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Trans-Pacific Partnership Agreement Amendment Bill: patent term extensions, proposed regulations

Introduction

1. The New Zealand Law Society (Law Society) welcomes the opportunity to comment on the consultation document *Trans-Pacific Partnership Agreement Amendment Bill: Patent Term Extensions Proposed Regulations* (consultation document).
2. The consultation document contains proposals for the regulations required to implement the patent term extension provisions in the Trans-Pacific Partnership Agreement Amendment Bill (the Bill). If the Act, when passed by Parliament, substantively differs from the Bill, the Law Society recommends that consultation should be reopened on all affected proposed regulations.
3. This submission responds to the questions in the consultation document (where appropriate) and comments on the following issues:
 - The request for extension of term (paragraph 12)
 - Extensions of term for unreasonable delays in grant (paragraphs 22 – 36)
 - Guidelines to be developed by Medsafe (paragraph 66)
 - Opposition procedure (paragraphs 70, and 72 – 74)

A. General Comments

The request for extension of term (paragraph 12)

4. Paragraph 12 of the consultation document says that the request for an extension of term will need to include a statement confirming that there are no relevant proceedings before the court in respect of the patent. Presumably that means that if there are relevant proceedings before the court the patentee cannot apply for an extension of term. The time limits for

applying for an extension of term mean that the patentee will miss out on being able to apply for an extension of term.

5. The proposal in paragraph 12 seems to misunderstand proposed new section 111N.¹ That new section will provide that the Commissioner cannot make a decision if court proceedings are pending, without the leave of the court. Proposed new section 111N only prohibits the making of the decision. It does not prohibit the making of an application. It does allow for the making of a decision with the leave of the court.
6. The Law Society suggests that the request for an extension of term should include a statement advising whether there are any relevant proceedings before the court in respect of the patent, but should not require a statement that there are no relevant proceedings.

Extensions of term for unreasonable delays in grant (paragraphs 22 – 36)

7. The choice of any option proposed is a matter of policy, balancing the interests of patent owners and society as a whole, and the Law Society expresses no view on that.
8. An alternative approach to the three options proposed would be for IPONZ automatically to provide to an applicant (i.e. without request) a certificate when any patent is issued outside the limits (of five years from patent date or three years from the date of request of examination). Such a certificate would specify if the applicant is entitled to an extension and if so, for how long. If the applicant was unsatisfied with the decision it could then request a hearing on the matter and any third party would have the right to oppose. The information that the Commissioner needs would be on the IPONZ file. IPONZ could record which periods of time were to be disregarded as the examination proceeds and keep a running tally of the length of extension to which the applicant is entitled. Whether or not an extension should be granted could be determined at minimal expense while all the information is fresh. This would create far more certainty than any of the three options set out in the consultation document. This would require removing clause 111A of the Bill and rewording clause 111B.
9. The policy that seeks to implement the TPP obligations is based on the assumption that patent applications are filed in the expectation that a patent will be granted within the respective five and three year limits. If IPONZ is unable to meet these time limits in any case, an applicant should not be expected to pay an extra fee and incur additional prosecution costs as a result of IPONZ's delay. It would not be an undue burden for IPONZ to adjust its procedures to keep a tally of times to be disregarded during the course of prosecution, and it would remove the uncertainties inherent in each of the three options outlined in paragraphs 23 to 36.

Guidelines to be developed by Medsafe (paragraph 66)

10. The consultation document (paragraph 66) indicates that the issue of the periods to be disregarded in the Certificate from the regulator (Medsafe) provided under new section 111F(2) will be dealt with through practice guidelines to be developed by Medsafe, rather than by regulations. The Law Society recommends that this be reconsidered. The periods to be disregarded should be specified in regulations rather than in practice guidelines. The consultation document (at paragraphs 61 and 62) identifies that uncertainty would be created if guidelines were to be made by the Commissioner of Patents. It is submitted that the same uncertainty would be created if Medsafe were to be left to develop its own guidelines.

¹ Clause 75, amendments to Patents Act 2013

Opposition procedure (paragraphs 70, and 72 to 74)

11. These paragraphs contain incorrect references to section numbers of the Patents Act 2013 and regulation numbers of the Patents Regulations 2014. Presumably it was intended that these paragraphs would refer to section 123 (which relates to opposing an application to restore a lapsed patent), rather than section 120 (which relates to when a request for restoration of a patent may be made).² Similarly, regulation 117 relates to when a request for restoration may be made, not to opposing such a request. The relevant regulations that relate to oppositions are 112 to 114 and 118 to 120.
12. Paragraph 71 suggests that oppositions filed under sections 87 and 92 have additional evidence rounds, however, the regulations do not appear to provide for anything more than the usual process – opponent’s evidence, applicant’s evidence, opponent’s evidence strictly in reply.³
13. Paragraph 72 suggests that the procedures for an opposition to restoration in regulations 112 to 114 and 118 to 120 are simpler than the procedures in regulations 89 and 94 because they may not involve the filing of evidence. This suggestion overlooks regulations 114 and 120, which do contemplate the filing of evidence. They are equivalent to regulations 89(4) – (6) and 94(4) – (6). In other words, there is little difference between the two types of procedures.
14. Opposition proceedings for patent term extensions for unreasonable curtailment are unlikely to be as complex as oppositions to grant. The evidence will be restricted largely to what is available in the Medsafe files. In contrast to this, oppositions to the grant of a patent can involve multiple grounds, many prior art documents and expert evidence. Their complexity is driven by these considerations, not the type of procedure involved.

B. Responses to questions in consultation document

Question 1: Do you agree with the content of the proposed regulations regarding the manner in which a request for extension of term must be made? If not, why not?

15. The procedure is straightforward and, given the comment in paragraph 13 of the consultation document that most of the information required is on the IPONZ file, it should not require the applicant to provide any information. It is not clear what further information the Commissioner of Patents might consider necessary⁴ to make a decision. Any additional powers should be limited to matters directly relevant to calculating the unreasonable delay.

Question 2: Should the applicant for extension of term for unreasonable curtailment be required to declare that the marketing approval referred to in the request is the first marketing approval for the pharmaceutical substance involved, or should this be contained in the declaration from Medsafe? Why?

16. It would be simpler for the applicant to make the declaration – they should have the best direct knowledge of what marketing approval has been granted.

² Paragraphs 79 and 80 correctly refer to section 123.

³ Reg 89(8)-(10), 94(4)-(6)

⁴ See paragraphs 15 and 16 of the consultation document.

Question 7: Should the time limit for requesting extensions of term for unreasonable curtailment [of the effective patent term] be extendable? If so, what extension should be available?

Question 8: Under what circumstances should an extension be granted?

17. The granting of extensions of time require the balancing of competing interests and are largely policy issues on which the Law Society expresses no view.
18. However, the Law Society does consider the right to a valuable patent extension should not be lost because of inadvertent failure to comply with a timeline. Accordingly, the Law Society suggests there should be a power for the Commissioner to extend the time if the patentee has inadvertently failed to apply in time. If the decision is made to provide for an extension to be granted, further consideration should be given as to whether an opposition procedure should be provided, such as those provided for in applications for restoration of a lapsed patent or application.

Question 9 (Disregarded periods): Which of the two options discussed do you prefer? Why?

19. The Law Society repeats the recommendation made in its submission to the March 2016 targeted consultation document⁵ that the periods to be disregarded should be specified in regulations, for the reasons set out in that submission.

Question 10: Considering the list of disregarded periods proposed in Appendix 1, are there any time periods on that list that you consider should not be disregarded? Why?

20. The periods of time listed under items iv and v of Appendix 1 of the consultation document are ultra vires the new section 111B(2)(b) to be added to the Patents Act 2013 by clause 75 of the Trans-Pacific Partnership Amendment Bill. That subsection does not include the acts or omissions of a person who opposes a request for amendment under section 87 of the Patents Act 2013. Either new section 111B(2)(b) needs to be amended or these items dropped.
21. The commencement date in line 2 of item xii is unclear. The “date of acceptance filed” (sic) could have been intended to refer to the date of acceptance or it could have been intended to refer to the date that a notice of opposition (or some other document) was filed. The end of the excluded period in sub-paragraphs (a) to (c) is clear.
22. Item xvi in Appendix 1 opens up the possibility that an opponent may effectively delay the grant of a patent for several years by lodging successive appeals to the courts. Because the time taken by the courts to reach a decision is to be disregarded, the applicant would not be entitled to an extension of patent term even though the patent issued well after the three- or five-year period.

⁵ NZLS submission dated 7 April 2016 on *Targeted Consultation Document: Implementation of the Trans-Pacific Partnership Intellectual Property Chapter*.

Question 11 (on page 15):⁶ Of the possible opposition procedures [to extension for unreasonable curtailment of the effective patent term] discussed, which do you prefer? Why?

Question 12: If you do not prefer either of the procedures discussed, what other procedures could be used?

23. For the reasons stated above the Law Society sees little difference, if any, between the procedures outlined and has not identified an alternative.

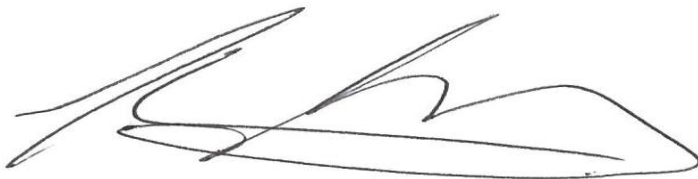
Question 14 (on page 17):⁷ Do you think that [the proposed] fee levels are reasonable? If not, should the fees be higher or lower than the estimates given? Why?

24. The Law Society has no comment on the quantum of the fees when IPONZ has not yet modelled what they might be.

Conclusion

25. This submission has been prepared with the assistance of the Law Society's Intellectual Property Law Committee. If you wish to discuss this further, please do not hesitate to contact the committee convenor Greg Arthur, through the committee secretary Jo Holland (04 463 2967 / jo.holland@lawsociety.org.nz).

Yours faithfully



Kathryn Beck
President

⁶ There are two questions numbered 11.

⁷ There are two questions numbered 14.