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

Your name and organisation

Name	Lynette Stanton, Intellectual Property Counsel
Organisation	Douglas Pharmaceuticals Ltd

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. In particular, objective (b) reflects the fact that current IP policy settings in new Zealand are already the result of substantial consultation, review and consideration to reflect a balance appropriate to New Zealand. This is particularly the case in respect of patent term.
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.
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?
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?
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.
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.

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?
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?
	Given that PTE is required, the proposal seems reasonable. The time periods before an extension would be possible significantly exceed the current typical IPONZ processing time. This means that not only would extension eligibility be rare, but it would also very rarely be worthwhile to raise an argument about what time periods were or were not included in the calculation. This accords with objective (b) [minimising change to settings ie the vast majority of patents will still have the basic 20 year term] and (c) [the expiry date will be certain and there would be little incentive for reviews/challenges]. Calculation of delay should explicitly exclude time spent in pre-grant opposition proceedings. This is because: (i) inclusion of this time would greatly increase the likelihood of PTE being granted, which is in conflict with the policy decision to minimise actual PTEs (objective (b)); (ii) inclusion of this time would potentially penalise third party opponents and disincentivise oppositions. In the case of a partially or wholly unsuccessful opposition, the opponent could be doubly penalised by the patent term being extended as a result of the time in oppostion. Pre-grant opposition is an important part of the checks and balances of the patent grant process, and should not be disincentivised; (iii) the time in opposition (even the time spent in consideration) is largely determined by the actions of the applicant and the opponent, for example, number of arguments pleaded, number of references cited, not IPONZ.
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?
	Yes. Providing a cap on the maximum extension would be in accord with objective (c). Generic pipeline time frames are long. One current advantage of the non-extendible 20 year NZ patent term is complete certainty with regard to maximum patent term and therefore generic entry. A cap on possible extension would offer a predictable date by which expiry would definitely have occurred. This would be particularly needed if the extension was the subject of review/appeal. [objective (c) – provide certainty]. Having a cap would also reduce the incentive to take reviews/appeals of extension eligibility [objective (c) – minimise compliance costs]. In order to meet objective (b) [minimise impact of changes], as well as over-arching policy considerations around early access to generic medicines and consequent public health savings, the cap should be the minimum which meets TPP obligations. We suggest 1 or 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?
	In general, we think the decision to extend should be subject to the minimum of discretion, so as to minimise the risks and incentives for any reviews or appeals. Publication of extremely clear and unambiguous guidelines as to how the times are calculated should assist in this. However, if applicants are to have a route of review/appeal, then third parties need to have a balancing route to oppose, in order to discourage gaming. An example could be where an applicant has unnecessarily prolonged the examination process by late production of additional prior art cited in overseas examination – it would be appropriate to allow a third party standing to object that the delay was attributable to the actions of the applicant (delay in bringing known art to examiner's attention), rather than IPONZ (time taken to consider late filed references).
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 (subject to the number of years being appropriate to meet objectives, see below).
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?
	It seems reasonable to allow a longer time frame for the more complex evaluation required for biologics. The time period used should be long enough to not only encompass all expected Medsafe periods, but ideally to cover the <u>total</u> processing time (Medsafe + applicant) in the vast majority of cases. This is in line with the objective of minimising the occasions of eligibility for extension (objective (b) – minimise impact of changes) and also reduces incentives for reviews and appeals over what sub-periods are included/excluded from the calculation (objective (c) – provide certainty and minimise compliance costs). According to the statistics available at ***http://www.medsafe.govt.nz/regulatory/Performance2015.asp*** the total time to conclude 90% of applications for various application types in 2015 varied from 174 days (priority assessment via abbreviated evaluation) to 824 days (intermediate risk medicine via full evaluation). The bulk of these assessments would currently represent small molecule – however the proportion of biologic applications may be expected to increase. We therefore suggest the time period should be 3.5 years (small molecule) and 5 years (biologics).
13	Do you agree with the proposed method of calculating the length of extensions for pharmaceutical patents?
	Yes.
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?

	Yes for reasons given under 9 above and provided that the calculation period is long enough that extensions are extremely rare.
15	Do you agree or disagree that only patents for pharmaceutical substances *per se* and for biologics should be eligible for extension? Why?
	Yes. This is the kind of patent which is most often applied for relatively early in the development timeline and therefore most likely to be effectively curtailed by the time taken to bring to market. Other kinds of patents such as formulations and later uses are not subject to such a degree of curtailment, being applied for later in the development timeline. Allowing more widespread extensions would encourage evergreening, which tips the balance too far towards lengthy protection and the consequent public health costs of delayed generic entry.
16	Do you think the Australian definition of "pharmaceutical substance" should be adopted? Why / why not?
	Largely yes. While no definition is perfect the advantages of having an established body of case law to refer to is valuable in a low litigation market for increasing certainty and reducing compliance costs (objective (c)). Prior statutory clarification of potential points of dispute, for example whether a mixture of 2 old substances meets the definition of a new substance, would be highly advisable, for example by referring to points already litigated and determined in Australia.
17	Do you agree that patent rights during the extended term should be limited in the manner proposed?
	Yes. This ensures that the "reward" of extended exclusivity is tied specifically to the commercial product as brought to market and does not restrict other purposes.
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, if and to the extent that the applicant is able to seek review/appeal, for reasons given in 10 above.
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?
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?
21	Do you agree or disagree with any of the exceptions or limitations proposed for a performer's right to be identified? Why?

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.
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?
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.
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.)
26	Do you agree or disagree with any of the exceptions or limitations proposed above? Why?
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.
28	Do you agree or disagree with any of the proposals above? Why?
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.
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.

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?

Other comments

The Patents (Trans-Tasman Patent Attorneys and Other Matters) Amendment Bill 2015 aims to enable a single patent application and examination process to be implemented between the Australian Patent Office (IP Australia) and the Intellectual Property Office of New Zealand (IPONZ). What work has been done to ensure that processing times as estimated under Point 61 of the consultation document, will be comparable under the new combined regime?

Because of this unknown, and in order to ensure that in particular objective (b) is met, care should be taken to ensure that maximum advantage is taken of exclusions from the IPONZ delay calculation and the smallest acceptable cap is applied.

Other procedural points that need to be addressed in order to meet in particular objective (c) include:

- Define a short and strict time frame in which to apply for extension.
- Publish the existence of applications for extension, progress, outcome and expiry dates, on the IPONZ patent register record for the patent. (The US system by contrast requires extensive searches through back files of documents and application of various calculations in order to determine the expiry date of a patent. This greatly increases uncertainty and compliance costs.) Currently, IPONZ is able to publish the expiry date up front on the Register record. This certainty should not be lost.