

Submission on consultation document: *Implementation of the Trans-Pacific Partnership Intellectual Property Chapter*

Your name and organisation

Name	David Tadjell
Organisation	Australian Institute of Patent and Trade Mark Attorneys (IPTA)

Responses to consultation document questions

1	Have the overarching objectives been framed correctly for this policy process? If not, what would be more appropriate objectives?
	Yes
Technological protection measures	
2	Do you agree with the exceptions or limitations proposed for TPMs? What would be the impacts of not providing these exceptions? Please be specific in your answers.
	No comment
3	Do you agree that the exceptions proposed for TPMs should apply to both prohibitions (i.e. circumventing a TPM and the provision of devices or services that enable circumvention)? Why / why not?
	No comment
4	Do you agree that, if our proposals are implemented, the current exception allowing a qualified person to circumvent a TPM that protects against copyright infringement to exercise a permitted act under Part 3 would no longer be required? Why / why not?
	No comment
5	Are there any other exceptions or limitations to the TPM prohibitions that should be included in the Copyright Act? Please explain why any additional exceptions would be necessary.
	No comment
6	Would there be a likely adverse impact on non-infringing uses in general if the exception for any other purpose that does not infringe copyright was not provided for? Please be specific in your answers.
	No comment
7	Should there be a regulation-making power to enable the exception for any other purpose that does not infringe copyright to be clarified, and if so, what criteria should be considered?

No comment

Patent term extension for delays in patent grant

8 Do you agree with the proposals for patent term extensions for unreasonable grant delays? Why / why not?

In view of the efficient processing of patent applications by IPONZ, there is no need to introduce provisions to compensate patentees for lost term as a result of the patent application and examination process. Indeed, we believe that in doing so, it is likely to lead to difficulties and uncertainties in the patent system. Introduction to any extension will create uncertainties when reviewing New Zealand patent families when conducting patent searches. There will be an additional burden to check each and every New Zealand patent found in a family to be certain that no patent term adjustment was applied. Particular difficulties will be created in the patent families where the term of one patent may be extended beyond the term of others. This will create significant difficulties in carrying out freedom to operate (infringement) searches in New Zealand. Australia relies on its efficient processing of patent applications, a requirement which was previously included in the AUSFTA signed several years ago, and we suggest that New Zealand do the same.

9 Do you think that there should be a limit on the maximum length of extension available for grant delays? If so, what should it be?

As for our comments above, we do not feel there is a need for an extension, but if an extension was to be allowed, it should be capped at 2 years.

10 Do you consider that third parties should be able to oppose decisions to extend patents on the ground of unreasonable delays in grant?

We do not feel that there is a need to oppose any decision to extend a patent, but a form of allowing third party comment should be provided for.

Patent term extension for pharmaceuticals

11 Do you agree with the proposed definition of “unreasonable curtailment” for pharmaceutical patent term extensions? If not, what other definition should be used?

We do not agree with the proposed definition of “*unreasonable curtailment*” as it would seem unreasonable to limit unreasonable curtailment directly to the time Medsafe takes to process an application for marketing approval. The TPP, with reference to Article 18.48.2, is asking that an extension of the patent term be available to compensate the owner of a pharmaceutical patent for any unreasonable curtailment of the effective patent term “*as a result of the marketing approval process*”. The wording of Article 18.48.2 extends beyond the delays directly attributable to Medsafe or any regulatory authority. Any adjustment to the New Zealand legislation needs to be in line with the TPP requirements and take into account “*the marketing approval process*”.

The marketing approval process is inclusive of delays caused by the patentee carrying 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 part of this delay. The actual application for marketing approval with Medsafe will occur well after initial steps have been taken to obtain the data that is necessary for the regulatory approval process to begin. It is reasonable that any “*unreasonable curtailment*” definition should be inclusive of the length of time it has taken to obtain regulatory approval,

	including conducting the necessary trials, and not just the time spent with the Medsafe process.
12	Do you agree that the definition of “unreasonable curtailment” should apply different time periods for small molecule pharmaceuticals and biologics? If so, what could these time periods be? If you consider that only one time period should apply to both, what should this be?
	The definition of “ <i>unreasonable curtailment</i> ” should take into account all regulatory approval delays, regardless of whether it relates to a small molecule pharmaceutical or biologics. Therefore only one time period should apply to both.
13	Do you agree with the proposed method of calculating the length of extensions for pharmaceutical patents?
	We do not agree with the proposed method of calculating any extension, as the length should be based upon time lost through the regulatory process, and not simply time lost through delays with Medsafe.
14	The proposed method of calculating extensions for pharmaceutical patents includes a maximum extension of two years. Do you agree with this? If not, what do you think the maximum extension should be?
	In our view, it is reasonable to have a maximum extension of 5 years, as there are many pharmaceuticals that lose at least 5 years, and often considerably longer, in obtaining regulatory approval.
15	Do you agree or disagree that only patents for pharmaceutical substances <i>per se</i> and for biologics should be eligible for extension? Why?
	The TPP does not ask for patent term extension beyond pharmaceutical products, so it is reasonable to limit any adjustment to pharmaceutical substance <i>per se</i> and for biologics.
16	Do you think the Australian definition of “pharmaceutical substance” should be adopted? Why / why not?
	We agree that the Australian definition of “ <i>pharmaceutical substance</i> ” should be adopted, as it is a definition that works well in Australia.
17	Do you agree that patent rights during the extended term should be limited in the manner proposed?
	We agree that the patent rights may be limited in the manner proposed.
18	Do you agree that third parties should be able to oppose decisions to extend patents for pharmaceuticals through the Commissioner of Patents? Why / why not?
	We agree that third parties should have the right to oppose the decision to extend patents for pharmaceuticals through the Commissioner of Patents, and appealable to the Courts.
Performers’ rights	
19	Do you agree that a performer’s moral rights should apply to both the aural and visual aspects of their live performance and of any communication of the live performance to the

	public? Why / why not?
	No comment
20	Should performers' moral rights apply to the communication or distribution of any recording (i.e. both sound recordings and films) made from their performances, rather than just sound recordings as required by WPPT? Why / why not?
	No comment
21	Do you agree or disagree with any of the exceptions or limitations proposed for a performer's right to be identified? Why?
	No comment
22	Are there any other exceptions or limitations to a performer's right to be identified that should be included in the Copyright Act? If so, can you please explain why they would be necessary.
	No comment
23	Do you agree or disagree with providing for any of the exceptions or limitations proposed for a performer's right to object to derogatory treatment? Why?
	No comment
24	Are there any other exceptions or limitations to a performer's right to object to derogatory treatment that should be included in the Copyright Act? If so, please explain why they would be necessary.
	No comment
25	Should the new property rights for performers be extended to apply to the recording of visual performances in films? Why / why not? (Please set out the likely impacts on performers and producers, and any others involved in the creation, use or consumption of films.)
	No comment
26	Do you agree or disagree with any of the exceptions or limitations proposed above? Why?
	No comment
27	Are there any other exceptions or limitations to the new performers' property rights that should be included in the Copyright Act? If so, can you please explain why they would be necessary.
	No comment
28	Do you agree or disagree with any of the proposals above? Why?
	No comment
29	Are there any other amendments that need to be made to the Copyright Act, and in particular to Part 9, to clarify the new performers' property rights? If so, can you please

explain why they would be necessary.

No comment

Border protection measures

30

Do agree that Article 4 of European Union Council Regulation (EC) No 3295/94 is an appropriate model for implementing *ex officio* powers into the border protection measures set out in the Copyright Act 1994 and Trade Marks Act 2001? If not, please explain why not and outline an alternative approach to implementing *ex officio* powers.

No comment

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Do you agree that the detention period of three business days following notification to the rights holder is appropriate? Can you outline the impact on both the right holders and any importer/exporter where you consider the period should be shorter or longer than three business days?

No comment

Other comments