

1988

THE PARLIAMENT OF THE COMMONWEALTH
OF AUSTRALIA

HOUSE OF REPRESENTATIVES

PATENTS AMENDMENT BILL 1988

EXPLANATORY MEMORANDUM

(Circulated by authority of the
Minister for Industry, Technology and Commerce,
Senator the Hon John N Button)

PATENTS AMENDMENT BILL 1988

GENERAL OUTLINE

1. The purpose of this Bill is to amend the *Patents Act 1952* to abolish the present procedures for extending patent term in Part IX of that Act. Those procedures are replaced with provisions enabling a once-off 4 year extension of term (no more and no less) for a standard patent for pharmaceutical substances for human use which are the subject of Department of Community Services and Health approval for importation and general marketing in Australia. The new extension provisions recognise the time necessarily taken to obtain marketing approval for new pharmaceuticals, but the present uncertain and costly court actions are replaced with more straightforward administrative procedures. Extensions under the new provisions will be available only for patents claiming pharmaceuticals for human use which have not previously been granted approval for importation and general marketing within Australia.

FINANCIAL IMPACT STATEMENT

2. Under the existing legislation, pharmaceutical companies regularly seek patent extensions of up to 10 years through the courts. The time taken by the present complex proceedings, particularly in cases where the extension is opposed, means that several years elapse before a decision is handed down. During that period, the patentee enjoys monopoly prices under the Pharmaceutical Benefits Scheme (PBS), whether or not an extension is subsequently granted. The more straightforward arrangements made by this Bill will result in earlier determination and substantially shorter extensions than may be granted at present. It is likely that patent extensions will be sought for more drugs than is the case at present. However, any increase in costs which may flow from an increase in numbers of extensions will be significantly offset by the more rapid introduction of competitor products after patent extensions expire, as a result of the provision which permits the testing of products by other manufacturers in the last 2 years of an extension.

3. Administration of the new scheme set up by the Bill may involve a small number of additional staff in the Patent Office and the Department of Community Services and Health.

ABBREVIATIONS

4. The following abbreviations are used in this Explanatory Memorandum:

Bill: Patents Amendment Bill 1988

Commissioner: Commissioner of Patents or a delegate of the Commissioner of Patents

Extension of term: extension of the term of a standard patent

Official Journal: the Official Journal published by the Commissioner under section 175 of the Patents Act

NOTES ON INDIVIDUAL CLAUSES

PART I - PRELIMINARY

Clause 1 : Short title etc

Clause 2 : Commencement

5. Clause 2 provides that the amending Act will come into operation on a day to be fixed by Proclamation. This will enable implementing regulations to be made.

PART II - AMENDMENTS OF THE PATENTS ACT 1952

Clause 3: Interpretation

6. Clause 3 inserts 4 new definitions into section 6 of the Patents Act.

7. An "extension eligibility certificate" obtained from the Department of Community Services and Health will be used by the Commissioner in determining whether a patent covering a pharmaceutical substance is eligible for an extension of term. Such a certificate will certify, first, that an importation and general marketing approval has been granted in respect of a pharmaceutical substance defined by a claim or claims of a patent specification. Second, it will certify to the effect that no previous approval has been granted in respect of that substance in another form, a different formulation or strength, or made by a different process, other than an approval in respect of a substance defined by a claim or claims of the same specification (or, in the case of a patent of addition, of the patent for the main invention). (The requirement in relation to previous approvals is explained further in relation to new section 90(1)(b), below.)

8. The definition of "importation and general marketing approval" is such that it would include a permission granted by the Secretary to the Department of Community Services and Health under the Customs (Prohibited Imports) Regulations in force under the *Customs Act 1901* to import a pharmaceutical substance into Australia for the purposes of general marketing. Such a permission is granted only after rigorous assessment of the pharmaceutical for safety and efficacy.

9. The definitions of "pharmaceutical substance" and "therapeutic use" have the effect that the new patent extension scheme will apply only to pharmaceuticals for human use. The scheme will be available for "therapeutic substances" in the terms of the Customs (Prohibited Imports) Regulations, with added limitations that:

- only substances for use in relation to humans are included (those solely for veterinary use would not be included);
- only substances whose use involves a chemical or physico-chemical interaction with a human physiological system are included (devices such as surgical ligatures are not included);

- . substances whose sole use is in *in vitro* diagnosis or testing are not included.

Clause 4: Duration of patent of addition

10. Clause 4 makes several changes to section 75 of the Patents Act, which relates to the duration of patents of addition, consequential on the changes made by the Bill to Part IX of the Act. Under section 75 as amended, the term of a patent of addition will be capable of extension under Part IX notwithstanding that the patent for the main invention in relation to the patent of addition has not been extended. In such a case, the patent of addition will then stand as an independent patent, but the extension of term will commence on the expiry of the term of the patent for the main invention.

Clause 5

11. Clause 5 repeals Part IX of the Patents Act and substitutes a new Part IX. The existing Part IX contains procedures for seeking an extension of term on the ground of inadequate remuneration (section 90) or war loss (section 95). New Part IX establishes new procedures enabling a 4 year extension of term of a patent so far as that patent's claims define a pharmaceutical for human use which is the subject of Department of Community Services and Health approval for importation and general marketing. The new procedures are contained in new sections 90 to 96C, outlined in more detail below.

New section 90: Application for extension of term of patent relating to a pharmaceutical substance

12. New section 90 sets out the circumstances in which a patentee is entitled to apply for an extension of term in respect of a pharmaceutical substance. The first prerequisite is that a claim or claims of the patent must define a "pharmaceutical substance" (section 90(1)(a)).

13. Second, there must have been no previous importation and general marketing approval granted in respect of that substance in another form, a different formulation or strength, or made by a different process (section 90(1)(b)(i) to (iv)). This bar does not apply, however, where the earlier approval was in respect of a substance defined by a claim or claims of the same specification (or, in the case of an extension of a patent of addition, by a claim or claims of the patent for the main invention) (section 90(1)(b)(v) and (vi)). Section 90(1)(b) thus has the effect that extensions will be available only for a patent claiming a substance which is subject to importation and general marketing approval for the first time. This provision recognises that subsequent marketing approvals for different forms, formulations or strengths of a substance, or for the substance made by a different process, are invariably granted much more rapidly than the original approval.

14. The other prerequisite to seeking an extension of term is that the patentee, or a person acting with the patentee's consent, must have applied for an importation and general marketing approval

for the substance concerned (section 90(1)(c)), and the patentee must have requested the issue of an extension eligibility certificate.

15. An application for an extension of term will need to be made in a prescribed form and to be lodged not later than 21 months before the end of the term of the patent.

16. Separate applications for an extension of term will need to be made in respect of different pharmaceutical substances defined in a patent's claims (section 90(2)).

17. Subsections 90(3) and (4) provide for applications for extensions of term to be sent to the Secretary to the Department of Community Services and Health, to be notified in the Official Journal published by the Patent Office, and to be open to public inspection. Subsections 90(5) and (6) provide for withdrawal of applications for extensions.

New section 91: Application for extension to lapse in certain circumstances

18. New section 91 requires an applicant for an extension of term to lodge, within the prescribed time, an extension eligibility certificate and a proposed claim or claims, or else the application will lapse. It is envisaged that the prescribed time will be 1 month after the granting of an importation and general marketing approval or after the application for an extension was made, whichever is the later.

New section 92: Issue of extension eligibility certificate

19. New section 92 provides for the Secretary of the Department of Community Services and Health (or the Secretary's delegate - see new section 96C) to issue an extension eligibility certificate on a patentee's request (section 90(a)). The certificate will be issued after an importation and general marketing approval has been granted in respect of the pharmaceutical substance concerned (section 92(b)), provided the Secretary is satisfied that no previous approval has been granted in respect of that substance in another form, a different formulation or strength, or made by a different process, other than an approval in respect of a substance defined by a claim or claims of the same specification (or, in the case of a patent of addition, by a claim or claims of the patent for the main invention).

New section 93: Advertisement of application for extension

20. New section 93 provides, where the documents referred to in section 91 have been given to the Commissioner, for notification in the Official Journal that the Commissioner proposes to consider the application for an extension (section 93(1)). The documents concerned, and later correspondence between the Patent Office and the applicant, are expressly made open to public inspection (section 93(2) and (3)).

New section 94: Opposition to extension

21. New section 94 entitles the Minister, the Secretary to the Department of Community Services and Health or a person interested to oppose the grant of an extension of the term of a patent. The grounds for opposition will be those on which the Commissioner must determine an application for an extension (see new section 95).

New section 95: Determination of application for extension

22. New section 95 sets out the criteria and procedures by which the Commissioner will determine applications for extensions of term.

23. Section 95(1) makes it clear that an application for an extension may be determined even though the term of the patent concerned has expired.

24. Section 95(2) makes it plain that the Commissioner must wait to allow any oppositions to be made before determining an application for an extension, and sets out the criteria by which an application for extension is to be determined. Those criteria are that the application for the extension, the extension eligibility certificate and the proposed claim or claims must be in accordance with the requirements of the Patents Act and Regulations, and that the proposed claim or claims do not claim matter other than the pharmaceutical substance concerned. Where the Commissioner is satisfied that the criteria are met, the Commissioner will grant an extension of the term of the patent for a period of 4 years in relation to the proposed claim or claims. Where the Commissioner is not satisfied, subject to section 95(3), the Commissioner will refuse to grant an extension.

25. Section 95(3) entitles the patentee to amend the proposed claim or claims. That might be expected to happen most commonly where the Commissioner is not initially satisfied that the criteria set out in section 95(2) are met.

26. Section 95(4) provides for determination by the Commissioner of an application for an extension on the basis of claims amended under subsection 95(3). Section 95(5) provides for notification in the Official Journal of grant or refusal of an extension of term. Section 95(6) requires the Commissioner to give applicants for extensions and opponents of extensions a reasonable opportunity of being heard.

27. Section 95(7) requires the Commissioner to obtain the leave of the court before determining an application for an extension in a case where the patent concerned is the subject of certain kinds of court proceedings.

New section 96: Limitation on infringement proceedings

28. New section 96 restricts the rights of a patentee whose patent term has been extended in such a way that an act done more than 2 years after the day on which the original term of the patent

expired will not be subject to action for infringement of the patent except if it constitutes sale, or offering or distribution for sale, of the pharmaceutical substance concerned. This provision would, for example, allow manufacturers of "generic" pharmaceutical products a 2 year period for "springboarding", before a patent term extension expires, to undertake testing and to prepare for entry into the market at the expiry of the 4 year extension period.

New section 96A: Actions in respect of acts done where patent expires before extension is granted

29. New section 96A has the effect that, where a patent's term is extended after the original term expired, the patentee's rights will backdate to the date of expiry. This provision recognises that interested third parties will have been warned, before the term expired, of the pending application for an extension, by way of the notice referred to in section 90(4).

New section 96B: Appeals

30. New section 96B provides a right of appeal to the Federal Court 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 from a decision of the Commissioner under section 95(2) or (4) granting or refusing to grant an extension of the term of a patent.

New section 96C: Delegation

31. New section 96C enables delegations by the Secretary to the Department of Community Services and Health of the Secretary's powers and functions under new Part IX.

Clause 6: Extension of times by reason of errors

32. Clause 6 limits the availability of section 160(2) of the Patents Act. Section 160 empowers the Commissioner to extend times for doing certain things under the Act where a time limit has not been complied with. Section 160(2) may be invoked where, by reason of an error or omission on the part of the person concerned or of the person's agent or attorney, or by reason of circumstances beyond the control of the person concerned, an act or step in relation to proceedings under the Patents Act (not being proceedings in a court) required to be done or taken within a certain time has not been so done or taken.

33. New section 160(4A), which is inserted by clause 6 of the Bill, provides that an application shall not be made under section 160(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 new Part IX. This provision recognises the need to ensure that the new procedures for extensions of term operate expeditiously, leaving those involved and third parties with the minimum period of uncertainty consistent with the need to resolve matters fairly.

PART III - APPLICATION AND TRANSITIONAL PROVISIONS

Clause 7: Interpretation

34. Clause 7(1) of the Bill explains what is meant, for the purposes of Part III of the Bill, by proceedings having been "commenced" under the present extension procedures in Part IX of the Patents Act. For the purposes of Part III, the operative factor will be a request to the Commissioner to advertise the patentee's intention in the Official Journal. Advertisement of intention is referred to in present sections 90(1) and 95(1) of the Act.

35. Clause 7(2) makes it clear that proceedings which have been commenced in the terms of clause 7(1) may be discontinued, if they have not proceeded to action in a court, by advertisement in the Official Journal. (Discontinuance of proceedings which are already under way in the court will be able to be undertaken in the usual way.)

Clause 8: Application

36. Clause 8 has the effect that an extension of the term of a patent under the new procedures will be precluded by an extension of the term of that patent under present Part IX.

Clause 9: Continued operation of Part IX of Principal Act

37. Clause 9 has the effect that present Part IX of the Patents Act will generally cease to apply after 3 June 1988 (the date of introduction of the Bill into the Parliament). Under clause 9(1), Part IX before repeal continues to apply to any extension of term proceedings pending on 3 June 1988. Clause 9(2) has the effect that any proceedings that were commenced under present Part IX after 3 June 1988, and are pending at the commencement date of the Bill, will automatically cease upon that date.

38. The provisions of clause 9 give effect to the policy change made by the Bill with effect from its date of introduction into the Parliament. These provisions recognise that public announcements were made in November 1986 of the Government's intention to abolish patent term extension procedures generally, and in September 1987 of the Government's intention to provide a procedure enabling 4 year extensions for pharmaceuticals for human use.

Clause 10: Extensions under new provisions for unexpired patents

39. Clauses 10 and 11 make special transitional provisions enabling patentees in certain circumstances to make applications under new Part IX of the Patents Act.

40. Clause 10 applies to a patent whose term had not, at 3 June 1988, expired, and which either expires before the commencement date of the Bill or whose remaining term at the commencement date is less than 24 months (see clause 10(1)). In such a case, the patentee will be able to apply, not later than 6 months after the commencement date, for an extension of term under new Part IX (clause 10(2)), but any proceedings pending under existing Part IX

will automatically cease if an extension of term is granted under new Part IX (clause 10(3)(b)). Proceedings under existing Part IX may be discontinued by a patentee after making an application under clause 10(2) (see clause 10(3)(a)). The 6 month time limit in clause 10(2) will not be subject to the possibility of extension.

41. It may be noted that the patentee of a patent whose term has between 21 and 24 months remaining at the commencement date of the Bill would in any event be able to seek an extension under new Part IX, without the need for clause 10. Recognising that the new provisions will be unfamiliar for a time, however, the effect of clause 10 in such circumstances differs from new Part IX in that such a patentee will, under clause 10(2), automatically have up to 6 months to make an application for an extension of term under the new provisions.

Clause 11: Extensions under new provisions for expired patents

42. Clause 11 applies to a patent whose term expired after 2 June 1986 and before 3 June 1988 if extension of term proceedings under existing Part IX of the Patents Act were pending on 3 June 1988 (clause 11(1)). In such a case, the patentee will be able to apply, not later than 3 months after the commencement date, for an extension of term under new Part IX (clause 11(2)). The somewhat restricted availability of clause 11 to expired patents (i.e. to those which expired after 2 June 1986 and before 3 June 1988) recognises the fact that an application for an extension of term under new Part IX will necessarily take some months to resolve, and that there needs to be a period of at least about a year remaining after an extension is granted if the 4 year extension is to have any practical effect.

43. Recognising that others may have arranged their affairs in the knowledge that the term of the patent had already expired when the Bill was introduced, however, clause 11(3) enables a person interested (or the Minister or the Secretary to the Department of Community Services and Health) to object in writing to an application under clause 11(2). Such an objection must be made within 3 months from a notification of the application in the Official Journal and, unless it is withdrawn within 3 months after it was made, it will act as a bar to the Commissioner from considering the application for an extension (clause 11(5)). It is not necessary for a person objecting to state any grounds for the objection (clause 11(4)). The bar created is thus intended to be effective solely at the discretion of a person entitled to object under clause 11(3).

44. If an application made in accordance with clause 11(2) does proceed to grant of an extension of term under new Part IX, the proceedings pending under existing Part IX will automatically cease (clause 11(6)(b)). Proceedings under existing Part IX may be discontinued by a patentee after making an application in accordance with clause 11(2) (see clause 11(6)(a)). Proceedings under existing Part IX may be continued, however, notwithstanding that an objection to the proceedings under new Part IX may have been made (see clause 11(7)). The time limits for taking actions specified in clause 11 will not be subject to the possibility of any extension.

Clause 12: Application of new provisions to applications made under this Part

45. Clause 12(1) makes it clear that the provisions of new Part IX apply to applications for extensions of term made under the transitional arrangements, except to the extent that they are modified by the transitional arrangements.

46. Clause 12(2) modifies the operation of new section 96A (inserted by clause 5) in the case of an application for an extension made under clause 11. In such a case, the right to take infringement proceedings conferred by section 96A, once an extension of term has been granted, will backdate only to the making of the application for an extension rather than to the date on which the term of the patent expired.

