

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

Your name and organisation

Name	Jude Ulrich
Organisation	PHARMAC

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?

Yes. The proposal appears to be consistent with achievement of the overarching objectives.

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?

No, taking into consideration the proposal that periods of time that are attributable to the patent applicant are excluded. Coupled with the efficiency of IPONZ's current processing time, this suggests that an extension cap is not necessary.

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

No, on the basis outlined in the discussion document, since there is little discretion available to the Commissioner of Patents there does not need to be an opposition process in respect of patent grant delays.

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?

Yes, however this support is dependent on the specified number of years.

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?

Yes, PHARMAC appreciates that biologics may take longer to process. We support a longer time period applying to biologics for this reason. Biologics also tend to be more expensive than small molecule pharmaceuticals, and therefore the additional cost to medicines purchasers associated with patent term extensions could be larger than for small molecules.

We suggest that a reasonable time period, if required to be specified as a number of years, should be based on the longest period of time within which standard assessments for each of these types of applications have been concluded over the past five years.

13 Do you agree with the proposed method of calculating the length of extensions for pharmaceutical patents?

Yes, however we suggest that consideration be given to reflecting the current standard processing times (excluding timeframes for medicines granted priority assessments).

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?

We agree that a cap would limit the potential impact on pharmaceutical expenditure and on

	publically subsidised access to pharmaceuticals. We do not think this should exceed two years and would be supportive of proposals for a more limited time extension.
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?
	Yes. The proposal appears to be consistent with achievement of the overarching objectives.
16	Do you think the Australian definition of “pharmaceutical substance” should be adopted? Why / why not?
	Yes, this definition would limit the potential costs to New Zealand and to medicines purchasers, compared to a broader ‘product’ definition.
17	Do you agree that patent rights during the extended term should be limited in the manner proposed?
	Yes. The proposal appears to be consistent with achievement of the overarching objectives.
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?
	Yes, this would provide PHARMAC with an opportunity to challenge in situations where it is appropriate to do so and where the potential cost to New Zealand is large.

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 <i>ex officio</i> 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 <i>ex officio</i> powers.
	No comment.
31	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

None.