



NEW ZEALAND  
LAW SOCIETY

NZLS EST 1869

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# Trans-Pacific Partnership Agreement Amendment Bill

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*22/07/2016*

## **Trans-Pacific Partnership Agreement Amendment Bill**

### **1 Introduction**

1.1 The Law Society welcomes the opportunity to comment on the Trans-Pacific Partnership Agreement Amendment Bill (Bill).

1.2 The Law Society's submission includes comments on the following aspects of the Bill:

- Part 1 – Amendments to Agricultural Compounds and Veterinary Medicines Act 1997
- Part 2 – Amendments to Copyright Act 1994:
  - A. Clause 14 – Power of Customs to detain items
  - B. Clauses 22-38 – Performers' Rights
  - C. Clauses 39-42 – Technological Protection Measures
- Part 8 – Amendments to Patents Act 2013
- Part 11 – Amendments to Trade Marks Act 2002

### **2 Part 1 – Amendments to Agricultural Compounds and Veterinary Medicines Act 1997**

2.1 There are three potential data protection schemes for innovative agricultural compound applications:

- The existing scheme under part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997;
- The amending scheme proposed under the Agricultural Compounds and Veterinary Medicines Amendment Bill (Ag Compounds Amendment Bill) as reported on 15 June 2016 by the Primary Production Committee; and
- The amending scheme proposed under the Bill (referred to in this paragraph as the TPPA Amendment Bill, to avoid confusion).

2.2 The explanatory note of the TPPA Amendment Bill, on page 5, acknowledges the proposed amendments in the Ag Compounds Amendment Bill, but does not indicate which of the two amending schemes might be enacted.

2.3 The TPPA Amendment Bill proposes amendments to the Veterinary Medicines Act 1997 that are inconsistent with some of the amendments proposed by the Ag Compounds Amendment Bill. This suggests either one or the other could be enacted, but not both.

2.4 Clause 2 of the Ag Compounds Amendment Bill provides that it will come into force the day after receiving Royal assent.

2.5 If the Ag Compounds Amendment Bill were to be enacted in its current form then part 1 of the TPP Amendment Bill would need to be amended to refer to the amended part 6 of the principal act. Such a series of amendments would require two sets of transitional provisions: one applying to the Ag Compounds Amendment Bill; and the second to part 1 of the TPP Amendment Bill.

2.6 The Ag Compounds Amendment Bill would create (in new section 74) several new categories of protection periods.<sup>1</sup> These new categories of protection periods are not included in the TPP Amendment Bill. The possibility of creating and then extinguishing categories of protection periods would exacerbate the regulatory confusion referred to in the Law Society's submission on the Ag Compounds Amendment Bill.

2.7 In its submission to the Primary Production Committee on the Ag Compounds Amendment Bill the Law Society stated:

*Interface with TPP*

*5. The TPP requires a minimum 10 year data protection period for a new agricultural product. The Law Society expects that the data protection regime proposed in this Bill will therefore need to be amended in the near future when Parliament implements the TPP. Accordingly, the Law Society proposes that Parliament should consider deferring the Bill until Parliament is implementing the TPP.*

*That is because:*

- a. it is not a sensible use of Parliamentary time and resources to deal with the Bill at this time; and*
- b. enacting the Bill may create an expectation that the 3 year extended period of protection will be included in the amendments to give effect to the TPP, thereby creating a total protected period of 13 years; and*
- c. there is a risk of creating regulatory confusion.*

*Use of resources*

*6. To comply with article 18.47.1 of the TPP, the basic protected period of 5 years will need to be replaced with a 10 year basic protected period.*

*7. The Bill's Regulatory Impact Statement (RIS) states that the policy was developed from an analysis of an independent study of the effects of New Zealand's protection rules on the market for agricultural compounds (the "Covec Study").*

*8. The Covec Study and the RIS are both predicated on the basic term of data protection for agricultural compounds being 5 years (not 10). The Bill provides additional terms of data protection for new uses of registered agricultural chemicals, to a maximum total of 8 years. When the TPP is implemented creating a 10 year basic protected period, there will need to be a reconsideration of the need for extended periods of protection.*

*Creating an expectation of a 13 year protected period*

*9. The introduction of extended periods of protection now may create an expectation that extended periods will also be included in the regime after the implementation of the TPP. It may be difficult to take away extended periods for new uses once extended periods are in force. So if the Bill is enacted and TPP later implemented, the possible outcome is a 10 year basic protected period and an extended protected period of up to 13 years.*

*Regulatory confusion*

*10. Enacting the Bill and then subsequently implementing TPP could lead to regulatory confusion. The current regime will be replaced by the one proposed in this Bill, and that regime is likely to be replaced shortly thereafter by one that is compliant with TPP.*

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<sup>1</sup> For applications to authorise new uses or methods of use of innovative trade name products and for non-innovative trade name product applications and their new uses.

*Recommendation:*

*11. That consideration be given to deferring progress of the Bill pending the implementation of the Trans-Pacific Partnership.*

**Recommendation**

2.8 For the reasons stated in paragraphs 2.1 to 2.6, as well as the reasons quoted from our earlier submission on the Ag Compounds Amendment Bill, the Law Society repeats its recommendation to defer progress on the Ag Compounds Amendment Bill until it has been determined whether the Trans-Pacific Partnership Agreement will come into force.

**3 Part 2 – Amendments to Copyright Act 1994**

**A. Clause 14 – Power of Customs to detain items**

3.1 The Law Society considers that a detention period of three working days is insufficient and should be extended. While the detention period would have an impact on both the rights holder and importer, the questions of identifying allegedly counterfeit or pirated goods, establishing that they are or are not counterfeit or pirated and lodging a border protection notice may not necessarily be straightforward. For this reason, it is suggested that five working days would be more appropriate and would strike the right balance.

**Recommendation**

3.2 In proposed section 135C(1)(a) and (b), replace the words “3 working days” with “5 working days”.

**B. Clauses 22-38 – Performers’ Rights**

3.3 The Bill introduces performers’ moral rights as distinct from performers’ property rights. For each type of right, a distinction is made between rights relating to making sound recordings of a performance and to making a film recording of a performance. This distinction is not made under the present law (Copyright Act 1994), and the Law Society considers that for the following reasons it should not be introduced.

3.4 The existing provisions in Part 9 of the Copyright Act (granting rights to performers in respect of illicit recordings of their performances) include both sound recordings and films. This creates a precedent to follow when legislating for additional performers’ rights.

3.5 When the World Intellectual Property Organisation Performers and Phonograms Treaty (WPPT) was being negotiated, the inclusion of audiovisual works was ‘unfinished business’ which the Diplomatic Conference on WPPT expressly recognised as needing to be addressed.

3.6 It is not logical to confine the rights to audio only. Frequently in the case of music performances, the artist or band releases new sound recordings together with a visual element i.e. a music video (in any number of file formats) clip in which they perform the sound recording. Music videos have been a mainstay of music television channels such as MTV, Edge TV and Juice over many years in New Zealand. The definition of ‘performance’ is widely regarded as including a performance in a studio that is recorded or fixed in an audio or audiovisual medium. It is not confined just to performances in concerts or elsewhere in public.

3.7 If the two intended moral rights are to be accorded to performers in respect of visual aspects of their live performance and any communication of these, it is not logical to give these rights just to music performers and not to other performers whose performances comprise solely a visual element such

as actors, circus performers, mime artists and others. (In practice such performers are likely to deal with their moral rights in contracts with film producers or those producing an authorised recording).

## **Recommendations**

- 3.8 Maintain consistency with existing law by including sound recordings and film within moral rights and TPMs. This would require the following:
- 3.9 Amend clause 22 as follows:
- Delete proposed section 170A(3) of the Copyright Act 1994
  - Delete proposed section 170(F)(2) of the Copyright Act 1994
- 3.10 Delete clauses 24 to 27.
- 3.11 Amend clause 28 as follows:
- delete from the heading the words “relating to sound recordings”
  - delete proposed new section 174A
  - delete “sound” from the title in proposed new section 174B
  - delete “sound” from the title in proposed new section 174C
- 3.12 Delete references in clause 31 to “(that is a sound recording)”.
- 3.13 Amend clause 38 so as to delete the word “sound” in proposed section 198(1A)(b).
- 3.14 Delete clauses 26 and 27.
- 3.15 Amend clauses 39 to 42 to refer to “recording”, not just a “sound recording”.
- 3.16 If the TPPA is not ratified, replace references to 70 years with 50 years in proposed new section 193 (in clause 32), in order to be consistent with other rights granted under the Copyright Act 1994.

### **C. Clauses 39 - 42 – Technological Protection Measures (TPMs)**

#### *Background*

- 3.17 Clauses 39 to 42 of the Bill would amend the Copyright Act 1994 to replace the existing regime for TPMs with a new regime.
- 3.18 TPMs are used to control access to and copying of digital material and are pervasive in commerce involving digital material, especially electronic/online commerce. The Australian Copyright Council has described TPMs and their place in commerce as follows (Australian Copyright Council, Information Sheet G127 v02, July 2015):

*A TPM is a way copyright owners control access to, and copying of, their digital material. There are two types of TPMs in the Copyright Act, access control TPMs and copy control TPMs. A copy control TPM prevents people from copying the material.*

*An access control TPM limits access to the material. Access control TPMs are very common and appear as passwords, paywalls, pop-up screens, time-limited access (for example, if you “rent” an item on iTunes, your access expires after 48 hours) and other things that restrict access.*

- 3.19 By analogy, access control TPMs are equivalent to doors in bricks and mortar commerce, each door allowing a person authorised to pass through it access to certain copyrights works for certain

purposes and/or a certain period. Some doors might provide authorised members of the public access to copyright material in an area in which they are able to trade with the copyright owner (for example, provide customers with access to the front end of the business) and other doors might provide authorised participants in the business access to copyright material in an area that supports the operation of the business (for example, provide authorised members of staff access to the back end of the business).

- 3.20 Access control TPMs are used for many purposes in a business relating to copyright. Continuing the analogy, there can be as many doors through which a person is able to pass (and terms on which they may pass) as a copyright owner decides are appropriate to prevent or control access to its copyright works for its business purposes.
- 3.21 Copy control TPMs are technological barriers to prevent copying, as the name suggests, although the relevant definition in the Bill confines the term to technology which "prevents or inhibits the infringement of copyright" (proposed section 226 (Definition of TPM terms)).
- 3.22 Access control TPMs are often used in conjunction with copy control TPMs. The unauthorised circumvention of TPMs is among activities commonly referred to as "hacking".
- 3.23 Article 18.68 of the TPP Agreement refers expressly to TPMs. Article 18.68(1) says that "to provide adequate legal protection and effective legal remedies" against the circumvention of TPMs that copyright owners "use in connection with the exercise of their rights and that restrict unauthorised acts in respect of their works" each Party shall provide the prohibitions in Article 18.68(1)(a) and (b).
- 3.24 The provisions which allow exceptions to the requirements for laws against circumvention are in Article 18.68(4)(a)-(c), which are reproduced below:

*Article 18.68: Technological Protection Measures (TPMs)*

*4. With regard to measures implementing paragraph 1:*

*(a) a Party may provide certain limitations and exceptions to the measures implementing paragraph 1(a) or paragraph 1(b) in order to enable non-infringing uses if there is an actual or likely adverse impact of those measures on those non-infringing uses, as determined through a legislative, regulatory, or administrative process in accordance with the Party's law, giving due consideration to evidence when presented in that process, including with respect to whether appropriate and effective measures have been taken by rights holders to enable the beneficiaries to enjoy the limitations and exceptions to copyright and related rights under that Party's law;*

*(b) any limitations or exceptions to a measure that implements paragraph 1(b) shall be permitted only to enable the legitimate use of a limitation or exception permissible under this Article by its intended beneficiaries and does not authorise the making available of devices, products, components, or services beyond those intended beneficiaries; and*

*(c) a Party shall not, by providing limitations and exceptions under paragraph 4(a) and paragraph 4(b), undermine the adequacy of that Party's legal system for the protection of effective technological measures, or the effectiveness of legal remedies against the circumvention of such measures, that authors, performers, or producers of phonograms use in connection with the exercise of their rights, or that restrict unauthorised acts in respect of their works, performances or phonograms, as provided for in this Chapter.*

*Clause 40 – Section 226A replaced (Prohibited conduct in relation to technological protection measure)*

3.25 Section 226A of the Copyright Act currently provides for the following in relation to copy control TPMs:

- (a) a prohibition against dealing in TPM circumvention devices (section 226A(1));
- (b) a prohibition against providing a TPM circumvention service (section 226A(2); and
- (c) a prohibition against publishing information with the intention that the information will be used to circumvent TPMs and infringe copyright (section 226A(3)).

3.26 Clause 40 of the Bill (new section 226A) would replace the prohibitions described at (a) and (b) above with prohibitions against dealing in circumvention devices and providing circumvention services, and would repeal and not replace the prohibition described at (c) above against the intentional publication of information to circumvent TPMs and infringe copyright.

3.27 Current section 226A(3) reads as follows:

*A person (A) must not publish information enabling or assisting another person to circumvent a technological protection measure if A intends that the information will be used to infringe copyright in a TPM work.*

3.28 Accordingly, section 226A(3) protects copyright owners and their licensees from the publication of information intended for use to circumvent TPMs and infringe copyright outside the business context of dealing in TPM circumvention devices and providing TPM circumvention services.

3.29 Notably, section 226A(3) is the only safeguard against the provision of information intended to facilitate circumvention, such as the publication of hacking instructions, outside a commercial context.

3.30 Given the balance achieved by section 226A(3) under the existing regime relating to TPMs, the Law Society queries whether the proposed repeal of section 226A(3) is intended under the new regime, particularly as the Explanatory Note to the Bill is silent on the issue.

### **Recommendation**

3.31 Review whether it is intended that section 226A(3) be repealed.

*Clause 42 – Prohibitions on TPM circumvention and Exceptions*

3.32 Proposed sections 226A, 226AB and 226AC would prohibit: dealing in TPM circumvention devices; providing a service to circumvent a TPM; and circumventing an access control TPM, respectively, and each of the proposed sections would include exceptions to these prohibitions by reference to the exceptions listed in proposed sections 226D to 226J.

3.33 The Law Society supports the proposed prohibitions in sections 226A, 226AB and 226AC on the basis that they comply with Article 18.68(1)(a) and (b) of the TPP Agreement.

3.34 The Law Society also supports in principle the specific exceptions to those prohibitions, as set out in proposed sections 226E to 226J, on the basis that the exceptions comply with:

- Article 18.68(4)(b) (exceptions permitted only to enable legitimate use by the intended beneficiaries); and
- Article 18.68(4)(c) (exceptions not to undermine the adequacy of New Zealand's legal system to protect effective TPMs or the effectiveness of legal remedies against circumvention).

*Blanket exceptions in proposed section 226D*

- 3.35 However, the Law Society queries whether the proposed blanket exceptions in section 226D comply with New Zealand's obligations under Article 18.68(4)(c) of the TPP Agreement.
- 3.36 As the Australian Copyright Council noted, access control TPMs are very common and appear as passwords, pay walls, pop-up screens, time-limited access and other things that restrict access to digital material.
- 3.37 These mechanisms reflect a range of very common and, in many cases, long standing commercial arrangements for the operation of businesses using copyright digital material.
- 3.38 More recent examples in the New Zealand context include cloud-based businesses, which provide various levels of TPM-protected online access to the copyright works embodied in the information, documents and services they provide in the course of their businesses. This is a high growth area in New Zealand's economy. Notable New Zealand businesses in this area include Xero, among others.
- 3.39 Cloud-based businesses and other businesses operating online or which conduct elements of their business online all commonly rely to some extent on access control and copy control in their daily business.
- 3.40 For example, a user of a cloud-based inventory control system may have rights to access and use copyright templates, spreadsheets and the like on the provider's system but may not be entitled to make copies of those templates, spreadsheets other materials.
- 3.41 Other examples where access control and copy control are commonly used in the New Zealand context include the owners of copyright works who exploit those works through chains of intermediaries, such as licensees and franchisees. In these businesses, access and the ability to copy may be controlled with reference to territory, time and various other factors according to the nature of the business.
- 3.42 In all these instances, the economics of the businesses depend on the ability of the owners and intermediaries to control access to and copying of their works.
- 3.43 For these reasons, the Law Society is concerned that the blanket exceptions as proposed in section 226D(1)(a) may undermine the adequacy of New Zealand's legal system to protect effective TPMs and the effectiveness of legal remedies against circumvention, contrary to Article 18.68(4)(c).
- 3.44 In this regard, the Law Society notes that a similarly broad exception was regarded as incapable of complying with the equivalent provisions of the Australia/US Free Trade Agreement when Australia's Standing Committee on Legal and Constitutional Affairs (Committee) concluded a review of TPM protection for the purposes of that agreement.
- 3.45 The Committee considered a general exception for TPM circumvention for access to lawfully acquired or possessed copyright material (see Review of technological protection measures exceptions, February 2006 at 4.199). The Committee was unable to recommend such an exception, as by its very nature, the exception was considered incapable of complying with the requirement for new exceptions under the agreement, namely, that exceptions must not impair the adequacy of legal protection or the effectiveness of legal remedies against circumvention (the equivalent to Article 18.68(4)(c) of the TPP Agreement).



### *Authorising hacking and possible "claim of right"*

3.46 The Law Society also queries whether the proposed blanket exceptions would amount to "authorisation" under section 248 of the Crimes Act so as to create a defence to the anti-hacking provisions of section 252 of the Crimes Act (Accessing computer system without authorisation).

3.47 Section 252 states:

#### *Accessing computer system without authorisation*

*(1) Every one is liable to imprisonment for a term not exceeding 2 years who intentionally accesses, directly or indirectly, any computer system without authorisation, knowing that he or she is not authorised to access that computer system, or being reckless as to whether or not he or she is authorised to access that computer system.*

*(2) To avoid doubt, subsection (1) does not apply if a person who is authorised to access a computer system accesses that computer system for a purpose other than the one for which that person was given access.*

3.48 Under section 248, "authorisation" is defined as follows:

*authorisation includes an authorisation conferred on a person by or under an enactment or a rule of law, or by an order of a court or judicial process.*

3.49 The proposed section 226D blanket exceptions would expressly allow the circumvention of TPMs for certain purposes and by certain persons, and may thereby create an "authorisation" defence to the anti-hacking provisions of section 252 of the Crimes Act 1961.

3.50 The blanket exceptions might also create a "claim of right" defence in relation to the balance of the "Crimes involving computers" in the Crimes Act (section 249, Accessing a computer system for dishonest purpose; section 250, Damaging or interfering with computer system; and section 251, Making, selling or distributing or possessing software for committing a crime).

3.51 The Law Society assumes that section 226D is not intended to amount to "authorisation" or provide a "claim of right" as outlined above.

### **Recommendation**

3.52 Review the proposed blanket exception in section 226D(1). In particular:

- Consider whether the blanket exception complies with Article 18.68(4)(c);
- Consider whether the blanket exception should be limited to copy control TPMs;
- Assess whether there is an unintended consequence of creating an authorisation or "claim of right" defence under the Crimes Act 1961.

#### *Regulation Making Powers (clauses 42 and 44)*

##### *Clause 42 – Proposed section 226K – Non-infringing acts expressly permitted by regulations*

3.53 These provisions would allow new exceptions to be added in exercise of a regulation making power under proposed section 234 (clause 44).

##### *Clause 42 – Proposed section 226L – sections 226E to 226K apply subject to prescribed modifications*

3.54 These provisions would allow the existing specific exceptions in sections 226E to 226J to be modified in exercise of regulation making power under proposed section 234 (clause 44).

*Clause 44 – section 234 amended (Regulations)*

- 3.55 These provisions would allow regulations to be made for the purposes of proposed sections 226K and 226L (creating new exceptions to prohibitions against circumvention and modifying the specific exceptions in sections 226E – 226J).
- 3.56 These provisions would also allow regulations to be made for the purpose of proposed section 226D(2), namely to provide exceptions to the exceptions in section 226D(1) in "prescribed circumstances" as described in section 234(2)(d).
- 3.57 The regulation-making powers in clauses 42 and 44 contain "Henry VIII" clauses in that they authorise regulations which have the effect of amending, suspending, overriding or effectively repealing the provisions in sections 226D(1) to 226J. Regulations should not have primacy over Acts of Parliament. Such powers are inconsistent with the principles of parliamentary government and are constitutionally objectionable.
- 3.58 Further, the reference in proposed section 234(2)(c) to the Minister having regard to "the purposes of [the Copyright Act]" causes uncertainty, as the Act has no express "purposes".
- 3.59 Accordingly, the Law Society opposes these regulation-making provisions. However, if they are to proceed, the Law Society submits that the provisions should comply with the TPP Agreement. We note that the proposed process for making regulations for the purposes of sections 226K and 226L, as set out in proposed section 234 does not currently comply with the TPP Agreement in that it:
- (a) is not confined to providing further specific exceptions or clarifying existing specific exceptions to prohibitions against the circumvention of TPMs;
  - (b) does not include effective obligations to provide "certain limitations and exceptions" to TPMs after giving "due consideration" to evidence presented during the process, contrary to Article 18.68(4)(a) (certain limitations to TPMs allowed via a duly considered evidenced based process); and
  - (c) is not otherwise required to comply with the TPP Agreement, contrary to New Zealand's obligations to comply with the Agreement.

Related to paragraph 3.59(b) above, the Law Society is concerned that proposed section 234(5) limits the usual powers to review the validity of the regulation making process.

*Approaches in Australia and UK*

- 3.60 In Australia and the UK, the regulation-making powers provided for similar purposes to those for which proposed section 234 is provided, are in each jurisdiction limited to special cases, require effective consultation and are certain.
- 3.61 In Australia, the Minister may only make recommendations for regulations if a formal submission has been made to prescribe an act. For the Minister to make a recommendation, the act must not infringe copyright and must relate to a particular class of works or subject matter, the actual or likely adverse impact of the doing of the Act must be demonstrated, and the adequacy of the protection and the effectiveness of remedies for TPMs must not be impaired if the act were prescribed by the regulations (section 249, Copyright Act 1968).
- 3.62 In the UK, a person may complain to the Secretary of State if they are prevented from carrying out a permitted act by a TPM. The Secretary of State will consider whether there are voluntary measures or agreements in place, and if there are not, the Secretary may direct the copyright owner or exclusive licensee to make available a means of carrying out the permitted act. This regime only

applies where the complainant or the class of persons that the complainant represents has lawful access to the protected copyright work (that is, it does not allow a complainant to effectively avoid a pay wall or breach confidentiality in order to exercise a right) (section 296Z, Copyright, Designs and Patents Act 1988).

**Recommendation:**

- 3.63 Remove the provisions for regulatory powers to amend the statute. While the Law Society recognises the attraction of being able to quickly “fix” a problem, the constitutional balance should not be overridden for convenience. Any amendments can be enacted by Parliament. Parliamentary amendment has the advantage of ensuring the consultation required by the TPP Agreement.
- 3.64 If the provisions are not removed, provide a process for the exercise of regulation making powers to create new exceptions to the prohibitions against circumvention of TPMs and modify existing specific exceptions to the prohibitions against circumvention, which:
- (a) is confined to certain special cases;
  - (b) provides effective obligations to consult;
  - (c) includes rights to challenge the validity of the regulations in all usual respects, including as to adequacy of consultation; and
  - (d) is otherwise required to comply with the requirements of a TPP Agreement;
- or which adopts the process of either the Australian model or the UK model or a hybrid of them.

**4 Part 8 – Amendments to Patents Act 2013**

*Clause 72 – Grace Period*

- 4.1 Article 18.38 TPP Agreement requires a grace period for publications up to 12 months prior to the filing of the application.
- 4.2 Current section 9(1)(a) – (e) create grace periods for the 1 year immediately preceding the filing date of the patent application.
- 4.3 Proposed section 9(1)(f) creates a grace period for publications for 1 year preceding the patent date.
- 4.4 The patent date is defined in section 103 as the date of filing the complete specification. For a patent application originally filed with a provisional specification the filing date of the patent application is typically almost one year before the “patent date”. In that circumstance the benefit of the grace period is greatly reduced because the grace period will be largely after the applicant has already filed the patent application.
- 4.5 For consistency with Article 18.38, consistency with existing section 9 and to create a meaningful grace period the Law Society recommends that the words “patent date” in clause 72 be replaced with “the filing date of the application”.

*Clause 75 – Patent Term Extensions – Delays in Granting*

- 4.6 Proposed sections 111A(1) and 111B(1) appear to be consistent with Article 18.46.4. But the Law Society queries why the drafters have chosen to express the requirements in language entirely different from Article 18.46.4. The language of article 18.46.4 is more easily understood and the Law Society recommends using the language from the TPP Agreement rather than the current language in the Bill.

## Recommendation

4.7 That proposed sections 111A(1) and 111B(1) be redrafted to reflect the language of article 18.46.4.

### *Section 111B Example*

4.8 The example given after new section 111B is not consistent with that section. Subsections 111B(2)(i) and (iii) provide that acts or omissions of the applicant and a person who opposes the grant of a patent, respectively, must be disregarded in calculating any extension of term. But paragraph three of the example appears only to disregard the time taken by the applicant to file a counterstatement and the time taken by the opponent to file evidence. Under the Patents Regulations 2014 the opponent also has to prepare and file a notice of opposition, a statement of case, evidence in reply, and is entitled to a hearing. The applicant has to file its evidence and also attend the hearing. In the example those additional actions by the applicant and the opponent do not appear to have been disregarded or even considered in the manner required by section 111B.

## Recommendation

4.9 The example after section 111B should be amended to make it clear which steps in an opposition will be subtracted and which will not, and this should also be made clear in the body of new section 111B.

### *“Biologic” Definition*

4.10 The definition of “biologic” in new section 111C is narrower than Article 18.52.2. The minimum under that article is “a product that is, or, alternatively, contains, a protein *produced using biotechnology processes*, for use in human beings for the prevention, treatment, or cure of a disease or condition.” “Biologic” is defined in section 111C as “a pharmaceutical substance that is produced by a process that involves *the use of recombinant DNA technology*.” Recombinant DNA technology is one example of a biotechnology process.<sup>2</sup>

4.11 Article 18.52 relates to data protection for biologics rather than patent term extensions, which is dealt with in Article 18.48. The effect of the narrow definition in section 111C would be that biologics made by the use of DNA technology would be advantaged over biologics made by other biotechnological processes in determining eligibility for patent term extensions. There is no apparent policy reason for this disparity.

## Recommendation

4.12 The definition of “biologic” in section 111C should be amended by replacing “the use of recombinant DNA technology” with “the use of a biotechnology process”.

### *Patent Term Extension of Unreasonable Curtailment*

4.13 Article 18.48 obliges member countries to adjust the patent term to compensate for unreasonable curtailment of patent term for pharmaceutical products. The article does not define either “unreasonable curtailment” or “pharmaceutical substance”.

4.14 Section 111F(1) would define “unreasonable curtailment” as more than five years for “biologics” and more than three years for all other pharmaceutical substances (including “biologics” made by biotechnological processes other than recombinant DNA technology). The footnote after section

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<sup>2</sup> The Encyclopaedia Britannica defines recombinant DNA technology as the joining together of DNA molecules from two different species that are inserted into a host organism to produce new genetic combinations that are of value to science, medicine, agriculture, and industry.

111F indicates that the precedents for this section are found in the Singapore Patents Act and Rules. But extensions provided in both the Singapore Act and Rules apply the same term to all pharmaceutical products. There is no special provision for biologics. In section 70 of the Australian Patents Act 1990 (although subsection (2) makes a distinction between pharmaceutical substances per se and pharmaceutical substances when produced by recombinant DNA technology) the length of the unreasonable curtailment is the same for both.

- 4.15 The policy objective behind the Patents (Trans-Tasman Patent Attorneys and Other Matters) Amendment Bill was to advance a single economic market where patent laws were more harmonised. It is inconsistent with that policy to have a different definition of “unreasonable curtailment” in New Zealand from that in Australia in those laws.

### **Recommendation**

- 4.16 Section 111F(1)(b) should be amended so that New Zealand law is harmonised with Australia’s on this issue.

### *Transitional Provisions*

- 4.17 Clause 77 of the Bill establishes three transitional provisions for the grace period and for patent term extensions for unreasonable curtailment during patent granting and for marketing approval. The effect of new paragraph 4 of part 2 of schedule 1 is that there is up to a one year delay in introducing the grace period. The grace period would not apply to any disclosure made before the commencement date. Therefore, applications made on or after the commencement date for up to 12 months would not benefit from a grace period for disclosures made before the commencement of the amended Act. This is not consistent with the transitional provision for patent term extensions provided in paragraph 4.

### **Recommendation**

- 4.18 New paragraph 4 being inserted under clause 77 of the Bill should be amended by deleting “disclosures that occur” and inserting “patent applications or patents with a patent date”.

### *Data Protection*

- 4.19 TPP Article 18.50.2(a) requires member countries to provide data protection for “new clinical information submitted as required in support of a marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration” for a period of 3 years. There is no provision in the Bill to protect new clinical data for a period of 3 years.
- 4.20 Data protection is given for confidential supporting information for active ingredients<sup>3</sup> of medicines for 5 years under section 23A, B and C of the Medicines Act 1991, but not for new clinical information.

### **Recommendation**

- 4.21 Sections 23A, 23B and 23C of the Medicines Act 1991 should be amended to provide data protection for new clinical information for a period of 3 years, consistent with Article 18.50.2(a).

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<sup>3</sup> “Ingredient” “includes a chemical or biological ingredient”.

## **Part 11 – Amendments to Trade Marks Act 2002**

### *Clause 96 – Power of Customs to detain items*

4.22 For the reasons set out above in paragraph 3.1 with regard to Customs detention of copyright infringements, it is suggested that five working days would be more appropriate.

### **Recommendation**

4.23 In proposed section 135B(1)(a) and (b) replace the words “3 working days” with “5 working days”.

## **5 Conclusion**

5.1 The Law Society does not wish to be heard, but is available to meet with the officials advising on the Bill if that would be of assistance.

A handwritten signature in black ink, consisting of a large, stylized loop followed by a horizontal stroke extending to the right.

Andrew Logan  
**Vice-President**  
22 July 2016