
6 ingredient) of which has been approved in any other applica-
7 tion under subsection (b), was approved during the period
8 beginning January 1, 1982, and ending on the date of the
9 enactment of this subsection, the Secretary may not make the
10 approval of an application submitted under this subsection
11 which refers to the drug for which the subsection (b) applica-
12 tion was submitted effective before the expiration of ten years
13 from the date of the approval of the application under subsec-
14 tion (b).

15 “(ii) If an application submitted under subsection (b) for
16 a drug, no active ingredient (including any ester or salt of the
17 active ingredient) of which has been approved in any other
18 application under subsection (b), is approved after the date of
19 the enactment of this subsection and if the holder of the ap-
20 proved application certifies to the Secretary that no patent
21 has ever been issued to any person for such drug or for a
22 method of using such drug and that the holder cannot receive
23 a patent for such drug or for a method of using such drug
24 because in the opinion of the holder a patent may not be
25 issued for such drug or for a method of using such drug for

1 any known therapeutic purposes the Secretary may not make
2 the approval of an application submitted under this subsection
3 which refers to the drug for which the subsection (b) applica-
4 tion was submitted effective before the expiration of four
5 years from the date of the approval of the application under
6 subsection (b) unless the Secretary determines that an ade-
7 quate supply of such drug will not be available or the holder
8 of the application approved under subsection (b) consents to
9 an earlier effective date for an application under this subsec-
10 tion.

11 “(5) If a drug approved under this subsection refers in
12 its approved application to a drug the approval of which was
13 withdrawn or suspended for grounds described in the first
14 sentence of subsection (e) or was withdrawn or suspended
15 under this paragraph or which, as determined by the Secre-
16 tary, has been withdrawn from sale for safety or effectiveness
17 reasons, the approval of the drug under this subsection shall
18 be withdrawn or suspended—

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

21 “(B) if the listed drug has been withdrawn from
22 sale, for the period of withdrawal from sale or, if earli-
23 er, the period ending on the date the Secretary deter-
24 mines that the withdrawal from sale is not for safety or
25 effectiveness reasons.

1 “(6)(A)(i) Within sixty days of the date of the enactment
2 of this subsection, the Secretary shall publish and make avail-
3 able to the public—

4 “(I) a list in alphabetical order of the official and
5 proprietary name of each drug which has been ap-
6 proved for safety and effectiveness under subsection (c)
7 before the date of the enactment of this subsection;

8 “(II) the date of approval if the drug is approved
9 after 1981 and the number of the application which
10 was approved; and

11 “(III) whether in vitro or in vivo bioequivalence
12 studies, or both such studies, are required for applica-
13 tions filed under this subsection which will refer to the
14 drug published.

15 “(ii) Every thirty days after the publication of the first
16 list under clause (i) the Secretary shall revise the list to in-
17 clude each drug which has been approved for safety and ef-
18 fectiveness under subsection (c) or approved under this sub-
19 section during the thirty-day period.

20 “(iii) When patent information submitted under subsec-
21 tion (b) or (c) respecting a drug included on the list is to be
22 published by the Secretary the Secretary shall, in revisions
23 made under clause (ii), include such information for such
24 drug.

1 “(B) A drug approved for safety and effectiveness under
2 subsection (c) or approved under this subsection shall, for
3 purposes of this subsection, be considered to have been pub-
4 lished under subparagraph (A) on the date of its approval or
5 the date of enactment, whichever is later.

6 “(C) If the approval of a drug was withdrawn or sus-
7 pended for grounds described in the first sentence of subsec-
8 tion (e) or was withdrawn or suspended under paragraph (5)
9 or if the Secretary determines that a drug has been with-
10 drawn from sale for safety or effectiveness reasons, it may
11 not be published in the list under subparagraph (A) or, if the
12 withdrawal or suspension occurred after its publication in
13 such list, it shall be immediately removed from such list—

14 “(i) for the same period as the withdrawal or sus-
15 pension under subsection (e) or paragraph (5), or

16 “(ii) if the listed drug has been withdrawn from
17 sale, for the period of withdrawal from sale or, if earli-
18 er, the period ending on the date the Secretary deter-
19 mines that the withdrawal from sale is not for safety or
20 effectiveness reasons.

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

23 “(7) For purposes of this subsection:

24 “(A) The term ‘bioavailability’ means the rate and
25 extent to which the active ingredient or therapeutic in-

1 ingredient is absorbed from a drug and becomes available
2 at the site of drug action.

3 “(B) A drug shall be considered to be bioequiva-
4 lent to a listed drug if—

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

12 “(ii) the extent of absorption of the drug does
13 not show a significant difference from the extent
14 of absorption of the listed drug when administered
15 at the same molar dose of the therapeutic ingredi-
16 ent under similar experimental conditions in either
17 a single dose or multiple doses and the difference
18 from the listed drug in the rate of absorption of
19 the drug is intentional, is reflected in its proposed
20 labeling, is not essential to the attainment of ef-
21 fective body drug concentrations on chronic use,
22 and is considered medically insignificant for the
23 drug.”.

24 SEC. 102. (a)(1) Section 505(b) of such Act is amended
25 by adding at the end the following: “The applicant shall file

1 with the application the patent number and the expiration
2 date of any patent which claims the drug for which the appli-
3 cant submitted the application or which claims a method of
4 using such drug and with respect to which a claim of patent
5 infringement could reasonably be asserted if a person not li-
6 censed by the owner engaged in the manufacture, use, or sale
7 of the drug. If an application is filed under this subsection for
8 a drug and a patent which claims such drug or a method of
9 using such drug is issued after the filing date but before ap-
10 proval of the application, the applicant shall amend the appli-
11 cation to include the information required by the preceding
12 sentence. Upon approval of the application, the Secretary
13 shall publish information submitted under the two preceding
14 sentences.”.

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

19 “(2) If the patent information described in subsection (b)
20 could not be filed with the submission of an application under
21 subsection (b) because the application was filed before the
22 patent information was required under subsection (b) or a
23 patent was issued after the application was approved under
24 such subsection, the holder of an approved application shall
25 file with the Secretary the patent number and the expiration

1 date of any patent which claims the drug for which the appli-
2 cation was submitted or which claims a method of using such
3 drug and with respect to which a claim of patent infringe-
4 ment could reasonably be asserted if a person not licensed by
5 the owner engaged in the manufacture, use, or sale of the
6 drug. If the holder of an approved application could not file
7 patent information under subsection (b) because it was not
8 required at the time the application was approved, the holder
9 shall file such information under this subsection not later than
10 thirty days after the date of the enactment of this sentence,
11 and if the holder of an approved application could not file
12 patent information under subsection (b) because no patent
13 had been issued when the application was filed or approved,
14 the holder shall file such information under this subsection
15 not later than thirty days after the date the patent involved is
16 issued. Upon the submission of patent information under this
17 subsection, the Secretary shall publish it.”.

18 (3)(A) The first sentence of section 505(d) of such Act is
19 amended by redesignating clause (6) as clause (7) and insert-
20 ing after clause (5) the following: “(6) the application failed
21 to contain the patent information prescribed by subsection (b);
22 or”.

23 (B) The first sentence of section 505(e) of such Act is
24 amended by redesignating clause (4) as clause (5) and insert-
25 ing after clause (3) the following: “(4) the patent information

1 prescribed by subsection (c) was not filed within thirty days
2 after the receipt of written notice from the Secretary specify-
3 ing the failure to file such information; or”.

4 (b)(1) Section 505(a) of such Act is amended by insert-
5 ing “or (j)” after “subsection (b)”.

6 (2) Section 505(c) of such Act is amended by striking
7 out “this subsection” and inserting in lieu thereof “subsection
8 (b)”.

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

12 (4) The second sentence of section 505(e) is amended by
13 striking out “(j)” each place it occurs in clause (1) and insert-
14 ing in lieu thereof “(k)”.

15 (5) Section 505(k)(1) of such Act (as so redesignated) is
16 amended by striking out “pursuant to this section” and in-
17 serting in lieu thereof “under subsection (b) or (j)”.

18 (6) Subsections (a) and (b) of section 527 of such Act are
19 each amended by striking out “under section 505(b)” and
20 inserting in lieu thereof “under section 505”.

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

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

8 “(A) a certification, in the opinion of the applicant
9 and to the best of his knowledge, with respect to each
10 patent which claims the drug for which such investiga-
11 tions were conducted or which claims a use for such
12 drug for which the applicant is seeking approval under
13 this subsection and for which information is required to
14 be filed under paragraph (1) or subsection (c)—

15 “(i) that such patent information has not
16 been filed,

17 “(ii) that such patent has expired,

18 “(iii) of the date on which such patent will
19 expire, or

20 “(iv) that such patent is invalid or will not
21 be infringed by the manufacture, use, or sale of
22 the new drug for which the application is submit-
23 ted; and

24 “(B) if with respect to the drug for which investi-
25 gations described in paragraph (1)(A) were conducted

1 information was filed under paragraph (1) or subsection
2 (c) for a method of use patent which does not claim a
3 use for which the applicant is seeking approval under
4 this subsection, a statement that the method of use
5 patent does not claim such a use.

6 “(3)(A) An applicant who makes a certification de-
7 scribed in paragraph (2)(A)(iv) shall include in the application
8 a statement that the applicant has given the notice required
9 by subparagraph (B) to—

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

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

18 “(B) The notice referred to in subparagraph (A) shall
19 state that an application has been submitted under this sub-
20 section for the drug with respect to which the certification is
21 made to obtain approval to engage in the commercial manu-
22 facture, use, or sale of the drug before the expiration of the
23 patent referred to in the certification. Such notice shall in-
24 clude a detailed statement of the factual and legal basis of the

1 applicant's opinion that the patent is not valid or will not be
2 infringed.

3 “(C) If an application is amended to include a certifica-
4 tion described in paragraph (2)(A)(iv), the notice required by
5 subparagraph (B) shall be given when the amended applica-
6 tion is submitted.”.

7 (b) Section 505(c) of such Act (as amended by section
8 102(a)(2)) is amended by adding at the end the following:

9 “(3) The approval of an application filed under subsec-
10 tion (b) which contains a certification required by paragraph
11 (2) of such subsection shall be made effective on the last ap-
12 plicable date determined under the following:

13 “(A) If the applicant only made a certification de-
14 scribed in clause (i) or (ii) of subsection (b)(2)(A) or in
15 both such clauses, the approval may be made effective
16 immediately.

17 “(B) If the applicant made a certification de-
18 scribed in clause (iii) of subsection (b)(2)(A), the ap-
19 proval may be made effective on the date certified
20 under clause (iii).

21 “(C) If the applicant made a certification de-
22 scribed in clause (iv) of subsection (b)(2)(A), the ap-
23 proval shall be made effective immediately unless an
24 action is brought for infringement of each patent which
25 is the subject of the certification before the expiration

1 of forty-five days from the date the notice provided
2 under paragraph (3)(B) is received. If such an action is
3 brought before the expiration of such days, the approv-
4 al may be made effective upon the expiration of the
5 eighteen-month period beginning on the date of the re-
6 ceipt of the notice provided under paragraph (3)(B) or
7 such shorter or longer period as the court may order
8 because either party to the action failed to reasonably
9 cooperate in expediting the action, except that—

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

14 “(ii) if before the expiration of such period
15 the court decides that any such patent has been
16 infringed, the approval may be made effective on
17 such date as the court orders under section
18 271(e)(4)(A) of title 35, United States Code.

19 In such an action, each of the parties shall reasonably
20 cooperate in expediting the action. Until the expiration
21 of the forty-five-day period beginning on the date the
22 notice made under paragraph (3)(B) is received, no
23 action may be brought under section 2201 of title 28,
24 United States Code, for a declaratory judgment with
25 respect to the patent. Any action brought under such

1 section 2201 shall be brought in the judicial district
2 where the defendant has its principal place of business
3 or a regular and established place of business.

4 “(D)(i) If an application (other than an abbreviat-
5 ed new drug application) submitted under subsection (b)
6 for a drug, no active ingredient (including any ester or
7 salt of the active ingredient) of which has been ap-
8 proved in any other application under subsection (b),
9 was approved during the period beginning January 1,
10 1982, and ending on the date of the enactment of this
11 subsection, the Secretary may not make the approval
12 of another application for a drug for which investiga-
13 tions described in clause (A) of subsection (b)(1) and
14 relied upon by the applicant for approval of the appli-
15 cation were not conducted by or for the applicant or
16 which the applicant has not obtained a right of refer-
17 ence or use from the person by or for whom the inves-
18 tigation were conducted effective before the expiration
19 of ten years from the date of the approval of the appli-
20 cation previously approved under subsection (b).

21 “(ii) If an application submitted under subsection
22 (b) for a drug, no active ingredient (including any ester
23 or salt of the active ingredient) of which has been ap-
24 proved in any other application under subsection (b), is
25 approved after the date of the enactment of this sub-

1 section and if the holder of the approved application
2 certifies to the Secretary that no patent has ever been
3 issued to any person for such drug or for a method of
4 using such drug and that the holder cannot receive a
5 patent for such drug or for a method of using such
6 drug because in the opinion of the holder a patent may
7 not be issued for such drug or for a method of using for
8 any known therapeutic purposes such drug, the Secre-
9 tary may not make the approval of another application
10 for a drug for which investigations described in clause
11 (A) of subsection (b)(1) and relied upon by the applicant
12 for approval of the application were not conducted by
13 or for the applicant or which the applicant has not ob-
14 tained a right of reference or use from the person by or
15 for whom the investigations were conducted effective
16 before the expiration of four years from the date of the
17 approval of the application previously approved under
18 subsection (b) unless the Secretary determines that an
19 adequate supply of such drug will not be available or
20 the holder of the application approved under subsection
21 (b) consents to an earlier effective date for an applica-
22 tion under this subsection.”.

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

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

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

8 “(2) if the Secretary has determined that the ap-
9 plication is not approvable and all legal appeals have
10 been exhausted,

11 “(3) if approval of the application under subsec-
12 tion (c) is withdrawn and all legal appeals have been
13 exhausted,

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

16 “(5) upon the effective date of the approval of the
17 first application under subsection (j) which refers to
18 such drug or upon the date upon which the approval of
19 an application under subsection (j) which refers to such
20 drug could be made effective if such an application had
21 been submitted.

22 “(m) For purposes of this section, the term ‘patent’
23 means a patent issued by the Patent and Trademark Office of
24 the Department of Commerce.”.

1 SEC. 105. (a) The Secretary of Health and Human
2 Services shall promulgate, in accordance with the notice and
3 comment requirements of section 553 of title 5, United States
4 Code, such regulations as may be necessary for the adminis-
5 tration of section 505 of the Federal Food, Drug, and Cos-
6 metic Act, as amended by sections 101, 102, and 103 of this
7 Act, within one year of the date of enactment of this Act.

8 (b) During the period beginning on the date of the enact-
9 ment of this Act and ending on the date regulations promul-
10 gated under subsection (a) take effect, abbreviated new drug
11 applications may be submitted in accordance with the provi-
12 sions of section 314.2 of title 21 of the Code of Federal Reg-
13 ulations and shall be considered as suitable for any drug
14 which has been approved for safety and effectiveness under
15 section 505(c) of the Federal Food, Drug, and Cosmetic Act
16 before the date of the enactment of this Act. If any such
17 provision is inconsistent with the requirements of section
18 505(j) of the Federal Food, Drug, and Cosmetic Act, the
19 Secretary shall consider the application under the applicable
20 requirements of such section. The Secretary of Health and
21 Human Services may not approve such an abbreviated new
22 drug application which is filed for a drug which is described
23 in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food,
24 Drug, and Cosmetic Act except in accordance with such sec-
25 tion.

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

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

7 **TITLE II—PATENT EXTENSION**

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

11 **“§ 156. Extension of patent term**

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

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

19 “(2) the term of the patent has never been ex-
20 tended;

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

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

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

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

9 “(B) in the case of a patent which claims the
10 product, the product is also claimed in a patent which
11 has an earlier issuance date or which was previously
12 extended and which does not identically disclose or de-
13 scribe the product and—

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

18 “(ii) the holder of the patent which has an
19 earlier issuance date or which was previously ex-
20 tended has never been and will not become the
21 holder of the patent to be extended;

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

1 “(i) no other patent has been issued which
2 claims the product or a method of using the prod-
3 uct and no other patent which claims a method of
4 using the product may be issued for any known
5 therapeutic purposes; and

6 “(ii) no other method of manufacturing the
7 product is claimed in a patent having an earlier
8 issuance date;

9 “(B) in the case of a patent which claims a
10 method of manufacturing the product which primarily
11 uses recombinant DNA technology in the manufacture
12 of the product—

13 “(i) the holder of the patent for the method
14 of manufacturing the product (I) is not the holder
15 of a patent for the product or for a method of
16 using the product, (II) is not owned or controlled
17 by a holder of a patent for the product or for a
18 method of using the product or by a person who
19 owns or controls a holder of such a patent, and
20 (III) does not own or control the holder of such a
21 patent or a person who owns or controls a holder
22 of such a patent; and

23 “(ii) no other method of manufacturing the
24 product primarily using recombinant DNA tech-

1 nology is claimed in a patent having an earlier is-
2 suance.

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

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

11 “(B) in the case of a patent which claims a
12 method of manufacturing the product which primarily
13 uses recombinant DNA technology in the manufacture
14 of the product, the permission for the commercial mar-
15 keting or use of the product after such regulatory
16 review period is the first permitted commercial market-
17 ing or use of a product manufactured under the process
18 claimed in the patent; and

19 “(8) the patent does not claim another product or
20 a method of using or manufacturing another product
21 which product received permission for commercial mar-
22 keting or use under such provision of law before the
23 filing of an application for extension.

24 The product referred to in paragraphs (4), (5), (6), and (7) is
25 hereinafter in this section referred to as the ‘approved prod-

1 uct'. For purposes of paragraphs (4)(B), (5)(B), the holder of a
2 patent is any person who is the owner of record of the patent
3 or is the exclusive licensee of the owner of record of the
4 patent.

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

8 “(1) in the case of a patent which claims a prod-
9 uct be limited to any use approved for the approved
10 product before the expiration of the term of the patent
11 under the provision of law under which the applicable
12 regulatory review occurred;

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

19 “(3) in the case of a patent which claims a
20 method of manufacturing a product, be limited to the
21 method of manufacturing as used to make the approved
22 product.

23 “(c) The term of a patent eligible for extension under
24 subsection (a) shall be extended by the time equal to the reg-

1 ulatory review period for the approved product which period
2 occurs after the date the patent is issued, except that—

3 “(1) each period of the regulatory review period
4 shall be reduced by any period determined under sub-
5 section (d)(2)(B) during which the applicant for the
6 patent extension did not act with due diligence during
7 such period of the regulatory review period;

8 “(2) after any reduction required by paragraph (1),
9 the period of extension shall include only one-half of
10 the time remaining in the periods described in para-
11 graphs (1)(B)(i), (2)(B)(i), and (3)(B)(i) of subsection (g);
12 and

13 “(3) if the period remaining in the term of a
14 patent after the date of the approval of the approved
15 product under the provision of law under which such
16 regulatory review occurred when added to the regula-
17 tory review period as revised under paragraphs (1) and
18 (2) exceeds fourteen years, the period of extension shall
19 be reduced so that the total of both such periods does
20 not exceed fourteen years.

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

1 under the provision of law under which the applicable regula-
2 tory review period occurred for commercial marketing or use.

3 The application shall contain—

4 “(A) the identity of the approved product;

5 “(B) the identity of the patent for which an exten-
6 sion is being sought and the identification of each claim
7 of such patent which claims the approved product or a
8 method of using or manufacturing the approved prod-
9 uct;

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

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

20 “(E) information to enable the Commissioner to
21 determine under subsections (a) and (b) the eligibility of
22 a patent for extension and the rights that will be de-
23 rived from the extension and information to enable the
24 Commissioner and the Secretary of Health and Human

1 Services or the Secretary of Agriculture to determine
2 the period of the extension under subsection (g);

3 “(F) a brief description of the activities undertak-
4 en by the applicant during the applicable regulatory
5 review period with respect to the approved product and
6 the significant dates applicable to such activities; and

7 “(G) such patent or other information as the
8 Commissioner may require.

9 “(2)(A) Within sixty days of the submittal of an applica-
10 tion for extension of the term of a patent under paragraph (1),
11 the Commissioner shall notify—

12 “(1) the Secretary of Agriculture if the patent
13 claims a drug product or a method of using or manu-
14 facturing a drug product and the drug product is sub-
15 ject to the Virus-Serum-Toxin Act, and

16 “(ii) the Secretary of Health and Human Services
17 if the patent claims any other drug product, a medical
18 device, or a food additive or color additive or a method
19 of using or manufacturing such a product, device, or
20 additive and if the product, device, and additive are
21 subject to the Federal Food, Drug, and Cosmetic Act,
22 of the extension application and shall submit to the Secretary
23 who is so notified a copy of the application. Not later than
24 thirty days after the receipt of an application from the Com-
25 missioner, the Secretary receiving the application shall

1. review the dates contained in the application pursuant to
2 paragraph (1)(E) and determine the applicable regulatory
3 review period, shall notify the Commissioner of the determi-
4 nation, and shall publish in the Federal Register a notice of
5 such determination.

6 “(B)(i) If a petition is submitted to the Secretary making
7 the determination under subparagraph (A), not later than one
8 hundred and eighty days after the publication of the determi-
9 nation under subparagraph (A), upon which it may reason-
10 ably be determined that the applicant did not act with due
11 diligence during the applicable regulatory review period, the
12 Secretary making the determination shall, in accordance with
13 regulations promulgated by such Secretary determine if the
14 applicant acted with due diligence during the applicable regu-
15 latory review period. The Secretary shall make such determi-
16 nation not later than ninety days after the receipt of such a
17 petition. The Secretary of Health and Human Services may
18 not delegate the authority to make the determination pre-
19 scribed by this subparagraph to an office below the Office of
20 the Commissioner of Food and Drugs.

21 “(ii) The Secretary making a determination under clause
22 (i) shall notify the Commissioner of the determination and
23 shall publish in the Federal Register a notice of such determi-
24 nation together with the factual and legal basis for such de-
25 termination. Any interested person may request, within the

1 sixty-day period beginning on the publication of a determina-
2 tion, the Secretary making the determination to hold an in-
3 formal hearing on the determination. If such a request is
4 made within such period, such Secretary shall hold such
5 hearing not later than thirty days after the date of the re-
6 quest, or at the request of the person making the request, not
7 later than sixty days after such date. The Secretary who is
8 holding the hearing shall provide notice of the hearing to the
9 owner of the patent involved and to any interested person
10 and provide the owner and any interested person an opportu-
11 nity to participate in the hearing. Within thirty days after the
12 completion of the hearing, such Secretary shall affirm or
13 revise the determination which was the subject of the hearing
14 and notify the Commissioner of any revision of the determi-
15 nation and shall publish any such revision in the Federal
16 Register.

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

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

1 “(e)(1) A determination that a patent is eligible for ex-
2 tension may be made by the Commissioner solely on the basis
3 of the information contained in the application for the exten-
4 sion. If the Commissioner determines that a patent is eligible
5 for extension under subsection (a) and that the requirements
6 of subsection (d) have been complied with, the Commissioner
7 shall issue to the applicant for the extension of the term of
8 the patent a certificate of extension, under seal; for the period
9 prescribed by subsection (c). Such certificate shall be record-
10 ed in the official file of the patent and shall be considered as
11 part of the original patent.

12 “(2) If the term of a patent for which an application has
13 been submitted under subsection (d) would expire before a
14 determination is made under paragraph (1) respecting the ap-
15 plication, the Commissioner shall extend, until such determi-
16 nation is made, the term of the patent for periods of up to one
17 year if he determines that the patent is eligible for extension.

18 “(f) For purposes of this section:

19 “(1) The term ‘product’ means any machine, manu-
20 facture, or composition of matter for which a patent
21 may be obtained and includes the following:

22 “(A) A drug product.

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

1 “(2) The term ‘drug product’ means the active in-
2 gredient of a new drug, antibiotic drug, new animal
3 drug, or human or veterinary biological product (as
4 those terms are used in the Federal Food, Drug, and
5 Cosmetic Act, the Public Health Service Act, and the
6 Virus-Serum-Toxin Act) including any salt or ester of
7 the active ingredient, as a single entity or in combina-
8 tion with another active ingredient.

9 “(3) The term ‘major health or environmental ef-
10 fects test’ means a test which is reasonably related to
11 the evaluation of the health or environmental effects of
12 a product, which requires at least six months to con-
13 duct, and the data from which is submitted to receive
14 permission for commercial marketing or use. Periods of
15 analysis or evaluation of test results are not to be in-
16 cluded in determining if the conduct of a test required
17 at least six months.

18 “(4)(A) Any reference to section 351 is a refer-
19 ence to section 351 of the Public Health Service Act.

20 “(B) Any reference to section 503, 505, 507,
21 512, or 515 is a reference to section 503, 505, 507,
22 512, or 515 of the Federal Food, Drug, and Cosmetic
23 Act.

1 “(C) Any reference to the Virus-Serum-Toxin Act
2 is a reference to the Act of March 4, 1913 (21 U.S.C.
3 151–158).

4 “(5) The term ‘informal hearing’ has the meaning
5 prescribed for such term by section 201(y) of the Fed-
6 eral Food, Drug, and Cosmetic Act.

7 “(6) The term ‘patent’ means a patent issued by
8 the United States Patent and Trademark Office,

9 “(g) For purposes of this section, the term ‘regulatory
10 review period’ has the following meanings:

11 “(1)(A) In the case of a product which is a drug
12 product, the term means the period described in sub-
13 paragraph (B) to which the limitation described in
14 paragraph (4) applies.

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

17 (i) the period beginning on the date—

18 “(I) an exemption under subsection (i)
19 of section 505, subsection (d) of section 507,
20 or subsection (j) of section 512, or

21 “(II) the authority to prepare an experi-
22 mental drug product under the Virus-Serum-
23 Toxin Act,

24 Became effective for the approved drug product
25 and ending on the date an application was initially

1 submitted for such drug product under section
2 351, 505, 507, or 512 or the Virus-Serum-Toxin
3 Act, and

4 “(ii) the period beginning on the date the ap-
5 plication was initially submitted for the approved
6 drug product under section 351, subsection (b) of
7 such section 505, section 507, section 512, or the
8 Virus-Serum-Toxin Act and ending on the date
9 such application was approved under such section
10 or Act.

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

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

17 “(i) the period beginning on the date a major
18 health or environmental effects test on the addi-
19 tive was initiated and ending on the date a peti-
20 tion was initially submitted with respect to the
21 product under the Federal Food, Drug, and Cos-
22 metic Act requesting the issuance of a regulation
23 for use of the product, and

24 “(ii) the period beginning on the date a peti-
25 tion was initially submitted with respect to the

1 product under the Federal Food, Drug, and Cos-
2 metic Act requesting the issuance of a regulation
3 for use of the product, and ending on the date
4 such regulation became effective or, if objections
5 were filed to such regulation, ending on the date
6 such objections were resolved and commercial
7 marketing was permitted or, if commercial mar-
8 keting was permitted and later revoked pending
9 further proceedings as a result of such objections,
10 ending on the date such proceedings were finally
11 resolved and commercial marketing was permit-
12 ted.

13 “(3)(A) In the case of a product which is a medi-
14 cal device, the term means the period described in sub-
15 paragraph (B) to which the limitation described in
16 paragraph (4) applies.

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

19 “(i) the period beginning on the date a clini-
20 cal investigation on humans involving the device
21 was begun and ending on the date an application
22 was initially submitted with respect to the device
23 under section 515, and

24 “(ii) the period beginning on the date an ap-
25 plication was initially submitted with respect to

1 the device under section 515 and ending on the
2 date such application was approved under such
3 Act or the period beginning on the date a notice
4 of completion of a product development protocol
5 was initially submitted under section 515(f)(5) and
6 ending on the date the protocol was declared
7 completed under section 515(f)(6).

8 “(4) A period determined under any of the preced-
9 ing paragraphs is subject to the following limitations:

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

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

17 “(i) no request for an exemption de-
18 scribed in paragraph (1)(B) was submitted,

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

22 “(iii) no major health or environmental
23 effects test described in paragraph (2) was
24 initiated and no petition for a regulation or

1 application for registration described in such
2 paragraph was submitted, or

3 “(iv) no clinical investigation described
4 in paragraph (3) was begun or product devel-
5 opment protocol described in such paragraph
6 was submitted,

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

11 “(C) If the patent involved was issued before
12 the date of the enactment of this section and if an
13 action described in subparagraph (b) was taken
14 before the date of the enactment of this section
15 with respect to the approved product and the
16 commercial marketing or use of the product has
17 not been approved before such date, the period of
18 extension determined on the basis of the regulato-
19 ry review period determined under such para-
20 graph may not exceed two years.

21 “(h) The Commissioner may establish such fees as the
22 Commissioner determines appropriate to cover the costs to
23 the Office of receiving and acting upon applications under
24 this section.”.

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

“156. Extension of patent term.”.

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

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

11 “(2) It shall be an act of infringement to submit an ap-
12 plication under section 505(j) of the Federal Food, Drug, and
13 Cosmetic Act for a drug claimed in a patent or the use of
14 which is claimed in a patent, if the purpose of such submis-
15 sion is to obtain approval under such Act to engage in the
16 commercial manufacture, use, or sale of a drug claimed in a
17 patent or the use of which is claimed in a patent before the
18 expiration of such patent.

19 “(3) In any action for patent infringement brought under
20 this section, no injunctive or other relief may be granted
21 which would prohibit the making, using, or selling of a pat-
22 ented invention under the paragraph (1).

23 “(4) For an act of infringement described in paragraph
24 (2)—

1 “(A) the court shall order the effective date of any
2 approval of the drug involved in the infringement to be
3 a date which is not earlier than the date of the expira-
4 tion of the patent which has been infringed,

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

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

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

16 SEC. 203. Section 282 of title 35, United States Code,
17 is amended by adding at the end the following: “Invalidity of
18 the extension of a patent term or any portion thereof under
19 section 156 of this title because of the material failure—

20 “(1) by the applicant for the extension, or

21 “(2) by the Commissioner,

22 to comply with the requirements of such section shall be a
23 defense in any action involving the infringement of a patent
24 during the period of the extension of its term and shall be

1 pleaded. A due diligence determination under section
2 156(d)(2) is not subject to review in such an action.”.

○