

1987-88

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA
HOUSE OF REPRESENTATIVES

Presented and read a first time, 3 June 1988

(Minister for Science, Customs and Small Business)

A BILL

FOR

An Act to amend the *Patents Act 1952*, and for related purposes

BE IT ENACTED by the Queen, and the Senate and the House of Representatives of the Commonwealth of Australia, as follows:

PART I—PRELIMINARY

Short title etc.

- 5 **1.** (1) This Act may be cited as the *Patents Amendment Act 1988*.
 (2) In this Act, “Principal Act” means the *Patents Act 1952*.

Commencement

- 2.** This Act commences on a day to be fixed by Proclamation.

PART II—AMENDMENTS OF THE PATENTS ACT 1952

Interpretation

3. Section 6 of the Principal Act is amended by inserting the following definitions:

- “‘extension eligibility certificate’, in relation to a pharmaceutical substance defined by a claim or claims of the complete specification of a patent, means a certificate given by the Secretary to the Department of Community Services and Health: 5
- (a) certifying that an importation and general marketing approval has been granted in respect of that substance to a person identified in the certificate on a day specified in the certificate; and 10
- (b) certifying that such an approval had not been granted before that day in respect of:
- (i) any other form of that substance; 15
- (ii) a different formulation of that substance;
- (iii) a different strength of that substance; or
- (iv) that substance made by a different process;
- otherwise than in respect of:
- (v) a substance that is defined by a claim or claims of the complete specification; or 20
- (vi) if the patent is a patent of addition—a substance that is defined by a claim or claims of the complete specification of the patent for the main invention;
- ‘importation and general marketing approval’, in relation to a pharmaceutical substance, means an act done under a law of the Commonwealth that permits the importation of the substance into Australia and the general marketing of the substance in Australia (whether or not that marketing is made subject to conditions); 25
- ‘pharmaceutical substance’ means a substance (including a mixture or compound of substances) for therapeutic use the application, or one of the applications, of which involves a chemical interaction, or physico-chemical interaction, with a human physiological system, but does not include a substance that is solely for use in *in vitro* diagnosis or *in vitro* testing; 30 35
- ‘therapeutic use’ means use for the purpose of:
- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons;
- (b) influencing, inhibiting or modifying a physiological process in persons; or 40
- (c) testing the susceptibility of persons to a disease or ailment;”.

Duration of patent of addition

4. Section 75 of the Principal Act is amended:

(a) by omitting subsection (1) and substituting the following subsections:

5 “(1) Subject to subsection (1A), a patent of addition remains in force for so long as the patent for the main invention remains in force.

10 “(1A) The term of a patent of addition may be extended under Part IX even though the term of the patent for the main invention is not so extended.

“(1B) An extension of the term of a patent of addition shall commence at the end of the term of the patent for the main invention.”; and

(b) by inserting after subsection (2) the following subsection:

15 “(2A) If the term of a patent of addition is extended under Part IX and the patent for the main invention is not so extended, the patent of addition becomes an independent patent and the fees payable after the patent becomes an independent patent, and the dates when they become payable, shall be determined by its date.”.

20 5. Part IX of the Principal Act is repealed and the following Part is substituted:

“PART IX—EXTENSION OF CERTAIN PATENTS

Application for extension of term of patent relating to a pharmaceutical substance

25 “90. (1) Where:

(a) a claim or claims of a standard patent define a pharmaceutical substance;

(b) an importation and general marketing approval has not been granted in respect of:

30 (i) any other form of that substance;

(ii) a different formulation of that substance;

(iii) a different strength of that substance; or

(iv) that substance made by a different process;

otherwise than in respect of:

35 (v) a substance that is defined by a claim or claims of the complete specification; or

(vi) if the patent is a patent of addition—a substance that is defined by a claim or claims of the complete specification of the patent for the main invention;

40 (c) the patentee or a person acting with the patentee’s consent has applied for an importation and general marketing approval in respect of that substance; and

- (d) the patentee has requested the issue of an extension eligibility certificate in respect of that substance;

the patentee may, by notice in writing in accordance with the prescribed form given to the Commissioner not later than 21 months before the end of the term of the patent, apply for an extension of the term of the patent in respect of that substance.

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“(2) If:

- (a) more than one pharmaceutical substance is defined by the claim or claims of the complete specification of a standard patent; and

- (b) the patentee wishes to make an application for an extension of the term of the patent in respect of more than one of those substances;

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the patentee shall make a separate application in respect of each such substance.

“(3) Where a patentee makes an application for an extension of the term of a patent, the patentee shall forthwith send a copy of the application to the Secretary to the Department of Community Services and Health.

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“(4) Where a patentee makes an application for an extension of the term of a patent, the Commissioner shall forthwith publish in the *Official Journal* a notice stating that the application has been made and is open to public inspection.

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“(5) A patentee who has made an application for an extension of the term of a patent may, by notice in writing given to the Commissioner, withdraw that application.

“(6) Where an application for an extension of the term of a patent is withdrawn, the Commissioner shall forthwith publish in the *Official Journal* a notice stating that the application has been withdrawn.

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Application for extension to lapse in certain circumstances

“91. An application for an extension of the term of a patent shall lapse if the applicant does not, within the prescribed period, give to the Commissioner:

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- (a) an extension eligibility certificate in respect of the pharmaceutical substance to which the application relates; and
- (b) a proposed claim or claims.

Issue of extension eligibility certificate

“92. Where:

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- (a) a patentee makes a request in writing to the Secretary to the Department of Community Services and Health for the issue of an extension eligibility certificate in respect of a pharmaceutical substance defined by a claim or claims of the complete specification of a patent;

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- (b) an importation and general marketing approval is granted in respect of that substance; and

(c) the Secretary is satisfied that such an approval has not previously been granted in respect of:

- (i) any other form of that substance;
- (ii) a different formulation of that substance;
- (iii) a different strength of that substance; or
- (iv) that substance made by a different process;

otherwise than in respect of:

- (v) a substance that is defined by a claim or claims of the complete specification; or
- (vi) if the patent is a patent of addition—a substance that is defined by a claim or claims of the complete specification of the patent for the main invention;

the Secretary shall give an extension eligibility certificate to the patentee in respect of that substance.

15 **Advertisement of application for extension**

“93. (1) Where:

- (a) a patentee makes an application for an extension of the term of a patent; and
- (b) the patentee gives to the Commissioner the documents referred to in section 91;

the Commissioner shall publish in the *Official Journal* a notice to the effect that the Commissioner proposes to consider the application.

“(2) Where such a notice is published, the following documents are open to public inspection:

- (a) the extension eligibility certificate;
- (b) the proposed claim or claims;
- (c) such other documents as are prescribed.

“(3) Where, after documents relating to an application for an extension of the term of a patent are open to public inspection under subsection (2), the applicant sends to the Patent Office any document relating to the application, or the Commissioner sends to the applicant any document relating to the application, that document or a copy of that document, as the case requires, is also open to public inspection.

Opposition to extension

“94. The Minister, the Secretary to the Department of Community Services and Health or a person interested may, in accordance with, and within the period prescribed by, the regulations oppose the grant of an extension of the term of a patent.

Determination of application for extension

“95. (1) The Commissioner may determine an application for an extension of the term of a patent even though the term of the patent has expired.

“(2) Where the time for opposing the grant of an extension of the term of a patent has expired, the Commissioner shall, if the Commissioner is satisfied that: 5

- (a) the application for the extension, the extension eligibility certificate and the proposed claim or claims are in accordance with the requirements of this Act and the regulations; and 10
- (b) the proposed claim or claims do not claim matter other than the pharmaceutical substance to which the application relates;

grant an extension of the term of the patent for a period of 4 years in relation to the proposed claim or claims, but if the Commissioner is not so satisfied the Commissioner shall, subject to subsection (3), refuse to grant an extension of the term of the patent. 15

“(3) The patentee may, within such period as the Commissioner allows, amend the proposed claim or claims.

“(4) If, after amendments are made under subsection (3), the Commissioner is satisfied as to the matters referred to in subsection (2), the Commissioner shall grant an extension of the term of the patent for a period of 4 years in relation to the proposed claim or claims, but if the Commissioner is not so satisfied the Commissioner shall refuse to grant an extension of the term of the patent. 20

“(5) Where the Commissioner grants, or refuses to grant, an extension of the term of a patent, the Commissioner shall forthwith publish in the *Official Journal* a notice setting out the terms of the decision. 25

“(6) The Commissioner shall not grant, or refuse to grant, an extension of the term of a patent unless the Commissioner has given to the applicant and any person who opposed the grant of the extension under section 94 a reasonable opportunity of being heard. 30

“(7) Where:

- (a) an action or proceeding for infringement of a patent is pending in a court; or
- (b) an action or proceeding in which the validity of a patent or of a claim of the complete specification of a patent is disputed is pending in a court; 35

the Commissioner shall not determine an application for an extension of the term of the patent without the leave of the court.

Limitation on infringement proceedings 40

“96. Where the term of a patent has been extended under this Part, an action or proceeding for infringement of the patent shall not be instituted in respect of an act done more than 2 years after the day on which the

term of the patent expired unless the act constitutes sale, or offering or distribution for sale, of the pharmaceutical substance concerned.

Actions in respect of acts done where patent expires before extension is granted

5 “96A. Where:

- (a) a patentee makes an application for an extension of the term of a patent under this Part;
- (b) before the application is determined, the term of the patent expires; and

10 (c) the extension is granted;

the patentee has, after the extension is granted, the same rights to bring an action or proceeding in respect of the doing of an act during the period commencing on the expiration of the term of the patent and ending on the day on which the extension is granted as if the extension had been granted at the time when the act was done.

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Appeals

“96B. An applicant for an extension of the term of a patent, or a person who has opposed or proposes to oppose the extension, may appeal to the Federal Court:

- 20 (a) from a decision of the Secretary to the Department of Community Services and Health under section 92 to give or not to give an extension eligibility certificate; or
- (b) from a decision of the Commissioner under subsection 95 (2) or (4) granting or refusing to grant an extension of the term of the patent.

25 **Delegation**

“96C. The Secretary to the Department of Community Services and Health may, by signed instrument, delegate to an officer of that Department all or any of the powers and functions of the Secretary under this Part.”.

Extension of times by reason of errors

30 6. Section 160 of the Principal Act is amended by inserting after subsection (4) the following subsection:

“(4A) An application shall not be made under subsection (2) for an extension of time for more than 3 months in respect of an act or step required to be done or taken for the purposes of Part IX.”.

35 **PART III—APPLICATION AND TRANSITIONAL PROVISIONS**

Interpretation

7. (1) For the purposes of this Part, proceedings for the extension of the term of a patent under Part IX of the Principal Act shall be taken to have been commenced if the patentee has given to the Commissioner a request that the Commissioner advertise in the *Official Journal* the patentee’s

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intention to take action in accordance with subsection 90 (1) or 95 (1) of the Principal Act.

(2) Where a patentee has advertised the patentee's intention to take action in accordance with subsection 90 (1) or 95 (1) of the Principal Act but has not taken any action in a court in relation to the extension, the patentee may discontinue those proceedings by advertising in the *Official Journal* the patentee's intention to do so. 5

Application

8. The term of a patent cannot be extended under Part IX of the Principal Act as amended by this Act if the term of that patent was extended under Part IX of the Principal Act. 10

Continued operation of Part IX of Principal Act

9. (1) Part IX of the Principal Act continues to apply to any proceedings that were pending under that Part on 3 June 1988.

(2) Any proceedings that: 15

(a) were commenced under Part IX of the Principal Act after 3 June 1988; and

(b) are pending at the commencement of this section;

cease upon that commencement.

Extensions under new provisions for unexpired patents 20

10. (1) This section applies to a patent if:

(a) the term of the patent had not, at 3 June 1988, expired; and

(b) either:

(i) the term of the patent expired before the commencement of this section; or 25

(ii) at the commencement of this section, less than 24 months of the term of the patent remained.

(2) The patentee of a patent to which this section applies may, not later than 6 months after the commencement of this section, make an application under Part IX of the Principal Act as amended by this Act for an extension of the term of the patent. 30

(3) Where a patentee makes an application in accordance with subsection (2) for an extension of the term of a patent to which this section applies:

(a) the patentee may discontinue any proceedings that were pending in relation to the patent under Part IX of the Principal Act; and 35

(b) if an extension of the term of the patent is granted under Part IX of the Principal Act as amended by this Act, any proceedings that were pending in relation to the patent under Part IX of the Principal Act shall cease.

Extensions under new provisions for expired patents

11. (1) This section applies to a patent if:

- (a) the term of the patent expired after 2 June 1986 and before 3 June 1988; and
- (b) proceedings under Part IX of the Principal Act for an extension of the term of the patent were pending on 3 June 1988.

(2) Subject to this section, the patentee of a patent to which this section applies may, not later than 3 months after the commencement of this section, make an application under Part IX of the Principal Act as amended by this Act for an extension of the term of the patent.

(3) The Minister, the Secretary to the Department of Community Services and Health or a person interested may, within 3 months of the publication in the *Official Journal* of a notice to the effect that the application for an extension of the term of a patent has been made, by notice in writing given to the Commissioner, object to the application.

(4) It is not necessary for a person objecting to state any grounds for the objection.

(5) If such an objection is made:

- (a) the Commissioner shall notify the making of the objection in the *Official Journal*; and
- (b) the Commissioner shall not consider the application for an extension of the term of the patent unless the person who made the objection, by notice in writing given to the Commissioner before the end of 3 months after the objection was made, withdraws the objection.

(6) Where a patentee makes an application in accordance with subsection (2) for an extension of the term of a patent to which this section applies:

- (a) the patentee may discontinue the proceedings that were pending in relation to the patent under Part IX of the Principal Act; and
- (b) if an extension of the term of the patent is granted under Part IX of the Principal Act as amended by this Act, the proceedings that were pending in relation to the patent under Part IX of the Principal Act shall cease.

(7) If an objection is made under subsection (3) and that objection is not withdrawn as mentioned in subsection (5), the proceedings that were pending in relation to that patent under Part IX of the Principal Act may be continued.

Application of new provisions to applications under this Part

12. (1) Except to the extent to which they are modified by this Part, the provisions of Part IX of the Principal Act as amended by this Act apply to an application for an extension of the term of a patent made under this Part.

(2) Section 96A of the Principal Act as amended by this Act has effect in relation to an application of the kind referred to in section 11 as if the reference in section 96A of the Principal Act as amended by this Act to the period commencing on the expiration of the term of a patent were a reference to the period commencing on the day on which the application was made.

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NOTE

1. No. 42, 1952, as amended. For previous amendments, see No. 14, 1954; No. 3, 1955; No. 107, 1960; No. 84, 1962; No. 93, 1966; No. 34, 1969; No. 216, 1973; No. 20, 1974; No. 162, 1976; No. 131, 1978; Nos. 9, 19 and 188, 1979; No. 176, 1981; No. 26, 1982; No. 91, 1983; Nos. 92 and 165, 1984; Nos. 65 and 193, 1985; and No. 23, 1987.