NEW ZEALAND INSTITUTE OF PATENT ATTORNEYS INC.

Submission to the Ministry of Business, Innovation & Employment (MBIE) on the Implementation of the Trans-Pacific Partnership Intellectual Property Chapter.

1. About the New Zealand Institute of Patent Attorneys Inc.

1.1 The New Zealand Institute of Patent Attorneys Inc (NZIPA) was established in 1912. It is an incorporated body representing most Patent Attorneys registered under the New Zealand Patents Act, and who are resident and practising in New Zealand. Current membership stands at approximately 288, made up as 151 Fellows, 44 Students, 15 Associates and 18 Overseas members.

1.2 The NZIPA is governed by a set of rules and a code of professional conduct to ensure its members maintain a consistent high standard of professionalism at all times.

1.3 A Council of 9 Fellow members is elected each year at the Annual General Meeting. They meet at least monthly throughout the year to manage the affairs of the NZIPA.

1.4 The Rules set out the objects of the NZIPA, which are as follows:

- To maintain a representative group of registered New Zealand patent attorneys.
- To promote the interests of the Institute.
- To assist in developing, promoting and maintaining the integrity of the laws and regulations relating to intellectual property matters.
- To preserve and maintain the integrity and status of the patent attorney profession by setting and administering Rules and a Code of Professional Conduct.
- To provide means to resolve differences between Members of the Institute, and between members of the public and Members of the Institute.
- To arrange and promote opportunities to acquire and share knowledge about the patent attorney profession.

2. The role of the patent attorney industry in boosting productivity

2.1 Patent attorneys advise on all parts of Intellectual Property. 'Intellectual property' or 'IP' is the term used to describe rights in intangible things. Those rights can be registered (as in the case of patents, designs, trade marks or plant variety rights) or unregistered (as in the case of copyright, trade secrets, goodwill and reputation).

2.2 As a profession, Patent Attorneys operate in the global arena assisting New Zealand business to take their ideas and innovations to the world. We understand the need to be smart about intellectual property – protection is important and commercialisation more so. We provide real support to New Zealand's innovators through identification and enhancement of ideas, protection and commercialisation.

2.3 NZIPA members have many touch points with their clients which enable them to easily detect relevant, marketable and commercial ideas. As a result of their engagement, patent attorneys:

- Regularly visit New Zealand businesses to enable early identification of innovative ideas;
- Educate New Zealand businesses about the range and scope of those intellectual property rights both in New Zealand and overseas;
- Occasionally take equity in New Zealand businesses to assist with the commercialisation of ideas and innovations that they see have potential and which may not otherwise get to market without our assistance;
- Are actively involved in the commercialisation of ideas and innovations by sitting at the negotiation table, drafting and reviewing related documents and providing strategic, commercially relevant and pragmatic advice across a broad range of issues (i.e. commercial issues, not just those that are IP related); and
- Develop strategies to protect those ideas and innovations in key markets through varied intellectual property rights.

2.4 Patent attorneys are a highly educated profession. Many of the registered patent attorneys in New Zealand are both legally (i.e. bachelor of laws or higher) and technically (i.e. Bachelor of Science or higher) qualified as well as being registered patent attorneys.

2.5 We work with New Zealand businesses across all sectors from fashion to telecommunications, and from wine to biotechnology. We are attuned to the opportunities and challenges which New Zealand businesses face both locally and internationally.

2.6 Our members are globally focussed. They travel regularly and are abreast of issues that will affect New Zealand businesses as they seek to commercialise their innovations and take them to the world.

2.7 Most importantly, patent attorneys have a unique insight into how New Zealand business can (and should) use the intellectual property systems in New Zealand, Australia and further afield to maximise commercial advantage on the world stage.

3. Technological protection measures

Question 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.

3.1 We agree with the proposed exceptions/limitations proposed for TPMs.

Question 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?

3.2 We agree that the exceptions proposed for TPMs should apply to both prohibitions. The act of circumventing a TPM and the act of providing devices or services would ordinarily be related. It does not make sense to excuse one and not the other.

Question 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?

3.3 We assume the exception referred to is section 226D of the Copyright Act 1994 that enables a qualified person to exercise a permitted act under Part 3. We would prefer to retain the current exception. It would be prudent to maintain this general exception in the event that there is any uncertainty around the proposed exceptions.

Question 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.

3.4 We don't believe any additional exceptions would be necessary.

Question 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.

3.5 There is a risk of adverse impact on non-infringing uses. There are likely to be non-infringing uses that we have not yet contemplated. It would be prudent to maintain a general exception for any other purpose that does not infringe copyright.

Question 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?

3.6 We agree that there should be a regulation-making power to clarify this exception.

4. Patent term extension for delays in patent grant

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

4.1 Yes. Where there are "unreasonable delays" in the processing and examination of a patent to grant as defined in TPP Article 18.46, we agree that a patent term extension should be allowed.

4.2 As noted in the Targeted Consultation Paper and several other publications[1], IPONZ's current examination timeframes are generally very efficient. Therefore, if the current examination rates are maintained, very few patent term extensions are likely to be granted.

4.3 However, it is possible that IPONZ's processing and examination times will increase if the Single Application Process (SAP) and Single Examination Process (SEP) for patents is implemented under the Single Economic Market initiative. This is because IP Australia currently has a large backlog of patent applications[2].

[1] For example, https://www.tpp.mfat.govt.nz/assets/docs/Trans-Pacific%20Partnership%20National%20Interest%20Analysis,%2025Jan2016.pdf
[2] http://www.ipaustralia.gov.au/uploaded-files/reports/economics_research_paper01.pdf

If the SAP/SEP is implemented, it is likely that at least some of the overflow from IP Australia will be delegated to IPONZ, potentially slowing the rate at which New Zealand patent applications are processed and examined.

4.4 If processing is not included in the determination of unreasonable delay then the passage of patent applications through processing and examination could be managed by keeping applications in the processing phase. The ability of the patent term extension option to incentivize efficient management would then be undermined.

4.5 The determination of unreasonable delay should take into account classified applications. Such applications are subject to a secrecy order that prevents publication (and grant) of such applications. The intent of the legislation would suggest that such applications be processed and examined within reasonable timeframes, and maintained in a pre-acceptance state pending lifting of the secrecy order. However, current IPONZ policy dictates that classified applications are not even examined until the secrecy order is lifted. Classified applications therefore experience delays in both examination and grant. Applicants should be compensated for such unreasonable delays.

4.6 The determination of unreasonable delay should also include delays incurred during other pre-grant procedures such as opposition, re-examination, and third party observations. For example, the processing of post-acceptance amendment applications made during the course of an opposition should be included.

4.7 For the avoidance of doubt, where a New Zealand patent application is processed and examined by IP Australia under the SAP/SEP, an extension of patent term should be available for unreasonable delays in the processing and examination of that New Zealand application by IP Australia. What is "unreasonable" should be judged based on New Zealand criteria not Australian criteria. The New Zealand Commissioner of Patents and the New Zealand Courts should have jurisdiction over any disputes.

Question 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?

4.8 NZIPA does not have a view on whether or not there should be a maximum length of extension.

4.9 This would at least provide a definite period to the patent term, and certainty for the public.

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

4.10 Yes.

4.11 The Commissioner of Patents will be required to decide on whether delays are, or are not, attributable to actions of the Commissioner of Patents or the actions of the patentee.

4.12 The patentee will be able to provide information in support of its application to extend the term of the patent.

4.13 A third party may also be able to provide information relevant to that decision. If so, it will be in the public interest for all available information to be available to Commissioner of Patents. Any patent term extension allowed will impact adversely on the public and it is therefore appropriate that relevant concerns are able to be addressed.

5. Patent term extension for pharmaceuticals

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

5.1 Rule 51A(7) of the Singapore Patents Rules defines "unreasonable curtailment" as taking place where:

a) the marketing approval was obtained after the date of issue of the certificate of grant; and

b) the interval between the date the application for marketing approval was filed and the date marketing approval was obtained, excluding any period attributable to an act or omission of the applicant for marketing approval, exceeds 2 years.

5.2 In common with many other countries, in Singapore the pharmaceutical product must be the first pharmaceutical product which uses the substance as an active ingredient to obtain marketing approval. Also, the term of the relevant patent must not previously have been extended[3].

5.3 In New Zealand, to gain marketing approval for a pharmaceutical, a person or company must apply to Medsafe. Medsafe aims to complete its initial evaluation

[3] https://www.cantab-ip.com/articles/patent-term-extensions/

for marketing approval within 200 calendar days of receipt of an application, however "the total time taken to reach a final decision can vary and depends on the amount and complexity of the information provided…"[4].

5.4 The Medsafe website provides details of its performance in the evaluation of medicines for 2015[5]. Medsafe divides these figures on the basis of application type, namely:

1. Higher risk medicine
2. Intermediate risk medicine
3. Lower risk medicine
4. Changed medicine
5. Priority assessment.

5.5 In 2015, the total time to conclude 90% of applications for marketing approval took:

- 560-783 calendar days for higher risk medicine;
- 694-824 calendar days for intermediate risk medicine;
- 174-324 calendar days for priority assessment medicine.

5.6 The time calculated is from the date of payment to the completion of the evaluation. It also includes the time taken by the applicant to respond to any requests for information (therefore some delays due to the applicant may be reasonable, in other cases they may not be).

5.7 There are three existing approval tracks which could be applicable to the proposed pharmaceutical extension that could be unreasonably curtailed (unlike the single process for a New Zealand patent application). The Changed Medicine option does not appear to be relevant.

5.8 It is only when the relevant track is "unreasonably" curtailed (and not due to actions of the patentee/applicant for approval) that the extension should be available.

5.9 On the basis of the above statistics, it does not seem "unreasonable" for intermediate risk medicines to take 824 calendar days to receive approval, given

[4] http://www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp
[5] http://www.medsafe.govt.nz/regulatory/Performance2015.asp

that 10% of applications are concluded later than this. However taking 824 days for assessment of a Priority Assessment Medicine may be "unreasonable".

5.10 Therefore, using the Singaporean single time period of 2 years (about 502 working days or 730 calendar days between 1/1/14 and 1/1/16) by way of example, this means that there will be a number of applications that will potentially be extendable under current statistics. Intermediate risk medicines will be particularly open to extension.

5.11 If a specified number of years is to be used consideration should be given to the period being divided into tracks mirroring those currently used by Medsafe (i.e. higher risk/intermediate risk/priority assessment) to avoid inconsistencies.

5.12 Alternatively, the specified number of years should be based on the minimum time reasonably taken for a notional application for marketing approval. Approval would then be considered on a case by case basis.

Question 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?

5.13 If Medsafe has different procedures and/or timeframes for biologics, then what is considered "unreasonable curtailment" should be based on a figure extrapolated from the usual time taken for approval.

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

5.14 Yes (although we refer to our submissions as set out above).

5.15 We observe that the period between the date of patent grant and the date on which marketing approval is granted is unlikely to be restrictive. The first patent application for a pharmaceutical substance per se will ordinarily have been filed and granted well before an application for marketing approval in New Zealand is made.

Question 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?

5.16 NZIPA does not have a view on whether there should be a maximum extension term.

Question 15 - Do you agree or disagree that only patents for pharmaceutical substances per se and for biologics should be eligible for extension? Why?

5.16 We agree.

5.17 We also suggest that consideration be given to extensions for patents directed to "veterinary substances per se".

5.18 An extension to the period of data protection for such substances provided for under the TPP (10 years).

5.19 An extension from 5 to 8 years for innovative trade name products was proposed in the Agricultural Compounds and Veterinary Medicines Amendment Bill 2015 to meet the policy objective of encouraging businesses that own trade name products to register new trade name products and to register more uses for existing trade name products.

5.20 Extensions of patent term for unreasonable curtailment of patent term resulting from delays in registration procedures may be justifiable for the same reasons the data protection period is to be extended. This would incentivise release of the latest veterinary products in New Zealand and thus support New Zealand's competitiveness in the agricultural sector.

Question 16 - Do you think the Australian definition of "pharmaceutical substance" should be adopted? Why / why not?

5.21 Yes. Australia has an established body of case law for interpreting the term and harmonization is appropriate.

5.22 However, use of "pharmaceutical substance per se" has led to the encompassing of unintended items (e.g. a bi-phasic tablet in Sanofi-Aventis [2007] APO 35 (2 October 2007)).

5.23 Issues surrounding "pharmaceutical substance per se" have been discussed at length in the Australian Pharmaceutical Patents Review Report 2013[6].

Question 17 - Do you agree that patent rights during the extended term should be limited in the manner proposed?

5.24 We agree with the time limits proposed within which extensions can be applied for.

[6] http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf

5.25 We submit that extensions for delays in patent grant and for unreasonable curtailment of the marketing approval should be cumulative. The reasons for the extensions are distinct. Further, if an extension for delays in patent grant is allowed, the incentive for efficient processing of the application for marketing approval is then removed as this will be known to Medsafe.

5.26 We agree that the extension should be limited to the therapeutic use (or uses) to which the application for marketing approval is directed.

5.27 We observe that it is possible that the therapeutic use(s) in the application for marketing approval may not be part of the patent applicable to the pharmaceutical substance per se that is to be extended. If so, this should not restrict the applicability of the patent extension. In addition, the patent should not be able to be attacked on the basis that the patent extends to the use of the pharmaceutical substance per se for that therapeutic use.

Question 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?

5.28 Yes.

5.29 Determination of unreasonable curtailment of marketing approval - we believe it would be helpful to have someone with an objective understanding of Medsafe regulatory processes and guidelines, and pharmaceuticals substances/biologics, to act as an independent advisor (or amicus curiae) to the Commissioner of Patents. The issues to be addressed are both the jurisdiction of the Commissioner of Patents over Medsafe procedures and relevant knowledge of those procedures.

6. Performers' rights

6.1 We agree in principle with what appears to be a basic proposal to extend the moral and property rights which performers have in live performances and recordings of live performances. This will match the minimum requirements of the WPPT (WIPO Performers and Phonograms Treaty) as well as adopting some further provisions from the UK legislation.

Question 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?

6.2 We agree. There is no rational reason why the musical component of a live performance should give rise to moral rights while the visual aspects do not.

Question 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?

6.3 Yes. The distinction between a performance captured as a sound recording and one captured on film is arbitrary and unnecessary and we endorse removing it

Question 21 - Do you agree or disagree with any of the exceptions or limitations proposed for a performer's right to be identified? Why?

6.4 We agree. As aforesaid, distinction between a performance captured as a sound recording and one captured on film is arbitrary and unnecessary and we endorse removing it.

Question 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.

6.5 The exception for "private and domestic use" currently relates to sound recordings only. It should be extended to other forms of recorded media (primarily films). We are also concerned by the interplay between this exception and dissemination of material via social media (which is arguably a private and domestic use of material). Performers should be reasonably able to object to widespread dissemination of a recording of a performance via a social media site under the guise of private and domestic use unless the person posting the material had used reasonable efforts to identify and name the performer. Thus the exception should be tempered by a reasonable efforts requirement or some greater definition provided in the Act as to what constitutes "private and domestic use".

Question 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?

6.6 We agree. Exceptions should be consistently applied across moral rights regardless of subject matter.

Question 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.

6.7 The Copyright Act currently contains no fair use provision for parody and satire. This would be a reasonable exception to the right to object to derogatory treatment.

Question 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.)

6.8 Yes. The proposal is to extend moral rights to performers for the visual aspects of a performance (ie those captured on film). There is no rational basis not to extend property rights to films of performances to those performers as well. Indeed, given that filming a performance will also almost inevitably also produce a soundtrack, it is difficult to see how the distinction could be applied in practice. Would the performer own the soundtrack embedded in a film but not the visual aspects of the film? Logic and consistency favour granting of property rights in both films and soundtracks of a performance. The commercial impacts will be no more significant than the current rules governing ownership of commissioned works. While those rules are complicated, ownership is largely resolved through contractual arrangements to alter the default position created by the Act. We would expect the same to apply to filmed and recorded performances.

Question 26 - Do you agree or disagree with any of the exceptions or limitations proposed above? Why?

6.9 We agree. Exceptions should be consistently applied across property rights regardless of subject matter.

Question 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.

6.10 We do not understand how there could be separate copyright rights owned by the performer and a "producer" (see para 125 which refers to "producer's copyright") in a recording of a performance since there is no "work" in which rights can be asserted until the performance is fixed in some tangible form. If all the "producer" does is record the performance on media, what is the time, labour, skill and judgment exercised sufficient for separate copyright to vest in the

producer's recording? Since the Act also provides that copyright only subsists in original works, and a work is not original if it is, or to the extent that it is, a copy of another work (s.14) what separate copyright would subsist in the mere recording of a performance over and above the performance itself? For these reasons we favour one property right arising from a recording of a performance which would vest by default in the performer.

Question 28 - Do you agree or disagree with any of the proposals above? Why?

6.11 We agree.

Question 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.

6.12 See our answer to Question 27.

7. Border protection measures

Question 30 - Do you 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.

7.1 We have no issue with what is proposed.

7.2 We query however whether any consideration has been given to adopting the process, or at least parts of it, that now operates in Australia for dealing with suspected infringements. See comments below.

Question 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?

7.3 It is accepted that the proposed detention period of three business days is the same as provided for in European Council Regulation (EC) No. 3295/94, but this period seems unnecessarily short. We would suggest that a longer period of five business days is more reasonable. We assume that for trade mark infringements, Customs would contact the listed address for service of the suspected infringement in the first instance, who would then contact the rights holder for instructions. The address for service should have the relevant rights holder

contact details. Often within an organisation specific personnel have responsibility for handling infringement matters, so to get instructions promptly all correspondence needs to be appropriately addressed. Recognising the importance of handling infringement matters, it still can take time to obtain instructions. This is because of the need to verify information, check sources of possible infringing product, get authority to file a Customs Notice (or not), instruct an application to be filed, arrange monies for payment of the bond etc. The process could take longer for a copyright infringement especially if it is not clear who is the owner, and enquiries have to be made to determine this. It is also important to determine what work is suspected of being infringed and this can take time to verify also.

7.4 There are also date issues to consider. A rights holder based in the USA would not receive a notice issued by Customs in New Zealand on say a Monday until Tuesday. Does the proposed three working days run from when the actual rights holder receives the notice or from when its address for service in New Zealand receives it? What consideration, if any, has been given to public holidays operating in the country where the rights holder is based which may not apply in New Zealand? Thanksgiving in the USA is an example.

7.5 There does need to be a balancing of positions here – an opportunity given to a rights holder to file a customs notice so that they have the ability to deal with suspected infringements, and for an importer to be able to gain access to goods they have bought and hope to sell for commercial gain. There is also another factor to take into consideration and that is of the public interest. Not having a procedure in place that gives a rights holder sufficient time to file a customs notice to be able to deal with suspected infringing goods could have detrimental consequences in some cases, particularly if the suspected infringements are medicines/pharmaceuticals or have a public safety or health component associated with them, like fireworks, batteries, machinery etc. The New Zealand public, quite apart from a rights holder, would not want infringing and potentially defective goods in the marketplace which could be dangerous. The measures adopted should deal effectively with unlawful counterfeit activity without impeding the freedom of legitimate trade.

7.6 The onus currently is on the rights holder to take steps to deal with suspected infringements in New Zealand. In Australia the onus has shifted to the importer who now needs to make a claim for goods seized by Customs. If no claim is made the goods are forfeited. The importer is required to provide name, address and telephone number and grounds for seeking the release of the seized goods. This information may be available to a rights holder which is helpful when dealing

with importers of counterfeit products across multiple jurisdictions. It is noted that Australian Customs will only seize goods that are the subject of a customs notice, not under ex officio powers. Despite this, the Australian system has aspects of it which are worthy of consideration if New Zealand wishes to provide better cost-effective mechanisms for rights holders to prevent counterfeit goods entering New Zealand.

7.7 We would also be concerned if Customs did not advise a rights holder each and every time they suspected the importation of potentially infringing goods. It is expensive to file a Customs Notice and pay the bond of $5000. A rights holder should be able to make a determination as to when the time is right to file a Customs Notice. They may for economic reasons chose not to file a Customs Notice if the imported quantity of product is not large. But if that situation changes and they are advised of increasing numbers of potential infringements, then this may be enough to change their position. A rights holder should be given every opportunity to deal with the infringement of its rights.