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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

PATENTS AMENDMENT BILL 1989

SUPPLEMENTARY EXPLANATORY MEMORANDUM

Amendments and New Clause to be Moved on Behalf of the Government

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

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PATENTS AMENDMENT BILL 1989

AMENDMENTS AND NEW CLAUSE TO BE MOVED ON BEHALF OF THE GOVERNMENT

OUTLINE

1. The main purpose of the amendments and new clause is to clarify and simplify the procedures contained in the Bill by which extensions of patent term for pharmaceutical substances will be obtained. In particular, the amendments will ensure that the patent extension scheme will cover all patented pharmaceuticals which receive marketing approval from the Department of Community Services and Health (DCSH) - whether or not they are imported; whether or not they had previously been approved in some other form or formulation; and including antibiotics, antivirals and antitoxins. The amendments will enable a patentee to obtain an extension for all pharmaceutical substances claimed in a particular patent - provided that marketing approval is obtained for one of those substances, and notwithstanding that the marketing approval granted may be restricted to a particular product or formulation containing the substance.

2. The working of the requirement that a pharmaceutical substance must be covered by a patent in order to be eligible for an extension of term is amended so as to correspond more closely to criteria employed elsewhere in the Patents Act in relation to requirements of patent claims. The time by which an extension application must be made is shortened from 21 months to 12 months before expiry of a patent. Express grounds on which a third party may oppose an extension are inserted (the grounds corresponding to the criteria already contained in the Bill on which the Commissioner of Patents must decide whether to grant an extension).

3. The "springboarding" provisions in proposed section 96 (clause 5, page 7) are varied so as to broaden slightly the basis for infringement proceedings during the last 2 years of a patent extension. This change will make it an infringement during that 2 year period to distribute a pharmaceutical substance covered by a patent extension for a purpose other than obtaining DCSH marketing approval (e.g. for clinical use except where clinical trials are required for marketing approval purposes). The Bill already enables infringement proceedings during that period against sale or offering for sale.

FINANCIAL IMPACT STATEMENT

4. The changes made by the amendments and new clause will not involve any change to the financial impact outlined in the Explanatory Memorandum to the Bill itself.

NOTES ON INDIVIDUAL AMENDMENTS

Amendment (1)

5. Amendment (1) simplifies the procedure for demonstrating that a pharmaceutical substance has received marketing approval from the Secretary to DCSH. The definitions of "extension eligibility certificate" and "importation and general marketing approval" presently proposed to be included in section 6 of the Patents Act are accordingly omitted in favour of a single definition of "marketing approval certificate". There are several features of this change:

- the Secretary (or a delegate) will not have to undertake any interpretation of a patent specification or patent claims in order to certify that a particular pharmaceutical substance has been given marketing approval;

- there will be no need for the Secretary to address the question whether a pharmaceutical substance has, in another form, another formulation, or a different strength, or when made by another process, been given marketing approval before the date on which the approval concerned was given; new forms, formulations, etc, will now be eligible for extensions of patent term;

- the relevant approval of the Secretary will be simply expressed as "marketing approval" rather than "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 ..."; this change reflects the practical reality of the marketing approval procedures of DCSH, avoids some of the complexity of the provisions in the Bill, and will enable patent term extensions for pharmaceuticals manufactured in Australia as well as those imported from abroad;

- the Secretary's approval for the marketing of either a pharmaceutical substance or a product containing the substance will suffice for the issue of a marketing approval certificate in respect of the substance.

Amendment (2)

6. Amendment (2) ensures that the definition of "pharmaceutical substance" which is proposed to be included in section 6 will clearly include antibiotics, antivirals, anti-toxins and other pharmaceuticals whose mode of action is on a poison in the body rather than on a human physiological system itself.

Amendment (3)

7. This amendment adds a further clause to the bill which will ensure that a patent of addition which becomes an independent patent by virtue of proposed section 75(2A) of the Patents Act (inserted by clause 4 of the bill) is not invalidated by the publication of the patent from which the patent of addition derives.

Amendment (4)

8. Amendment (4) simplifies and changes the criteria set out in proposed new section 90(1) under which a patentee is entitled to apply for an extension of patent term for a pharmaceutical substance. Section 90(1)(a), which sets out the necessary relationship between the pharmaceutical substance and the patent concerned, is to be replaced by a criterion corresponding closely to criteria employed elsewhere in the Patents Act in relation to the allowability of new or amended claims in a specification.

9. The omission of proposed section 90(1)(b) and (c) goes hand in hand with the changes which are outlined above in connection with amendment (1).

Amendment (5)

10. This amendment changes the wording of section 90(1) consequential on the changes made by amendment (1) whereby an "extension eligibility certificate" is replaced by a "marketing approval certificate".

Amendment (6)

11. This amendment to proposed section 90(1) reduces the time before the end of a patent's term by which an extension application must be made. That time is reduced from 21 months to 12 months.

Amendments (7) and (8)

12. The changes to proposed section 90(1) made by amendments (7) and (8) will enable a patentee to seek an extension of term for <u>all</u> pharmaceutical substances covered by a patent in a <u>single</u> extension application, provided that one of those substances (or a product containing it) has received marketing approval from the Secretary to DCSH.

Amendment (9)

13. This amendment to the wording of proposed section 91 is consequential on the changes made by amendment (1) to replace an "extension eligibility certificate" with a "marketing approval certificate".

Amendments (10) and (11)

14. The revised criteria and procedures for issuing a marketing approval certificate under section 92 which are introduced by amendments (10) and (11) go hand in hand with the changes which are outlined above in connection with amendment (1).

Amendment (12)

15. This amendment to proposed section 92 is consequential on the changes made by amendment (1) to replace an "extension eligibility certificate" with a "marketing approval certificate", and adds the requirements that the certificate be issued forthwith on the granting of marketing approval and that it be issued in the prescribed form.

Amendment (13)

16. This amendment to the wording of proposed section 93(2) is consequential on the changes made by amendment (1) to replace an "extension eligibility certificate" with a "marketing approval certificate".

Amendment (14)

17. Amendment (14) clarifies proposed section 94 by setting out expressly the grounds on which an extension of term may be opposed by a third party. Those grounds correspond to the criteria on which the Commissioner of Patents must be satisfied before granting an extension of term (see section 95(2)).

Amendment (15)

18. This amendment to the wording of proposed section 95(2)(a) is consequential on the changes made by amendment (1) to replace an "extension eligibility certificate" with a "marketing approval certificate".

Amendment (16)

19. Amendment (16) omits an unnecessary reference to "the regulations" in proposed section 95(2).

Amendment (17)

20. Amendment (17) adds a reference in proposed section 95(2) to take account of the fact that an extension application may be in respect of more than one pharmaceutical substance. This is consequential on the change to section 90(1) made by amendment (7).

Amendments (18) and (19)

21. These amendments to proposed section 96 modify the "springboarding" arrangements which in effect will enable generic pharmaceutical manufacturers to undertake certain activities without being subject to infringement proceedings during the last 2 years of a patent term extension. Under the amended provision, it will be an infringement during that period to sell, offer for sale, or distribute for a purpose other than obtaining DCSH marketing approval, a pharmaceutical substance covered by the extended patent.

Amendment (20)

22. This amendment to the transitional provisions in clause 10 of the bill reflects the new time limit for making extension applications which is introduced by amendment (6).

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