

By email ONLYtpp.ip.policy@mbie.govt.nz

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Business Law
Building, Resources and Markets
Ministry of Business, Innovation & Employment
PO Box 1473
Wellington 6140

Dear Sirs,

We refer to the consultation paper entitled "Trans-Pacific Partnership Agreement Amendment Bill: Patent Term Extensions - Proposed Regulations" seeking feedback on proposed regulations for implementing the patent term extension provisions contained in the Trans-Pacific Partnership Agreement Amendment Bill ("the Bill") currently before the Foreign Affairs, Defence and Trade Select Committee.

About IPTA

The Institute of Patent and Trade Mark Attorneys of Australia (IPTA) is a voluntary organization representing registered patent attorneys, registered trade marks attorneys and student members in the process of qualifying for registration as a patent or trade marks attorney in Australia. The membership of IPTA includes over 87% of registered patent attorneys located in Australia and it is believed that its members make up more than 90% of registered patent attorneys in active practice in Australia. The membership of IPTA includes registered patent attorneys in private practice as well as patent attorneys working in industry, universities, research institutes and others that practice as barristers. IPTA members represent large local and foreign corporations, SMEs, universities, research institutes and individual inventors. Most IPTA members who are patent attorneys are also registered New Zealand patent attorneys.

IPTA members not only work with local clients to assist them in developing strategies for protecting and enforcing their intellectual property rights in Australia, New Zealand and overseas, but they also represent overseas individuals and companies in their efforts to obtain and enforce their intellectual property rights in Australia and New Zealand. IPTA members also assist patentees of pharmaceutical patents obtain patent term extensions in Australia to compensate for the patent term lost as a result of the extensive and expensive clinical trials which need to be carried out to convince the regulatory authorities that the pharmaceutical product is safe and effective. For this reason, IPTA members are well placed to assist the Ministry in its efforts to introduce appropriate patent term extension provisions and regulations to compensate patent owners for unreasonable curtailment of the effective patent term as a result of the marketing approval process.

Before commenting on the proposed regulations we make the following comments on the patent term extension provisions contained within the Bill. Although the consultation document suggests that the proposed regulations are "necessary for New Zealand to comply with the obligations contained in the Intellectual Property Chapter of the Trans-Pacific Partnership (TPP)", the provisions contained within the Bill do not appear to come close to complying with the patent term extension provisions contained within the TPP.

Article 18.48 of the TPP relates to patent term extensions. Subsection 2) of 18.48 stipulates the following:

"With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for **unreasonable curtailment of the effective patent term as a result of the marketing approval process.**" (emphasis added).

In order to give effect to this provision it is important to understand what is meant by "unreasonable curtailment of patent term as a result of the marketing approval process". This unreasonable curtailment of patent term is the term lost as a result of the need to satisfy regulatory authorities in relation to the safety and efficacy of the pharmaceutical product. This includes the time following the filing of the patent application during which the patentee carries out the necessary clinical trials to satisfy the regulatory authorities that the product is indeed safe and efficacious. The time spent by MEDSAFE looking at the regulatory application represents only a small part of this delay. Compared to other types of inventions, the amount of patent term lost as a result of the time needed to conduct the necessary studies to satisfy the regulatory authorities that the pharmaceutical product is safe and efficacious is often "unreasonable", in the sense that the patent term available from the date the patentee is authorised to sell its pharmaceutical product in the jurisdiction is substantially reduced relative to the patent terms available for other inventions which are not required to go through such an extensive (and expensive) regulatory approval process.

It appears from the Bill that New Zealand has taken the view that under the TPP it is only required to compensate patent owners for "unreasonable curtailment" which is due to processing delays caused by MEDSAFE, the New Zealand regulatory body. It would appear that this view is not correct.

The TPP includes another provision for providing patent term extensions/adjustments in circumstances where there is a delay in granting the patent by the granting authority, i.e. the patent office. This is Article 18.46 "Patent Term Adjustment for Unreasonable Granting Authority Delays". The time periods mentioned in subsection 4) make it clear that the additional patent term is calculated with reference to delays occurring within the granting authority. In fact, periods of time that are not directly attributable to the granting authority may be excluded. This is in direct contrast to the provisions of Article 18.18 which draw no connection between the patent term adjustment and processing delays within the regulatory authority. If the additional patent term was only to be available where delays are caused by a regulatory authority such as MEDSAFE, the provision would have been worded in a similar manner to Article 18.46. Instead, Article 18.48 refers generally to unreasonable curtailment of patent term as a result of the marketing approval process. The most important part of the marketing approval process is the conduct of toxicology studies and clinical trials to demonstrate the safety and efficacy of the pharmaceutical product. These studies take many years and cost millions of dollars, often over a billion dollars. Any patent term extension regime implemented to compensate patentees for unreasonable curtailment of patent term as a result of the marketing approval process would need to take into account the time taken to carry out these mandated studies.

The Australian system for compensating patentees for unreasonable curtailment of patent term as a result of the marketing approval process calculates the period between filing the patent application and obtaining marketing approval in Australia, and then subtracts 5 years. The additional term will be the time period calculated, subject to a maximum extension of 5 years. Since most pharmaceutical products take between 10 and 15 years to obtain marketing approval, this generally leaves pharmaceutical patentees with an effective patent term in Australia of between 10 and 15 years. While this effective patent term is less than that available for most non-pharmaceutical products, the Australian PTE system does go some way towards compensating pharmaceutical patent owners for lost patent term as a result of the marketing approval process. IPTA recommends that New Zealand gives consideration to introducing a patent term extension scheme similar to the one currently in effect in Australia in order to meet its obligations under the TPP.

IPTA does not believe that New Zealand's current proposal for providing patent term extensions represents a reasonable attempt to comply with Article 18.48. This view is evident in the original consultation paper on the Bill which included the following statement: *"If the patent term extension regime were implemented as set out below, then few (if any) patents would be likely to be eligible for extension, and only in exceptional circumstances."* Accordingly, although the consultation paper contains questions in relation to the way the scheme might operate in practice, IPTA expects that actual mechanics of the system as proposed will be largely irrelevant if New Zealand does not amend the draft Bill to provide more meaningful compensation for reduced effective patent term caused by the marketing approval process for pharmaceuticals.

Assuming that the provisions will be amended as proposed above, IPTA provides the following responses to the questions raised in the consultation paper.

Manner of making a request for extension of term

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 do you disagree?

There are significant problems with the proposed regulations regarding the manner in which a request for an extension of term must be made. For example, where a single patent encompasses two different pharmaceutical substances *per se* or biologics which are the subject of separate marketing approval applications, it is unclear whether the request for a patent term extension must be based on the pharmaceutical substance or biologic which is the subject of the earliest approval, or whether the applicant has a choice to base the application on the later approval.

This is a very important issue given the infringement exemption set out in proposed Section 111(i). In this regard, it would appear that enforcement of the patent following grant of the patent term extension is limited to the scope of the marketing approval upon which the patent term extension request has been based. If it is intended to require the patentee to rely on the earliest marketing approval, then the infringement exemption set out in section 111(i) should not be limited with reference only to the scope that marketing approval.

Also, the consultation paper sets out a number of proposed time limits for filing patent term extension requests. Some of those time limits could expire prior to the grant of any marketing approval. Accordingly, at the deadline for making application, a patentee may not be able to refer to a certificate from MEDSAFE relating to the first marketing approval for a product. If the patentee will always be given a period of, for example, six months following the grant of a marketing approval by MEDSAFE to file the patent term extension request, then it is not unreasonable to require the patentee to provide information relating to that marketing approval.

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?

IPTA does not see any harm in requiring the applicant for the patent term extension to declare that the marketing approval referred to in the request is the first marketing approval for the relevant pharmaceutical substance. IPTA is not aware of the information published by MEDSAFE in relation to the dates of grant of marketing approval certificates, but assumes that the correctness of the declaration made by an applicant for a patent term extension could be readily checked by examination of the publicly available records of MEDSAFE.

Time limit for requesting extensions of term for unreasonable delays in patent grant

Question 3: Which of the three options discussed do you prefer? Why do you prefer this option?

IPTA does not support any of options 1-3 for the following reasons.

In the experience of IPTA members, and based on the proposed wording of Sections 111A and 111B, it is unlikely that a patentee will ever be eligible for additional patent term as a result of delays attributable to IPONZ. However, the presence of such provisions in the *Patents Act 2013* will always create some uncertainty regarding the actual expiry date of a New Zealand Patent. Therefore any infringement or Freedom to Operate search carried out for New Zealand following the introduction of such provisions will require additional work (and expense) in confirming the actual expiry date. There will also be an increased burden on patentees and patent attorneys since every patent granted by IPONZ will need to be checked against complex criteria to confirm in nearly all cases that no patent term extension is applicable. This extra burden and cost to patentees is simply not justified.

IPTA also expects that extra work will be required within IPONZ to ensure that the expiry date of each patent is clearly indicated to the public in the IPONZ database. Accordingly, IPTA does not believe that New Zealand needs to introduce into the *Patents Act 2013* any provisions for extending the term of patents to compensate for delays in granting patents. This is the approach taken in Australia to comply with similar provisions contained in the Australia–United States Free Trade Agreement (AUSFTA).

If New Zealand pursues its intention to introduce these or similar provisions, IPTA believes that there should be no need whatsoever for a patentee to request a patent term extension. It would appear from Sections 111A and 111B that nothing that occurs after grant can impact on the additional term available to the patentee. Since it is only delays attributable to IPONZ that factor into the calculation, particularly since the single application and examination processes with IP Australia have now been abandoned, IPONZ should be in a position to calculate and apply any adjustment of patent term at the time of grant. In such circumstances the patentee could be provided with a short period within which to contest the calculation. Since it is unlikely that any patent term extensions will need to be granted under these provisions, this approach will not in any way add to the workload of IPONZ.

IPTA also finds unreasonable the whole concept of requiring a patentee to seek, and pay for, an extension of term attributable to delays in patent grant caused by IPONZ.

Question 4: Options 2 and 3 require the setting of time limits for making requests for extension of term. If either of these options was adopted, what do you think the time limit should be?

For the reasons mentioned above, IPTA does not believe that options 2 and 3 are appropriate.

Time limit for requesting extensions of term for unreasonable curtailment of the effective patent term

Question 5: Which of the three options discussed do you prefer? Why?

IPTA believes that, with a slight modification, option 3 is the preferred option.

While option 1 is a workable option, IPTA believes that a balanced system for providing patent term extensions would not allow patentees to wait until the last possible moment to request a patent term extension in circumstances where they have already been aware that they are eligible to apply for a patent term extension. In this regard, IPTA believes it would be preferable to require patentees to request patent term extensions, where possible, well prior to the final expiry date.

Option 2 may be suitable for some patents, but will not be suitable where the marketing approval is obtained late in the patent term, and after the deadline for filing an application for a patent term extension. It does not seem sensible to IPTA to require a patentee to request a patent term extension at a time prior to the grant of marketing approval, and prior to the patentee being able to calculate whether the patent term extension is available and the term of an extension.

Option 3 will be suitable in the vast number of cases, since patents are normally granted well prior to the grant of marketing approval. For the reasons mentioned above, it does not seem sensible to require a patentee to request a patent term extension at a time where the patentee is not aware that an extension is available, or is at least not aware of the term of such an extension.

IPTA believes that the time limit for applying for a patent term extension should be the later of six months from the date of grant of marketing approval, and six months from the date of grant of the patent. This time frame for requiring patentees to request patent term extensions is the same as currently provided for in the Australian *Patents Act 1990*. Since nearly all marketing approvals are granted after the date of grant of the patent, this way of calculating the time limit for filing patent term extension requests will require patentees to file their patent term extension requests at the earliest opportunity following the grant of marketing approval. The only exceptions will be where the patent is granted after the grant of marketing approval.

It would seem under proposed Section 111G that it is not intended to provide patent term extensions in circumstances where marketing approval is obtained prior to patent grant. However, for the reasons mentioned above, we believe that provisions in the Trans-Pacific Partnership Agreement Amendment Bill need to be amended in order to provide meaningful compensation for unreasonable curtailment of patent term resulting from the marketing approval process. Accordingly, IPTA believes that there will be circumstances where patent term extensions should be granted even though the marketing approval is granted prior to the grant of the patent. In this regard, it is possible for a marketing approval to be granted prior to the grant of patent in circumstances where the patent application is a divisional application, or where the application has undergone a protracted opposition with appeals to the New Zealand courts.

Question 6: Options 2 and 3 would impose time limits by which a request for extension must be made. If one of these options was adopted, what do you think the time limits should be? Why?

As explained above, IPTA believes that the time limit for applying for a patent term extension should be the later of six months from the date of grant of marketing approval, and six months from the date of grant of the patent.

Extensions of the time limit for requesting extensions of term for unreasonable curtailment of the effective patent term

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

As explained above, IPTA believes that IPONZ should be responsible for calculating and applying any additional term to compensate for delays attributable to IPONZ. This would mean that the patentee would not need to apply for the additional term and no extensions of time would be required.

However, in the case of patent term extensions for pharmaceutical patents IPTA believes that reasonable extension of time provisions should be available. A major difficulty that leads to late applications for patent term extension applications in Australia is that there is often no direct relationship between the local regulatory arm of a pharmaceutical company responsible for obtaining the marketing approval in Australia and the overseas patent department responsible for handling the patent, and applying for any available patent term extensions. There are also often complex licensing arrangements involving numerous corporate entities, and it is not uncommon for the local sponsor of the product for which marketing approval is sought to be different, and unrelated to, the patentee. Accordingly, while six months will be sufficient in most cases for a patentee to determine eligibility for a patent term extension and apply for the extension, additional time might be required in some circumstances. IPTA believes that a system providing extensions of time for filing patent term extensions should be provided to allow for circumstances where the failure to meet the 6 month deadline is unintentional. It is interesting to note that as of November 2015 there were 44 applications for extensions of time to file patent term extension requests in Australia, and 15 of those requests were for a period in excess of 2 years.

IPTA appreciates that granting extensions of time to file patent term extensions requests after expiry of the normal 20 year term is likely to cause uncertainty and difficulties for generic companies, and that excluding extensions of time beyond the 20 year expiry date can be justified. However, if IPTA's proposal regarding timing of the extension of time request is adopted, most applications for patent term extensions will be submitted well before the 20 year expiry date, even with extensions of time. On one hand allowing reasonable extensions of time based on an "unintentional" criterion is unlikely to cause difficulties for generic companies. On the other hand, it will allow a patentee to obtain the patent term in New Zealand to which it would be entitled, but for the failure to meet the relevant deadline.

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

As explained above, IPTA believes that extensions of time for the late filing of applications to extend the term of a pharmaceutical patent to compensate for unreasonable curtailment of patent term should be based on an "unintentional" standard. There should be no upper limit on the length of time of such an extension, except that it should not carry on beyond the normal 20 year term. This is consistent with the current approach in Australia.

Disregarded Periods

Question 9: Which of the two options discussed do you prefer? Why?

As explained above, IPTA believes that it is not necessary to introduce specific provisions for providing additional patent term to compensate for delays in granting a patent due to processing delays within IPONZ. In this regard, the experience of IPTA members with IPONZ is that patent applications are processed efficiently and expeditiously, such that granting delays do not occur. However, if such provisions are to be introduced IPTA agrees that the regulations should specify the time periods which are to be disregarded.

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?

IPTA believes that the extensive list of periods set out in Appendix 1, many of which are likely to overlap, provides further support for the view that IPONZ should not introduce such provisions. For all patents granted by IPONZ, the patentee or the patentee's attorney will need to check whether or not the patent is eligible for additional term. This will be the case even if IPTA's proposal for IPONZ to calculate the adjusted term at the time of grant is accepted, because the patentee or patentee's attorney will still need to confirm the calculation. However, if New Zealand continues with its proposal care will need to be taken to ensure disregarded periods are not counted twice.

Question 11: Considering the list of disregarded periods proposed in Appendix 1, are there any periods that are not on the list, but that you consider should be there?

As explained above, IPTA would prefer for the provisions relating to patent term adjustment due to processing delays within IPONZ to be removed from the Trans-Pacific Partnership Agreement Amendment Bill.

Procedure for opposition to extension of term for unreasonable curtailment of the effective patent term

Question 12(11): Of the possible opposition procedures discussed, which do you prefer? Why?

Oppositions relating to patent term extensions are likely to be based on eligibility requirements, and in particular, whether a particular patent term extension request meets the requirements of the provisions which are introduced, and whether the request has been based on the correct marketing approval. It is difficult to see why such an opposition would need to progress through the various evidentiary stages required when opposing the grant of a patent. Accordingly, while the current Australian provisions require such oppositions to proceed through various evidentiary stages similar to the section 87 and 92 oppositions, IPTA believes that the simpler process applicable to oppositions under sections 120 and 127 is likely to be more suitable.

Question 13(12): If you do not prefer either of the procedures discussed, what other procedures could be used?

IPTA has no other preference.

Time limit for filing a notice of opposition to an extension of term for unreasonable curtailment of the effective patent term

Question 14(13): What should the time limit be for filing a notice of opposition to an extension of term?

IPTA believes the period should be three months from the date acceptance of the patent term extension request is advertised in the journal.

Question 15(14): Should the time limit for filing a notice of opposition to extension of term for unreasonable curtailment be extendable? If so, what extension should be available? Under what circumstances should an extension be granted?

IPTA believes that extensions of time for filing oppositions should only be granted if the failure to meet the deadline for opposition was "unintentional".

Fees

Question 16(14): Do you think that such fee levels are reasonable? If not, should the fees be higher or lower than the estimates given? Why?

IPTA believes that the proposed fees are reasonable.

Conclusion

IPTA thanks the Ministry for Business Innovation & Employment for this opportunity to comment on the Consultation Paper. If the Ministry has any questions in relation to the observations above please contact the undersigned.

Yours faithfully

**Michael Caine**

Vice President and Convenor, Patents Legislation Committee

IPTA

c/- Davies Collison Cave

1 Nicholson Street

Melbourne VIC 3000 Australia

T: + 61 3 9254 2777

F: + 61 3 9254 2770

E: mcaine@davies.com.au