MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

Regulatory Impact Statement

Analysis of Options Relating to Implementation of Certain Intellectual Property Obligations under the Trans-Pacific Partnership Agreement

New Zealand Government

Agency Disclosure Statement

This Regulatory Impact Statement (**RIS**) has been prepared by the Ministry of Business, Innovation and Employment (**MBIE**).

This RIS relates to New Zealand's implementation of the Intellectual Property Chapter of the Trans-Pacific Partnership Agreement (**TPP**). It provides an analysis of options relating to those TPP intellectual property (**IP**) obligations that provide some flexibility for New Zealand in how the obligations are implemented.

This RIS has been prepared in the following context:

- Formal negotiations on TPP concluded on 5 October 2015. On 5 November 2015, New Zealand released the text of TPP. This was superseded by the legally verified text that was publically released on 26 January 2016.
- TPP was signed by New Zealand on 4 February 2016. It was referred to the Foreign Affairs, Defence and Trade Select Committee (**FADTC**) for examination on 9 February 2016, together with the Government's National Interest Analysis, including the advantages and disadvantages of ratifying TPP. The four intellectual property treaties to which New Zealand will need to accede under TPP and National Impact Analyses for each of those treaties were also referred to FADTC.
- Before New Zealand is bound by the obligations set out in TPP:
    - A bill must be passed by Parliament making the changes to New Zealand law necessary to comply with TPP obligations. (These changes will only come into effect once TPP enters into force for New Zealand.)
    - The Government must make or modify any regulations, and change any practices, necessary to comply with TPP obligations.
    - New Zealand must ratify TPP.
- The Government has prepared an extended National Interest Analysis for TPP (which incorporates the RIS requirements) that addresses the implications of TPP for New Zealand and the means of implementing TPP domestically.
- The TPP IP Chapter will require New Zealand to implement a range of amendments to our IP legislation. Most of the changes require minimal policy development. However, as TPP provides some flexibility for New Zealand in how it implements aspects of the IP changes, there are a number of ways in which some of the IP obligations could be met.
- MBIE has been directed to prepare the IP legislation necessary to enable New Zealand to ratify TPP.
- MBIE released the *Implementation of the Trans-Pacific Partnership Intellectual Property Chapter* targeted consultation document (**the targeted consultation document**) for a three week consultation period, commencing Wednesday, 9 March 2016. The targeted consultation document only focused on the proposed implementation approach for those areas with policy flexibility in the implementation approach. Fifty-five submissions were received by MBIE, ranging from individuals and user groups to rights holders and industry groups. MBIE also held workshops for key stakeholder groups during the consultation period.

For the purposes of this RIS, it is assumed that TPP will enter into force for New Zealand and New Zealand will become bound by the obligations set out in TPP.

The RIS has been prepared over a relatively short period and with a short public consultation period. This has prevented detailed assessment of some options. There will be further opportunities for submitters to comment on the proposals through the select committee process.

While we are confident that the broad conclusions justify the options proposed to meet the Government's objectives, time constraints have meant that quantified estimates of impact — difficult to establish in the area of IP law — have not generally been provided.

Gus Charteris

Manager, Business Law
Building, Resources and Markets
Ministry of Business, Innovation and Employment 8 April 2016

Executive summary

1. As identified in the Government's National Interest Analysis, there are overall net benefits to New Zealand in becoming a party to the Trans-Pacific Partnership Agreement (**TPP**). In order to meet all of the requirements to receive the broader gains of TPP, the implementation of some intellectual property (**IP**) obligations has the potential to impose costs. However, TPP provides some flexibility for New Zealand in how it implements aspects of the IP changes, and therefore New Zealand has the ability to minimise these costs.

2. On that basis, the Ministry's overarching objectives in developing its approach to implementing the IP chapter of TPP are to:

    - enable New Zealand to meet the TPP obligations
    - minimise the impacts of changes to IP settings to maintain an appropriate balance between rights holders and users
    - provide certainty and minimise compliance costs.

3. The specific legislative proposals have their own policy objectives to deliver these overarching objectives.

4. This RIS considers five issues where TPP provides some flexibility for New Zealand in how it implements the TPP obligations. These are the obligations to provide:

    - an extension of the patent term to compensate the patent owner for any unreasonable delay in the grant of a patent
    - an extension of the patent term, in respect of a pharmaceutical substance that is the subject of a patent, to compensate the patent owner for any unreasonable curtailment of the effective patent term as a result of Medsafe's marketing approval process
    - Customs with the power to detain suspected infringing goods on its own initiative (ex officio), without first having accepted a border protection notice from a rights holder
    - civil and criminal prohibitions against people circumventing technological protection measures (**TPMs**), including what exceptions and limitations should be provided for
    - a more extensive regime for performers' rights, including what exceptions and limitations should be provided for in relation to those rights

5. The RIS concludes that:

    - The Patents Act 2013 should be amended to make term extensions available for delays in the grant of a patent only if they are more than three years from the date of a request for examination or five years from the date of filing, disregarding any delays not attributable to the Intellectual Property Office of New Zealand (**IPONZ**). This is the minimum requirement under TPP.
    - The Patents Act 2013 should be amended to make term extensions available for pharmaceuticals:
        i. only for patents disclosing a pharmaceutical substance per se, where products consisting of, or containing, the substance have been approved for marketing by the New Zealand Medicines and Medical Devices Safety Authority (**Medsafe**)

ii. if the time period between filing of the application approval, and the grant of approval is more than three years for small molecule pharmaceuticals and five years for biologics.

- The Copyright Act 1994 and Trade Marks Act 2002 should be amended to provide a procedure for Customs to invite notices from rights holders to provide ex officio powers to Customs (similar to the approach taken in the European Union (**EU**)).
- In relation to TPMs, the Copyright Act 1994 should be amended to:
    i. prohibit the circumvention of a TPM that controls access to a copyright work
    ii. prohibit providing devices or services to circumvent TPMs that control access to a copyright work
    iii. provide exceptions for situations where copyright is not infringed
    iv. provide that civil remedies and criminal procedures and penalties do not apply to non-profit libraries, museums, archives, educational institutions and public non-commercial broadcasting entities in appropriate circumstances.
- In relation to the rights of performers, the Copyright Act 1994 should be amended to provide for:
    i. new performers' moral rights that apply to both the audio and visual aspects of a performance whenever a person produces or puts on a performance and in any live communication of that performance
    ii. exceptions and limitations to the new performers' moral rights which mirror the exceptions and limitations to authors' moral rights already provided in the Copyright Act, and additional exceptions where it would be impractical or unreasonable for the rights to apply
    iii. exceptions and limitations to the new performers' property rights which mirror the exceptions and limitations to producers' copyright already provided in the Copyright Act.

Patent term extension for delays in grant of a patent

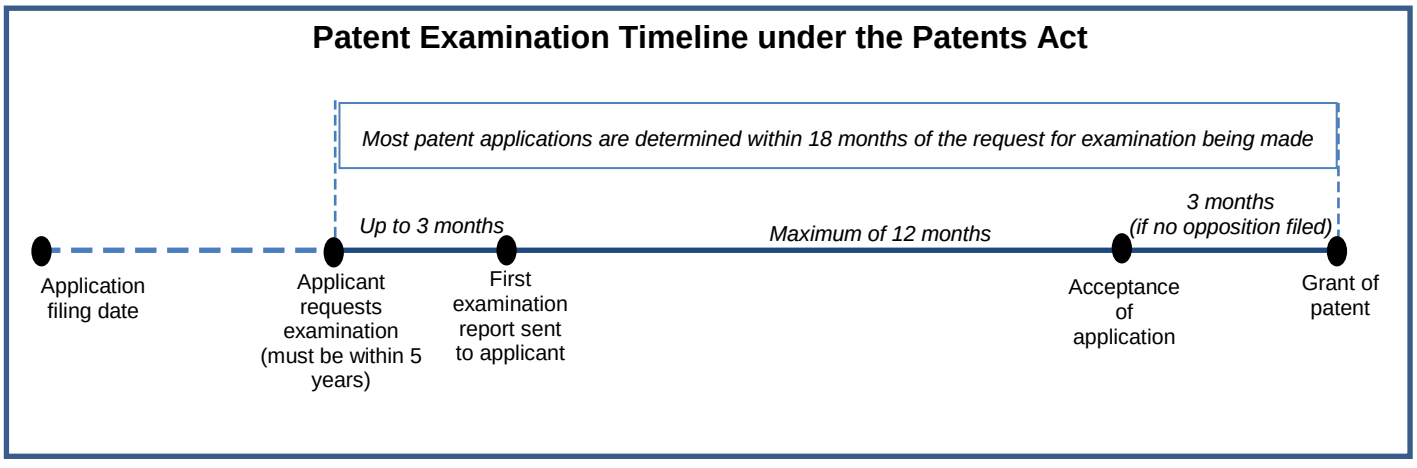
Background

6. A patent for an invention provides the patent owner with the right to prevent others from commercially exploiting the invention for the term of the patent. This provides an incentive for new inventions. Currently the patent term in New Zealand is twenty years from the date of filing of the patent application, with no provision for any extension.

7. Before a patent can be granted in New Zealand, the patent application must be examined by IPONZ to determine whether it complies with the requirements of the Patents Act 2013 (**the Patents Act**). Applications will only be examined if the applicant requests examination, which must be requested within five years of filing of the patent application. If a request is not made within five years, the application lapses.

8. When a patent application is examined it is referred to an examiner. If the examiner finds that the application does not meet the requirements of the Patents Act, the examiner will send an examination report to the applicant setting out the objections made by the examiner (this process can take up to three months). The applicant then has 12 months to overcome all objections made by the examiner, or to argue that the examiner's objections are not justified. There may be several exchanges of letters between the examiner and applicant before the application is granted or refused.

9. On current IPONZ examination timeframes, most patent applications are determined within 18 months of the request for examination being made.



Status quo and problem definition

Main problem

10. Article 18.46 of the IP Chapter of TPP requires New Zealand to provide, at the request of the patent owner, extensions of the patent term to compensate the patent owner if there are unreasonable delays in grant of a patent. In implementing this obligation, New Zealand has to decide:

    - how long a delay is before it constitutes an 'unreasonable' delay
    - what types of delay should be counted when calculating the length of the delay.

11. Although TPP provides some flexibility for New Zealand to determine how long a delay is before it constitutes an 'unreasonable' delay, TPP puts an upper limit on how long this can be. At a minimum, an unreasonable delay must include a delay in the grant of a patent of more than the later of:

    - five years from the filing date of the patent application, or
    - three years from the filing date of the request for examination.

12. In determining whether there has been an unreasonable delay, TPP allows New Zealand to exclude periods of time that:

    - do not occur during the processing or examination of the application by IPONZ
    - are not caused by IPONZ
    - are due to the actions of the patent applicant.

    In other words, it is only necessary to include delays that are directly attributable to the actions of IPONZ.

Secondary problem

13. An obligation to provide patent term extensions could result in costs to the New Zealand economy.

14. New Zealand is a net importer of patented technology. Most (85 – 90%) of the patents granted in New Zealand are granted to offshore applicants. If the terms of any of these patents are extended, this could impose a cost on the New Zealand economy as local businesses and consumers would have to pay higher prices for longer on products using patented technology. The cost could be particularly high if a patent related to a pharmaceutical were to be extended. When the patent on a pharmaceutical expires, the price may drop as much as 80 – 90% as generic versions of the patented pharmaceutical enter the market. Extensions of patent term could have a significant impact on the Pharmaceutical Management Agency (**PHARMAC**) as well as businesses and consumers. The actual costs will depend on the nature of the invention concerned, and the length of any extension granted.

15. Most patents are granted to offshore applicants and, given the small size of the New Zealand market compared with world markets, an extension of patent term in New Zealand will make no difference to foreign innovators' decisions to invest in innovation. This is typically also true for most local innovators – the small local market means that they will not usually be able to recoup their investment in innovation from the New Zealand market alone, and will need to look offshore.

16. In light of this, providing extensions of patent term could result in very large net costs to the New Zealand economy, particularly if the patent relates to a pharmaceutical.

17. If provision is made for patent term extensions due to delays in grant, there would be some administrative costs imposed on IPONZ in processing requests for extension if any are made. However, as IPONZ operates on a cost recovery basis, any processing costs would be recovered from fees charged to patentees who make requests for extensions of term.

Objectives

18. To meet the overarching objectives, changes to the patent term required by TPP should be implemented in a manner that:

- meets New Zealand's obligations under Article 18.46 of TPP
- minimises the impact of extensions to the patent term to maintain an appropriate balance between patent owners and users of patented technology
- provides certainty and minimise compliance costs for patent owners and third parties.

Options and impact analysis

19. To meet the above objectives, this RIS examines four regulatory options for providing an extension of the patent term for unreasonable delays in the grant of a patent:

- **Option 1 (preferred option):** Provide term extensions for delays only if they are more than the three and five year terms, only counting delays for which IPONZ is directly responsible.
- **Option 2:** Provide term extensions for delays if they are less than the three or five year terms, only counting delays for which IPONZ is directly responsible.
- **Option 3:** Provide term extensions for delays only if they are more than the three and five years, counting delays other people are responsible for as well as IPONZ delays.
- **Option 4:** Provide term extensions for delays if they are less than the three or five years, counting delays other people are responsible for as well as IPONZ delays.

20. As there are no provisions for patent term extension in the Patents Act 2013, there is no status quo against which the options below can be compared.

Option 1 (preferred option): Provide term extensions for delays only if they are more than the three and five years, only counting delays for which IPONZ is directly responsible

21. Option 1 would involve providing for extensions of the patent term where:

    - the patent was granted after a delay of more than five years after its filing date or more than three years from the time the patent applicant requested its examination (whichever was later)
    - the delay is directly attributable to the actions of IPONZ.

22. This is the minimum required to give effect to TPP obligations in terms of providing extensions of the patent term for unreasonable delays.

Advantages

23. Option 1 will enable New Zealand to comply with the TPP obligation to provide patent term extensions for delays in grant.

Disadvantages

24. The main disadvantage is that IPONZ's determination of the periods of delay for which IPONZ is responsible would be open to challenge. This may lead to uncertainty for patent owners and third parties as to when extensions would be granted.

Option 2: Provide term extensions for delays if they are less than the three or five years, only counting delays for which IPONZ is directly responsible

25. This option would involve providing for extensions of the patent term where:

    - the patent was granted after a delay of less than five years after its filing date or less than three years from the time the patent applicant requested its examination (whichever was later)
    - the delay is directly attributable to the actions of IPONZ.

Advantages

26. Proceeding with this option would enable New Zealand to comply with the TPP obligation to provide patent term extensions when required.

Disadvantages

27. This option could result in more extensions being granted, longer extensions, and therefore a risk of greater costs than under Option 1. IPONZ's determination of the periods of delay would also be open to challenge. This may lead to uncertainty for patent owners and third parties as to when extensions would be granted.

Option 3: Provide term extensions for delays only if they are more than the three and five years, counting delays other people are responsible for as well as IPONZ delays

28. Option 3 would involve providing for extensions of the patent term where:

    - the patent was granted after a delay of more than five years after its filing date or more than three years from the time the patent applicant requested its examination (whichever was later)

- the delays that occurred during the processes or examination of the application by IPONZ are directly attributable to IPONZ, or are due to the actions of the patent applicant or third parties.

Advantages

29. Proceeding with this option would enable New Zealand to comply with the TPP obligation to provide patent term extensions when required.

Disadvantages

30. Under this option, more patents would be eligible for extension, and extensions would be longer, compared with Options 1 and 2. This is because delays due to the actions of applicants and third parties would be included in determining whether there had been ”unreasonable delay” in grant and not simply delays directly attributable to IPONZ. There is also a risk that some applicants and third parties may game the system, for example by deliberately delaying responses or actions, in order to gain an extension.

31. Another disadvantage is that IPONZ’s determination of the periods of delay would be open to challenge. This may lead to uncertainty for patent owners and third parties as to when extensions would be granted.

Option 4: Provide term extensions for delays if they are less than the three or five years, counting delays other people are responsible for as well as IPONZ delays

32. Option 4 would involve providing for extensions of the patent term where:

- the patent was granted after a delay of less than five years after its filing date or less than three years from the time the patent applicant requested its examination (whichever was later)
- the delays occurred during the processes or examination of the application by IPONZ, are directly attributable by IPONZ, or are due to the actions of the patent applicant or third parties.

Advantages

33. Proceeding with this option would enable New Zealand to comply with the TPP obligation to provide patent term extensions when required.

Disadvantages

34. Of the options considered, Option 4 provides the broadest definition of what constitutes a delay, and the shortest timeframe before a delay is deemed unreasonable. The number of extensions, and length of any required extensions, would be greatest under this option.

35. IPONZ’s determination of the periods of delay would be open to challenge. This may lead to uncertainty for patent owners and third parties as to when extensions would be granted.

Recommendation

36. We recommend proceeding with Option 1 on the basis that it meets the objectives in providing an extension of the patent term for unreasonable delays in IPONZ’s grant of a patent.

Consultation

37. Sixteen submitters commented on the section regarding *Patent term extension for delays in grant of a patent* in the targeted consultation document. Some submitters argued that there was no need to provide for patent term extension for delays in grant, as IPONZ's processing times are such that it is most unlikely that extensions will need to be granted – this is the approach taken by Australia in relation to a similar obligation in the Australia and United States Free Trade Agreement (**AUSFTA**).

38. Concerns were raised that implementation of the proposed Single Examination Process between IPONZ and IPAustralia could result in longer processing times for New Zealand patent applications, possibly resulting in some patents becoming eligible for extension.

39. There were differences of opinion as to whether the time taken in pre-grant opposition proceedings should be excluded or included when considering whether there has been 'unreasonable delay" in grant. Patent owners tended to argue that this time should not be excluded; others, such as generic pharmaceutical manufacturers argued that it should be.

40. Although most submitters agreed with the method of determining whether there had been "unreasonable delay", some argued that excluding all of the time taken by the applicant to respond to, for example, examination reports, was unreasonable as there will always be some delay. It was suggested that the response time should only be considered "unreasonable" if it exceeded a certain threshold, for example the time periods set by the Commissioner of Patents for responses.

Comment

41. New Zealand's approach to obligations contained in treaties such as TPP, is that any legislative changes that might be required to comply with those obligations should made before the treaty enters into force for New Zealand. On this basis, legislative provisions to provide for patent term extension for delays in grant are required prior to entry into force for New Zealand of TPP.

42. The differences of opinion among submitters in regard to the time periods to be excluded from the calculation of "unreasonable delay" suggest that these could be a source of dispute. The targeted consultation document suggested that a list of excluded time periods would be published by the Commissioner of Patents. However, in light of the submissions we consider that, to provide certainty for IPONZ, patent owners and third parties, and to avoid disputes, the time periods to be excluded should be specified in the Patents Regulations.

Patent term extension for pharmaceuticals to compensate for delays in granting marketing approval

Background

43. A patent for an invention provides the patent owner with the right to prevent others from commercially exploiting the invention for the term of the patent. This provides an incentive for new inventions to be produced. Currently the patent term in New Zealand is twenty years from the date of filing of the patent application, with no provision for any extension.

44. Before a pharmaceutical can be marketed in New Zealand it must obtain approval from Medsafe. To obtain approval, the manufacturer of the pharmaceutical must provide evidence that the pharmaceutical is safe and effective. Much of this information is gathered from clinical trials of the pharmaceutical.

45. Given the time required to collect the information required, marketing approval is usually granted after any patents covering the pharmaceutical are granted. This means that the 'effective patent term' during which the pharmaceutical can be sold under patent is often less than the twenty year patent term provided for under the Patents Act 2013. Pharmaceutical companies argue that this reduces their ability to recoup their investment in developing the pharmaceutical and may reduce the incentive to develop new pharmaceuticals. In response to this, a number of countries, including the United States and the EU, provide for the patent term for pharmaceuticals to be extended, at the request of the patent owner. In Free Trade Agreement (**FTA**) negotiations, both the EU and the United States have required their FTA partners to provide for patent term extensions for pharmaceuticals.

Status quo and problem definition

46. Article 18.48.2 of TPP requires New Zealand to make available an extension to the patent term to compensate owners of patents for pharmaceuticals to compensate them for "unreasonable curtailment" of the effective patent term due to the marketing approval process.

47. Article 18.48 of TPP is set out below:

> 1. *Each Party shall make best efforts to process applications for marketing approval of pharmaceutical products in an efficient and timely manner, with a view to avoiding unreasonable or unnecessary delays.*
>
> 2. *With respect to a pharmaceutical product [45] that is subject to a patent, each Party shall make available an adjustment [46] of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.*[47, 48]
>
> 3. *For greater certainty, in implementing the obligations of this Article, each party may provide for conditions and limitations, provided that the Party continues to give effect to this Article.*
>
> 4. *With the objective of avoiding unreasonable curtailment of the effective patent term, a Party may adopt or maintain procedures that expedite the processing of marketing approval applications.*

[Footnotes:]

[45]A Party may comply with the obligations of this paragraph with respect to a pharmaceutical product, or, alternatively, with respect to a pharmaceutical substance.

[46]For greater certainty, a Party may alternatively, make available a period of sui generis protection to compensate for unreasonable curtailment of the effective patent term as a result of the marketing approval process. This sui generis protection shall confer the rights conferred by the patent, subject to any conditions and limitations pursuant to paragraph 3.

[47]Notwithstanding Article 18.10, (Applications of Chapter to Existing Subject Matter and Prior Acts), this Article shall apply to all applications for marketing approval filed after the date of entry into force of this Article for this Party.

[48]Annex 18-D applies to this paragraph. [Not relevant to New Zealand]

48. Article 18.48 does not define 'unreasonable curtailment', so the obligation provides some flexibility for each TPP Party to determine what should be deemed unreasonable curtailment in its domestic law. The obligation contemplates that the marketing approval process will curtail the effective patent term to a certain degree. It is therefore important to give effect to the ordinary meaning of the term 'unreasonable', in accordance with the customary rules of international treaty interpretation. In addition, there is no obligation to make an extension of term automatic – it need only be provided if the patent owner requests an extension and the criteria for extension are met.

49. There is unlikely to be any benefit to New Zealand in providing for an extension of the patent term for pharmaceuticals. All, or nearly all, of the patented pharmaceuticals available in New Zealand have been developed outside New Zealand. Given the small size of the New Zealand market for pharmaceuticals, the length of the patent term in New Zealand is unlikely to have any effect on the decisions of overseas pharmaceutical companies to invest in the development of new pharmaceuticals. This will be the case even for New Zealand researchers, as the costs involved in developing a new pharmaceutical are so large that they could not be recouped from the New Zealand market alone.

50. If a patent covers a pharmaceutical, any extension of the patent term will have the effect of delaying entry into the market of generic versions of the patented pharmaceutical. Typically, when a generic version of a patented pharmaceutical enters the market after the patent expires, the price can drop by as much as 80 – 90%. In the New Zealand context, a delay in generic entry can impose significant costs on the public health system to compensate for the lost savings, or reduce health outcomes. It is estimated that this cost to the government will be on average no more than $1 million per year because New Zealand practices are already very efficient. This is based on one product being extended by six months each year, but the actual costs, if any, will be lumpy and will vary over time. Costs will also be imposed on consumers (in the case of over-the-counter pharmaceuticals).

51. On this basis, extending the patent term for pharmaceuticals has the potential to impose a significant net cost on the economy. The actual costs to the economy of any extension would depend on the nature of the pharmaceutical concerned, and the length of the extension. If the extension applies to a high cost pharmaceutical, or one that is dispensed in high volumes, the costs could be very high.

52. The patent term extension provisions will be implemented by IPONZ under the authority of the Commissioner of Patents. The costs incurred by IPONZ in administering the patent term extension system will be recovered through fees charged to those using the patent term extension procedure on a cost recovery basis. Medsafe will also need to set up a certification system, monitor the processing of applications and offer a dispute mechanism. It may also be able to recover at least some of these costs from applicants. There will be no additional costs to government.

Objectives

53. To meet the overarching objectives, changes to the patent term for pharmaceuticals required by TPP should be implemented in a manner that:

- meets New Zealand's obligations under Article 18.48 of TPP
- minimises the impact of extensions to the patent term for pharmaceuticals to maintain an appropriate balance between patent owners and users of patented pharmaceuticals.
- provides certainty regarding the expiry date of patents for pharmaceuticals for third parties including generic manufacturers and PHARMAC.

Options and impact analysis

54. In considering the regulatory options, there are a number of issues where decisions regarding amendments to the Patents Act 2013 are required, including what (if any) conditions and limitations should be imposed. These are:

- **Issue 1:** What patented subject matter should be eligible for extension – patents for pharmaceutical products or for pharmaceutical substances?
- **Issue 2a:** How should we define "unreasonable curtailment" of the patent term?
- **Issue 2b:** What should the specific time period(s) for unreasonable curtailment be?
- **Issue 3:** Should there be limits on the maximum extension that can be granted?
- **Issue 4:** Should there be a limit on the number of extensions per patent and if so what limit should be imposed?
- **Issue 5:** Where there is more than one marketing approval, which should be considered when deciding eligibility for extension?
- **Issue 6:** What limits should be imposed on the rights of the patent owner during the extended term?
- **Issue 7:** Should the Commissioner of Patents be permitted to enquire into information provided by Medsafe for extension applications?
- **Issue 8:** Should it be possible for third parties to oppose the grant of an extension?

55. It is intended that the procedures and time limits associated with applications for extensions of patent term will be prescribed in regulations. These will be the subject of a separate RIS.

56. As there are no provisions for patent term extension in the Patents Act 2013, there is no status quo against which the options below can be compared.

Issue 1: What subject matter should be eligible for extension – pharmaceutical products or pharmaceutical substances?

57. Under the provisions of TPP Article 18.48.2, patent term extensions may be provided for pharmaceutical products, or pharmaceutical substances.

Option 1 (preferred option): Pharmaceutical Substances

58. Under this option, only patents disclosing a pharmaceutical substance where products consisting of, or containing, the substance that have been approved by Medsafe, would be eligible for extension. Patents disclosing and claiming different dosage forms, or new uses of an already patented pharmaceutical substance would not be eligible for extension. In this context, the term "pharmaceutical substance" includes biological pharmaceuticals.

59. If extensions are limited to pharmaceutical substances, only patents for the actual substance can be extended. For example, the pharmaceutical substance omeprazole and products containing omeprazole was the subject of a patent (sold under the trade mark "Losec®"). This patent could be extended. However later patents for products containing omeprazole, such as the patent for omeprazole in the form of a pill with an enteric coating to protect it from stomach acid, cannot be extended under this option.

60. The main benefit of limiting eligibility for extension in this fashion is that, for any particular pharmaceutical substance, only one patent is likely to be eligible for extension. This will minimise the impact of extensions by limiting the number of patents that are extended. This meets the objective of minimising the impact on extensions to the patent term for pharmaceuticals.

61. There appear to be no particular costs to the economy of limiting eligibility for extension to pharmaceutical substances.

Option 2: Pharmaceutical Products

62. Under this option, patents claiming pharmaceutical products that have been granted marketing approval by Medsafe would be eligible for extension.

63. A "pharmaceutical product" can be defined as a product that consists of, or contains, a pharmaceutical substance as an active ingredient. A patent claiming a pharmaceutical substance will usually also claim a product or products containing the substance. Subsequent patents may claim product(s) containing the previously patented substance, different to the product(s) claimed in the original substance patent.

64. There are no significant benefits in providing patent term extensions for pharmaceutical products, as opposed to pharmaceutical substances. There are, however, significant disadvantages.

65. As described earlier, it is possible for different pharmaceutical products containing the same pharmaceutical substance to be covered by different patents.

Example:

The pharmaceutical substance omeprazole (used to treat gastric reflux) was the subject of a patent, and pharmaceutical products containing omeprazole were approved by Medsafe. Some years later, another patent was granted for a pharmaceutical product that contained omeprazole, and also an enteric coating. This was also approved by Medsafe.

66. If patent term extensions are made available for pharmaceutical products, it would be possible for both of the omeprazole products referred to in the example above to be granted extensions. This would not meet the objective of minimising the impact of extensions to the patent term for pharmaceuticals compared with Option 1 where only one extension would be granted.

Issue 2a: How should we define "unreasonable curtailment" of the patent term?

67. TPP Article 18.48.2 requires patent term extension to be available for "unreasonable curtailment" of the effective patent term as a result of the marketing approval process. However, there is no definition of "unreasonable curtailment". This obligation provides some flexibility for each TPP Party to determine what should be deemed unreasonable curtailment in its domestic law .

68. There are two viable options:

- adopt a definition based on the time period between the patent application filing date, and the date marketing approval was obtained
- adopt a definition based on the time taken to process an application for marketing approval.

Option 1: Adopt definition based on time between patent filing and marketing approval

69. Under this option, an "unreasonable curtailment" is deemed to occur if the gap between patent filing and grant of marketing approval exceeds a specified period. Both Australia and the EU use this approach to determining whether a patent is eligible for an extension, and, if so, how long the extension should be.

70. Under the Australian and EU approaches, a patent relating to a pharmaceutical substance is eligible for an extension if the interval between the filing date of the patent application and the date of first marketing approval in the relevant jurisdiction for a product containing that substance is at least five years. Any extension is calculated as this time interval, reduced (but not below zero) by five years, with a maximum extension of five years.

71. This system of determining eligibility for, and the length of, extensions of patent term for pharmaceuticals is simple and relatively cheap to administer both for patent owners and for the relevant patent granting authorities.

72. However, eligibility for an extension and the length of any extension is not directly linked to the time actually taken by the relevant regulatory authority to process applications for marketing approval.

73. Consider the following examples, based on the Australian approach:

Example 1

An application for marketing approval for a pharmaceutical is filed **nine years** after the patent application covering the pharmaceutical is filed. Marketing approval is granted **ten** years after the patent application filing date, and **one** year after the application for marketing approval is filed.

The interval between filing of the patent application and the grant of marketing approval is **ten** years. As this interval is more than five years, the patent is eligible for extension, and the extension is **five** years, the maximum available.

Example 2

An application for marketing approval for a pharmaceutical is filed **five years** after the patent application covering the pharmaceutical is filed. Marketing approval is granted **ten** years after the patent application filing date, and **five** years after the application for marketing approval is filed.

The interval between filing of the patent application and the grant of marketing approval is **ten** years. As this interval is more than five years, the patent is eligible for extension, and the extension is **five** years, the maximum available.

74. Comparing Examples 1 and 2 above, the patents concerned would both be eligible for an extension of five years. However, in example 1, the marketing approval process took just 1 year, while in example 2 the marketing approval process took five years. That is, the length of the extension bears no relationship to the actual time taken to grant marketing approval.

75. Under this approach a patent would be eligible for extension if the gap between patent filing and marketing approval is more than five years. This will often be the case, as patent applications must be filed well before the patentee has gathered the information required for the marketing approval application.

76. The disadvantages of this option could be reduced by adopting time periods longer than the five year periods used by the EU and Australia. This would probably result in fewer, shorter extensions. However, as the length of any extension is not directly linked to the time taken by the regulatory authority to process application for marketing approval, the number and length of extensions will still likely be higher than for Option 2.

77. This option does not meet the objectives of minimising the impact of extensions of the patent term for pharmaceuticals.

Option 2 (preferred option): Adopt a definition based on the time taken to process the application for marketing approval

78. Under this approach, an “unreasonable curtailment” is deemed to occur if the time period between filing of the application for marketing approval, and the grant of approval is more than a specified period. This is the approach taken in Singapore.

79. Singapore has provided for a definition of “unreasonable curtailment” in Rule 51A(7) of the Singapore Patents Rules. The main features of this definition are:

i. Marketing approval was obtained after the date of grant of the patent

ii. The interval between the date the application for marketing approval was filed and the date that marketing approval was obtained, excluding any period attributable to an act or omission of the applicant for marketing approval, exceeds two years.

80. Any extension of term is calculated as the period by which the interval specified in subparagraph (ii) above exceeds two years, with a maximum extension of five years.

81. This approach links eligibility for extensions of term to the actual time taken by the regulatory authority to process an application for marketing approval. The exclusion of time periods attributable to acts or omissions of the applicant ensures that only delays attributable to the regulatory authority are taken into account. Delays caused by the applicant will not be taken into account (as the regulator is not responsible for these delays).

82. Compared to Option 1, Option 2 is likely to lead to fewer patents being eligible for extensions of term. Using the examples set out in Option 1, and using the Singapore definition of unreasonable curtailment, Example 1 would result in no extension, while Example 2 would result in an extension of no more than three years (and in practice less when periods attributable to the applicant are taken into account). This meets the objectives of minimising the impact of extensions of the patent term for pharmaceuticals.

83. As a result, Option 2 is likely to impose significantly lower costs on the economy than Option 1. However, Option 2 is likely to be more costly to implement. Medsafe would need to keep track of processing times of applications for marketing approval, and how much of this time was attributable to the applicant. Medsafe may also have to bear the costs of any disputes regarding its evaluation of the portion of the processing time not attributable to Medsafe. The costs of this could be recovered from the applicant by Medsafe. The costs are also likely to be substantially less than the additional impacts of Option 1.

Issue 2b: What should the specific time period(s) for "unreasonable curtailment" be?

84. TPP Art 18.48.2, does not define "unreasonable curtailment", so the obligation provides some flexibility for New Zealand to determine what should be deemed unreasonable curtailment in its domestic law. Whatever time period(s) are chosen, they must be reasonable for New Zealand, which has a small and geographically remote market and other unique market circumstances. This means that they must be long enough to allow Medsafe to efficiently conduct a high quality evaluation of applications to market new pharmaceuticals, taking account of the resources and expertise available to Medsafe. Where Medsafe has conducted its evaluation efficiently, there should be no "unreasonable curtailment" of the patent term, and therefore no need for a patent term extension.

85. The preferred option for the definition of "unreasonable curtailment" is based on the model used in the Singapore Patents Act. The Singapore definition provides that "unreasonable curtailment" is deemed to occur if the time period between the date of application for marketing approval and the date of grant of marketing approval is more than two years. Time periods attributable to the actions of the applicant are excluded from this period.

86. While the two year time period may be appropriate in Singapore, it may not be appropriate in New Zealand. For example, the same time period is applied to both small molecule and biologic pharmaceuticals. There is a strong case for applying different time periods for small molecule and biologic pharmaceuticals, with a longer period applying to biologics. The complexity of biologics may need to be longer as the complexity of these pharmaceuticals means that the marketing approval process may be longer.

87. Biologics are a new and emerging area of technology, as compared to small molecule pharmaceuticals, which are a “mature” and well understood technology. It is unclear how biologics will develop and change over time, and there will be a need to provide some flexibility for Medsafe to respond to future changes in technology.

88. Growth in biologics is set to continue at a rapid pace. In 2012, the 21 largest pharmaceutical companies had 429 biotech products in clinical development, of which 58 per cent were monoclonal antibody products. The total number of biologics in clinical trials has grown 155 per cent in 11 years, from 355 in 2001 to 907 in 2012.[1] By 2017, it is estimated that 30 per cent of the drugs in the pharmaceutical industry pipeline will be comprised of biologics.

89. Biologics are much more complex to evaluate, and Medsafe does not have the resources to provide a full evaluation. Instead, in many cases it will only be able to begin an evaluation once the biologic concerned has received approval in a foreign jurisdiction such as the EU. If that foreign approval has not been granted at the time of the New Zealand application, at least some of the processing time taken by the foreign jurisdiction will be added to the time taken by Medsafe to process the New Zealand application.

90. Other relevant factors in identifying an appropriate time period or periods for unreasonable curtailment are Medsafe’s current processing times, and the potential for them to increase.

91. Figures obtained from Medsafe indicate that, over the period from 1 July 2010 to 30 June 2015, a total of 93 applications for marketing approval of new medicines involving a new active ingredient were received. These new medicines include those that may be covered by patents, and include biologic as well as small molecule pharmaceuticals. Some of these applications were able to use an abbreviated evaluation which, by relying on approvals in other countries, is able to be done in a shorter timeframe using fewer resources.

92. Medsafe’s mean processing time for these applications was 242 calendar days with a maximum of 594 calendar days. These time periods are Medsafe processing times only, and exclude time periods not attributable to Medsafe.

93. The market circumstances under which Medsafe achieved these processing timeframes is predicted to change dramatically. There are expected to be more biologics coming to market and that they will represent an increasing proportion of new pharmaceuticals in development. Analysis of global trends confirms that the growth in biologics is set to continue at a rapid pace. The number of patents for biologics applied for every year has been growing at 25 percent annually since 1995.

1 http://csdd.tufts.edu/files/uploads/Summary_NovDecImpactRpt13_v2-1.pdf.

94. The total number of biologics in clinical trials has also grown 155 per cent in 11 years, from 355 in 2001 to 907 in 2012[2]. The success rate for these biologics has so far been over twice that of small-molecule products, with 13 percent of such products that enter the Phase I trial stage going on to launch. The success of the clinical pipeline is leading to an unprecedented number of new molecule launches with a steep increase predicted in future years.[3] By 2017, it is estimated that 30 per cent of the drugs in the pharmaceutical industry pipeline will be comprised of biologics.

95. Biologics are much more complex than small molecule pharmaceuticals. They take longer to evaluate and this requires more resources, In the future, it is clear that there will be more regulatory approval applications for biologics. It is also likely that more of these applications will require full evaluations, where Medsafe will not be able to rely on approvals granted elsewhere. In some cases, given limitations on expertise and capacity, Medsafe may even need to purchase independent advice to assist with evaluations. In these predicted circumstances, average processing times could rise significantly. This trend has already begun as currently the mean processing time for Medsafe to make a full evaluation of a "high risk medicine" is 348 calendar days, and for an "intermediate risk medicines" 406 calendar days[4].

96. New Zealand also needs to account for the fact that biologics are a new and emerging area of technology compared with small molecule pharmaceuticals which are a "mature" and well understood technology. We know that they will be more prevalent, but it is unclear how biologics will develop and change over time. There is therefore a need to provide some flexibility for Medsafe to respond to future changes in technology.

97. Two options have been considered:

    i. A period of two years for both small molecule pharmaceuticals and biologic pharmaceuticals (the same as in Singapore)

    ii. A period of three years for small molecule pharmaceuticals, and a period of five years for biologic pharmaceuticals.

Option 1: Two years for small molecule and biologic pharmaceuticals

98. Based on Medsafe performance figures, and taking into account possible future increases in processing times, two years is unlikely to be sufficient to allow Medsafe to carry out a high quality evaluation for most applications. This is particularly true for biologics, where processing times are likely to be well in excess of two years. Providing for a two year time period for all pharmaceuticals would be unreasonable, as it would likely result in patent term extensions even where Medsafe was operating as efficiently as its resources allow. This does not meet the objective of minimising the impact of patent term extensions.

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2 http://csdd.tufts.edu/files/uploads/Summary_NovDecImpactRpt13_v2-1.pdf

3 http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/rapid-growth-in-biopharma

4 See http://www.medsafe.govt.nz/regulatory/Performance2015.asp

Option 2 (preferred option): Three years for small molecules and five years for biologics

99. On the basis of predictions around the growth of biologics and accounting for current Medsafe performance figures, which are expected to increase over time and building in some flexibility, we consider that three years is a reasonable time for Medsafe to complete a high quality, efficient, full evaluation of a small molecule drug. Similarly, we consider that five years is a reasonable period to complete a high quality, efficient full evaluation of a biologic.

100. Adoption of these periods should ensure that patent term extensions will only be granted in cases where Medsafe has not conducted its evaluation in an efficient manner, thus minimising the impact of patent term extension.

Issue 3: Should there be limits on the maximum length of extension that can be granted?

101. TPP Article 18.48 is silent on the maximum length of any patent term extension obtained under this provision, although, of course, it must be greater than zero. However, Article 18.48.3 allows Parties to provide for conditions and limitations. Other countries which provide for patent term extension for pharmaceuticals provide for limits on the maximum extension. Australia, the EU and Singapore provide for a maximum five year extension. The United States limits extensions such that the effective patent life is no more than 14 years. The Canada – EU FTA allows the Parties to cap extensions at between 2 and 5 years. Canada is also a TPP Party.

102. Consistent with the objective of limiting the impact of any extensions granted, New Zealand should impose a cap on the length of term extensions.

103. Given that there is likely to be a significant net cost in providing for extensions, the maximum extension/effective patent life should be as low as possible consistent with our obligations under TPP Article 18.48. . Canada, a TPP partner, has, in its FTA with the EU, negotiated the ability to impose a cap of 2 years. We recommend that New Zealand adopt a cap of 2 years as well.

Issue 4: Should there be a limit on the number of extensions per patent and if so what limit should be imposed?

104. Providing a limit on the number of extensions is consistent with the approach of similar jurisdctions and with the objectives, particularly our objective to minimise impacts. Most patents claiming pharmaceutical substances claim large numbers of substances, although only a few may have any therapeutic value. It is therefore possible for one patent to contain claims to two or more distinct pharmaceutical substances, each of which would have to go through a separate approval process. In the absence of any provision to the contrary, this could mean a patent might get more than one extension, one for each substance.

105. There are two viable options: allow a patent to be extended more than once; or restrict the number of extensions to one per patent.

Option 1: Allow more than one extension per patent

106. Under this option, a patent could receive multiple extensions. In some cases this could lead to a patent receiving an aggregate extension extending well beyond the normal 20 year term and the cap discussed earlier in this RIS.

107. Such an outcome is inconsistent with the objective of minimising the impact of any extensions granted.

Option 2 (preferred option): Allow only one extension per patent

108. Under this option, once a patent relating to a pharmaceutical substance has received an extension to compensate for unreasonable curtailment of the patent term, no further extensions will be granted, even if the other criteria for extension are met.

109. Compared with Option 1, this will lead to shorter extensions. This is consistent with the obligation to offer compensation for unreasonable curtailment of effective patent life and the objective of minimising the impact of any extensions granted. Jurisdictions that provide for patent term extension for pharmaceuticals typically also provide that, once a patent has had its term extended, the same patent cannot be extended again.

Issue 5: Where there is more than one marketing approval, which should be considered when deciding eligibility for extension?

110. Medsafe's marketing approval process grants approval for products consisting of, or containing pharmaceutical substances, rather than the pharmaceutical substances themselves. It is therefore possible for several different products, containing the same patented pharmaceutical substance to receive separate marketing approvals at different times throughout the term of the patent for the substance concerned. The separate products will often not be patented, but some may be.

111. In this situation, there is a question of which of these marketing approvals should be considered when deciding whether a patent is eligible for extension on the ground of "unreasonable curtailment".

112. The options are:

- allow any of the marketing approvals to be used as a basis for determining whether a patent is eligible for extension
- allow only the first marketing approval of a product containing the pharmaceutical concerned to be used to determine whether a patent is eligible for extension.

113. Other options that were discounted because they were not viable were:

- allow only the shortest marketing approval to be used
- allow only the longest marketing approval to be used.

114. These options were not considered viable as they would effectively allow patent owners to wait until the end of the patent term before applying for approval (assuming that the other criteria for making an application are met). This could cause considerable uncertainty for third parties who may wish to make or deal in the pharmaceutical after the patent expires, such as generic pharmaceutical manufacturers and PHARMAC, as they might not know until just before a patent expires as to whether or not it will be extended. This is likely to delay entry onto the market of generic versions of patented pharmaceuticals as, for example, generic pharmaceutical manufacturers must begin preparations for marketing their generic version some time (often a year or more) before the patent expires.

Option 1: Allow any marketing approval to be used

115. Under this option, where two or more products containing the same patented pharmaceutical substance have received separate marketing approvals, the patentee may nominate any one of the approvals for the purpose of determining eligibility for term extension.

116. A problem with this option is that it would encourage patentees to choose the approval that would provide the longest term extension. This is not consistent with the objective of minimising the impact of any extensions granted.

117. Another problem is that, since product approvals could be granted throughout the life of the patent, the patentee might choose to nominate an approval that was granted shortly before the expiry of the normal 20 year term. This could cause uncertainty for manufacturers intending to place a generic version of a product containing the patented pharmaceutical on the market shortly after the patent expired. To do this, preparations to market the generic version must be in place before the patent expires. Generic manufacturers might be reluctant to make the investment required to place the generic version on the market if there is uncertainty over whether the relevant patent might be extended. This would likely result in delays in the generic version entering the market.

118. This uncertainty could also cause problems for PHARMAC in planning its future subsidisation decisions if it did not know when generics would be available in the market. It could also adversely affect local generic manufacturers who export their generic pharmaceuticals – they cannot manufacture and export a generic pharmaceutical until any New Zealand patent covering the pharmaceutical has expired. This is inconsistent with the objective of providing certainty for third parties.

Option 2 (preferred option): Allow only the first marketing approval to be used

119. Under this option, only the first marketing approval for a product containing the patented pharmaceutical substance could be used in determining eligibility for patent term extension. If this option is adopted, patentees would be required to apply for extension within a specified period (for example six months) of the grant of the first approval. If patentees did not file an application for extension within this time, the patent would no longer be eligible for extension, even if, subsequently, other products containing the same patented substance obtain marketing approval.

120. This would provide a fair degree of certainty as to when the relevant patent would expire, as, in most cases, the first marketing approval will be obtained many years prior to patent expiry. Third parties would know well in advance of the impact of any extension granted.

Issue 6: What limits should be imposed on the rights of the patent owner during the extended term?

121. A patent gives the patent owner the right to prevent others from commercially exploiting anything that is covered by the claims of the patent without the patent owner's permission. If a patent for a pharmaceutical substance is extended to compensate the patent owner for "unreasonable curtailment" of the patent term, the extension will have been obtained on the basis of a marketing approval for a particular pharmaceutical substance.

122. This raises the question as to what patent rights the patent owner should have during the extended patent term. The options are:

- the patent owner's rights during the extended term are the same as for the original term
- the patent owner's rights are limited to the particular pharmaceutical substance for which marketing approval was sought, and only when the substance is used for therapeutic purposes.

Option 1: Patent rights same as for original term

123. Under this option, patent owners would have the same rights to exploit anything covered by the patent during the extended term. However, the extension will have been obtained on the basis of delays in the marketing approval for one particular substance covered by the patent. Typically, a patent covering a pharmaceutical substance will also cover many other substances for which marketing approval was never sought, and which may have non-therapeutic uses. For those substances for which marketing approval was not sought, the patent owner would have been free to market them from the date of filing of the patent application if their use did not require any sort of regulatory approval. There would have been no "curtailment of the effective patent term" for these substances.

124. Extending the term for non-pharmaceutical substances for which the effective patent term was not curtailed by the marketing approval process would be going further than required by TPP. There is unlikely to be any net benefit to New Zealand from extending the patent term for non-pharmaceutical substances.

Option 2 (preferred option): Patent rights limited to the pharmaceutical substance for which marketing approval was sought

125. Under this option, if the term of a patent covering a pharmaceutical substance was extended, the patent rights would only cover the particular substance that was specified in the application for extension. These rights would only apply when the substance was used for therapeutic purposes. For example, if a substance had both a therapeutic use and some other non-therapeutic use, the patent rights during the extended term would not extend to the non-therapeutic use.

126. There would be no patent rights in anything else covered by the patent during the extended term.

127. This approach minimises the impact on New Zealand of the patent term extension provisions.

Issue 7: Should the Commissioner of Patents be permitted to enquire into information provided by Medsafe for extension applications?

128. Under the preferred option for the definition of "unreasonable curtailment" noted above, an "unreasonable curtailment" is deemed to occur if the time period between filing of the application for marketing approval and the grant of approval is more than a specified period. This time period excludes time periods not attributable to the actions of Medsafe, such as time taken by applicants to respond to requests for information from Medsafe.

129. Applicants for extension of patent term on the grounds of "unreasonable curtailment" of the effective patent term will be required to provide to the Commissioner of Patents a certificate from Medsafe setting out:

- the date on which the application for marketing approval was filed;
- the date on which marketing approval was granted; and
- the portion of the time interval between filing and approval which is not attributable to the actions of Medsafe.

130. This raises the question of whether the Commissioner of Patents should have the power to enquire into the accuracy or veracity of the certificate provided by Medsafe. There are two options:

- Allow the Commissioner of Patents to enquire into the accuracy of the certificate provided by Medsafe
- Provide explicitly that the Commissioner of Patents cannot make such an enquiry.

Option 1: Allow the Commissioner to enquire into the accuracy of Medsafe's certificate

131. Implementing this option would mean that an applicant for extension of patent term could dispute the accuracy or veracity of Medsafe's certificate in proceedings before the Commissioner of Patents. This might result in the Commissioner having to summons[5] Medsafe officials, and ask them to produce documents. It might also result in the Commissioner effectively deciding how Medsafe is to determine what time periods are "not attributable to the actions of Medsafe". This could impose significant costs on Medsafe.

132. Allowing the Commissioner to consider the accuracy of Medsafe's certificate would likely increase the number and complexity of any disputes between applicants for term extension and the Commissioner. It would also effectively mean that the Commissioner would be resolving what is effectively a dispute between Medsafe and the applicant for extension. Such disputes are more properly left for Medsafe to resolve through its own internal procedures.

Option 2 (preferred option) Provide that the Commissioner of Patents cannot enquire into the accuracy or otherwise of Medsafe's certificate

133. Under this option, the Patents Act would provide explicitly that the Commissioner must rely on the certificate provided by Medsafe and cannot enquire into the accuracy of any statements in the certificate.

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5 The Commissioner of Patents has the power to issues summonses under section 211 of the Patents Act 2013.

134. This provision would avoid the possibility of the Commissioner of Patents having to summons Medsafe officials or otherwise enquire into Medsafe's procedures. Compared with Option 1, it would reduce the cost and complexity of any disputes between applicants for patent term extension and the Commissioner. If applicants for extension wish to question the accuracy of Medsafe's certificate, this will be a matter between the applicant and Medsafe.

Issue 8: Should it be possible for third parties to oppose the grant of an extension?

135. If the term of a pharmaceutical patent is extended, this may affect the interests of third parties, in particular generic pharmaceutical manufacturers and PHARMAC. As a result, these third parties may wish to challenge the grant of the extension, its length, or both. There are two viable options:

- provide that decisions to extend patents can only be pursued through the High Court
- provide for an opposition process conducted before the Commissioner of Patents.

Option 1: Challenge only through the High Court

136. This option would not require amendment to the Patents Act 2013. Section 214 of the Act already provides for a right of appeal to the High Court for any person who is aggrieved by a decision of the Commissioner of Patents.

137. However, challenges through the High Court are costly, and this cost may deter some potential opponents from challenging decisions to extend a patent.

Option 2 (preferred option): Opposition process conducted before the Commissioner of Patents

138. Under this option, a third party who wished to challenge a determination by the Commissioner of Patents that a patent be extended can file a notice of opposition with the Commissioner of Patents. The opponent and the patent owner would then file evidence supporting their case with the Commissioner, who would then make a decision, after hearing the parties if they so wished. The Commissioner's decision could be appealed to the High Court.

139. This type of opposition procedure, which would be similar to the procedure for opposing the grant of a patent is likely to be cheaper and simpler than going to the High Court. Australia provides for this type of opposition procedure. The costs of administering the opposition system would be recovered from fees charged to the patent owner and opponent(s), so there would be no additional costs to government. Note that, in this opposition procedure, opponents will not be able to challenge the accuracy of the certificate provided by Medsafe consistent with the recommendation in issue 7 above.

Consultation

140. Fifteen submitters commented on the section regarding *Patent term extension for Medsafe delays* in the targeted consultation document.

141. Patent owners, while broadly supportive of most of the proposals, were not happy with the proposal that the definition of "unreasonable curtailment" be restricted to the Medsafe processing time. These submitters argued that time taken for clinical trials should also be taken into account, as in the US and Japan. They also argued that, because the relevant TPP provision does not mention the regulator, restricting the definition to Medsafe processing time is not consistent with TPP.

142. Many submitters agreed that the definition of “unreasonable curtailment” should apply different time periods for biologics and small molecule drugs, although most did not suggest any time periods. One submitter suggested that there should be several different time periods based on the type of application, for example, higher risk medicine and intermediate risk medicine.

143. A few submitters asked whether the Commissioner of Patents should be able to enquire into the accuracy of information supplied by Medsafe regarding the time taken by Medsafe to process a marketing approval application, and the portion of this time that was not attributable to Medsafe. This information would be used by the Commissioner to determine whether a patent is eligible for extension, and how long any extension should be.

Comment

144. Adding time taken for clinical trials into the definition of “unreasonable curtailment” is not required by TPP. If this time was included, it would likely mean that a significant number of patents would be eligible for extension. Clinical trials for pharmaceuticals sold in New Zealand will generally be conducted overseas, and outside the control of New Zealand companies. There would therefore be no value to New Zealand (and a considerable cost) in including the time taken up by clinical trials in the definition of “unreasonable curtailment”.

145. Regarding the ability of the Commissioner of Patents to enquire into the information provided by Medsafe, we consider it undesirable for the Commissioner to be able to do this. Allowing the Commissioner to consider the accuracy of the information provided by Medsafe would likely increase the number and complexity of any disputes between applicants for term extension and the Commissioner. It would also effectively mean that the Commissioner would be resolving what is effectively a dispute between Medsafe and the applicant for extension. Such disputes are more properly left for Medsafe to resolve through its own internal procedures.

146. To this end we recommend that the Patents Act explicitly provide that the Commissioner cannot enquire into the accuracy of information provided by Medsafe. In addition, we also recommend that the Patents Regulations prescribe detail of the information to be provided, to provide certainty, and reduce the likelihood of disputes between Medsafe and applicants for extension.

New powers for Customs relating to copyright and trade mark infringement

Background

147. Under the border protection measures (**BPM regime**) of the Copyright Act 1994 and the Trade Marks Act 2002, trade mark owners and copyright owners (**rights holders**) are able to file notices with Customs requesting the detention of imported goods, which includes goods in transit, that appear to infringe copyright or a registered trade mark (**infringing goods**).

148. Customs is able to use its resources to target and identify commercial imports of potentially infringing goods. If Customs suspects that goods within its control are infringing goods for which it has accepted a notice from a rights holder, it can detain the goods and serve a notice of determination on the importer or consignor (claimant) of the goods and the rights holder who filed the notice with Customs.

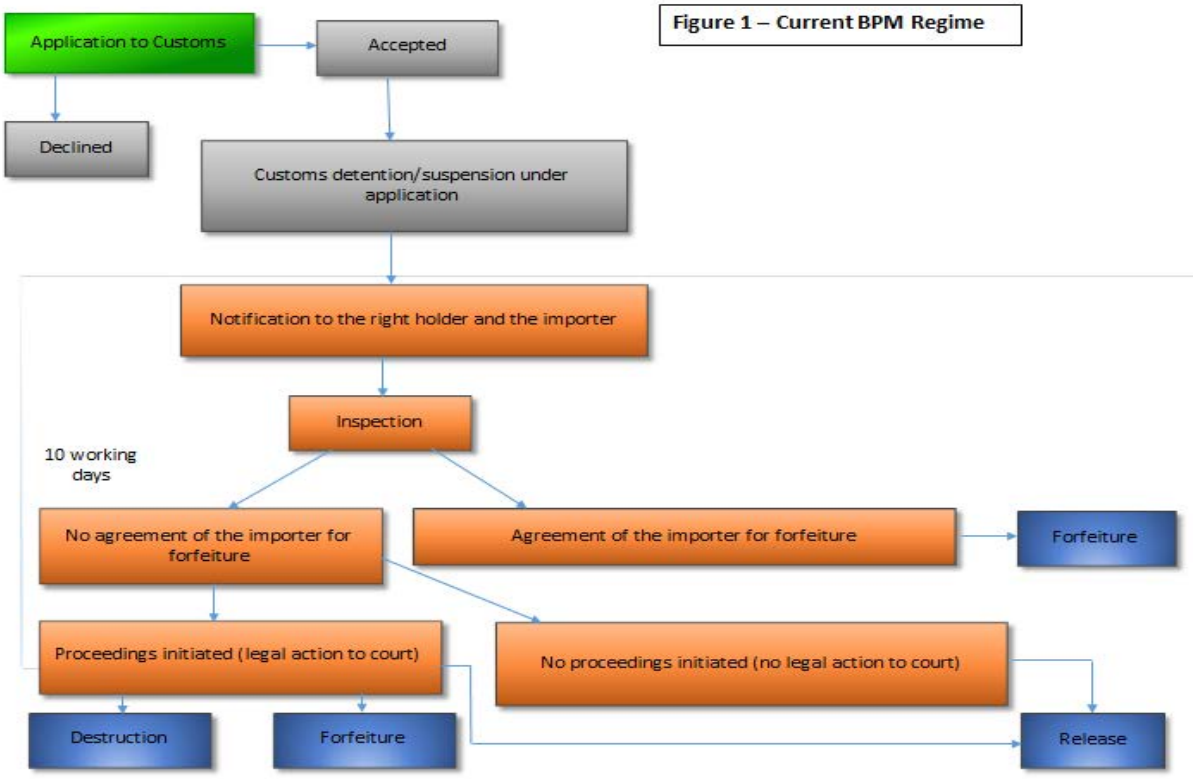
149. Importers who have had a notice of determination served on them have the option of voluntarily forfeiting the goods to the Crown. When this happens Customs arranges for goods to be destroyed. If an importer disputes a notice of determination, the rights holder has 10 working days (extendable to 20 by Customs) from the date the notice of determination was issued to either:

- persuade the importer to forfeit the goods; or
- obtain an order from the High Court declaring the goods to be infringing goods.

150. If the rights holder chooses to take no action against an importer who disputes a notice of determination, Customs will release the detained goods.

151. The following diagram illustrates the procedures of the BPM regime.

Figure 1 – Current BPM Regime



152. Customs currently has around 340 active notices from rights holders related to copyright works and registered trade marks.

Status quo and problem definition

153. Article 18.76(5) of TPP requires New Zealand to empower Customs to initiate the BPM regime ex officio (i.e. without first needing a formal complaint from a rights holder) with respect to goods under customs control that are:

- imported,
- in transit, or
- destined for export,

and that are suspected of being counterfeit trade mark goods or pirated copyright works.

154. As discussed above, Customs can only initiate border measures once it has received a notice from a rights holder. At present the Copyright Act and the Trade Marks Act do not apply to infringing goods being exported from New Zealand. In order to provide border protection measures ex officio in respect of exports, the border protections measures in the Copyright Act and Trade Marks Acts must first be extended to include exports. This RIS assumes that the border protection measures apply to exports of infringing goods.

155. There are a number of ways New Zealand could implement ex officio powers to comply with TPP.

Objectives

156. To meet the overarching objectives, changes to the BPM regime required by TPP should be implemented in a manner that:

- meets New Zealand's obligations under Article 18.76(5) of TPP
- ensures Customs is provided with relevant and necessary information from rights holders to assist in the identification of suspected infringing goods
- deters and reduces the volume and range of infringing goods entering and leaving the New Zealand
- raises rights holders' awareness of suspected infringing goods being imported and exported into New Zealand
- ensures that rights holders remain responsible for enforcement of their intellectual property rights.

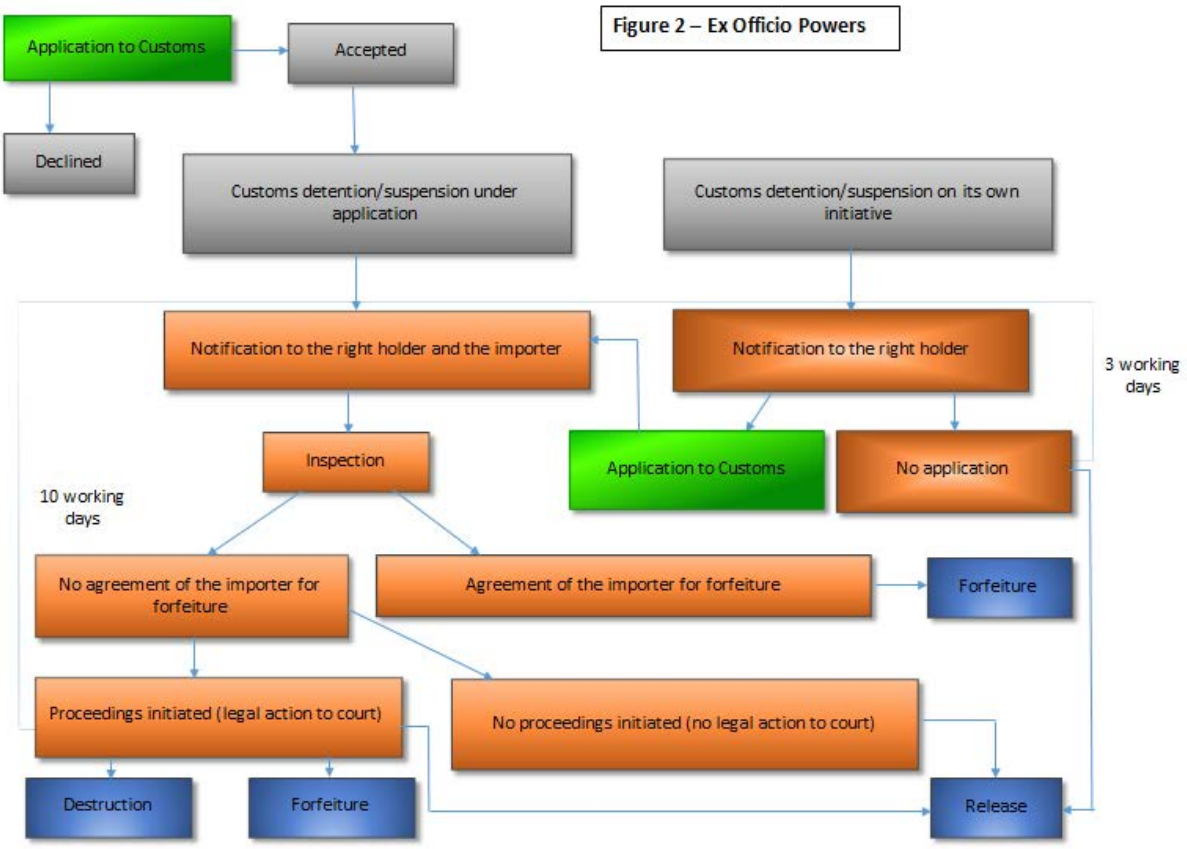
Options

Option 1 (preferred option): Provide a procedure for Customs to invite notices from rights holders in legislation (the EU approach)

157. This option is based on Article 4 of the European Union Customs Regulations. It would involve amending the Copyright Act and the Trade Marks Act to clarify that if a Customs officer has reasonable cause to believe that goods in the control of Customs may infringe copyright or a registered trade mark, Customs may suspend release of those goods for three working days and invite the rights holder (where known) to file a notice in accordance with either section 136 of the Copyright Act or sections 136 and 137 of the Trade Marks Act.

158. On receipt of an acceptable notice, Customs would apply the existing border protection measures regime as if the notice had been received and accepted before the goods came into the control of Customs.

159. The following figure illustrates the proposed procedure:



160. The requirement that a Customs officer must have "reasonable cause to believe" would provide Customs with a threshold operational discretion and clarify that Customs would not need to examine every shipment with the purpose of ascertaining whether an intellectual property right might be infringed by the goods in the shipment. This would help to minimise the burden and costs to Customs. The threshold would also assist to guard against and reassure claimants that Customs will not be stopping every shipment because there is a chance they might be infringing goods.

161. Providing a three working day detention period for suspected infringing goods by Customs and for rights holders to provide a notice to Customs would assist to minimise delays, and resulting costs, to importers (and claimants). The new powers would also help raise rights holders' awareness, who had not previously filed a notice with Customs, that people might be infringing their property rights. It would therefore provide rights holders with a better opportunity to take action to enforce their property rights before goods were offered for sale to the public.

162. While the three day initial detention period would be consistent with the EU approach, a longer detention period may be more convenient to rights holders. The longer the period, however, the greater the inconvenience and costs to Customs (to hold the goods) and the claimant of the goods in question arising from, for example, missing any delivery timelines.

163. Requiring a rights holder to file a notice would ensure that Customs has sufficient information to form an opinion as to whether or not the goods detained are likely to be infringing goods and, therefore, further detention of the goods under the border measures is warranted to protect the interests and rights of rights holders.

164. The notice requirement would also help minimise the costs to Customs. A key component of the notice for Customs is the indemnity rights holders must provide against Customs costs arising from the measures. Any costs to Customs from assisting rights holders under the border protection measures regime can be recovered from rights holders through the indemnity. Requiring the notice also ensures that the onus is clearly upon the rights holder to take action once alerted by Customs to the existence of potentially infringing goods.

Option 2: Provide for Customs to solicit notices from rights holder under an administrative policy (the Canadian approach)

165. Under this option either the Customs and Excise Act 1996 or the Copyright and Trade Marks Acts would be amended to clarify that Customs may detain goods when a Customs officer has reasonable cause to believe that goods in the control of Customs may be infringing goods.

166. The application of the BPM regime to any detained goods would still be dependent, however, on rights holders filing a notice with Customs. The circumstances under which Customs may solicit a notice from rights holders for goods detained under the ex officio powers and, therefore, for the BPM regime to be applied to those goods would be left for administrative policy to specify.

167. The cost and benefits arising under this option would be similar to those discussed under Option 1. Under this option, however, Customs would have more flexibility to develop, implement and review administrative policies around the procedure of soliciting a notice from a rights holder, especially around how long the rights holder would be given to file a notice before any detained goods under the ex officio powers would be released to the claimant.

168. While it may create some additional uncertainty for importers or claimants, the impact would be similar to Option 1 provided Customs published its administrative policies regarding the detention of suspected infringing goods under its ex officio powers.

Option 3: Customs apply the border measures without a notice from rights holder

169. Under this option the Copyright Act and the Trade Marks Act would be amended to provide Customs the discretion to apply the border measures where a notice had not been previously accepted from a rights holder where a Customs officer had reasonable cause to believe infringing goods had come into the control of Customs and the rights holder is known to Customs. Customs would give a notice of determination on the claimant and the rights holder.

170. Claimants who have had a notice of determination served on them have the option of voluntarily forfeiting the goods to the Crown. When this happens Customs arranges for the destruction of the goods. If the claimant disputes a notice of determination, the rights holder has 10 working days from the issue date of the notice of determination to either persuade the claimant to forfeit the goods or initiate court action to declare the goods to be infringing goods.

171. This option is not preferred because it would require Customs to determine whether or not goods might infringe an intellectual property right without the benefit of expert or technical information from rights holders. This in turn increases the risk that the border protection measures regime would be applied by Customs to non-infringing goods, increasing the costs to both Customs and claimants.

172. Customs would be able to reasonably identify the trade mark owner whose registered trade mark rights may be infringed by the detained goods from the online register of trade marks maintained by IPONZ. The absence of a comparable register of copyright, however, would make the task of identifying the relevant copyright owner difficult. This could lead to a situation where the principal beneficiaries would be trade mark owners because they are more readily identifiable.

173. This option would also reduce the incentives for rights holders to take an active role enforcing their intellectual property rights through filing a notice. Rights holders might increasingly rely on ex officio powers as a substitute for filing a notice. It could also increase the risk that infringing goods would not be detained by Customs, because Customs officers would not be in possession of sufficient information to identify suspected infringing goods.

174. Furthermore, without the notice indemnifying Customs of its costs, Customs would not be able to recover its costs from rights holders. This could act as a disincentive to Customs exercising its ex officio powers.

Consultation

175. Nine submissions received in response to the targeted consultation document commented on the implementation of ex officio powers for Customs under the border protection measures.

176. There was broad support for adopting Option 1. However, submitters were divided on whether the three day period for a rights holder to file their notice was appropriate. Some submitters preferred a five day period for the convenience of rights holders, others considered the period should be shorter than three days. Those submitters favouring a five day detention period did not address the impact the longer detention period would have on importers and exporters. Officials do not recommend extending the detention period because of the negative impact a longer period would have on importers and exporters.

Protection for technological protection measures

Background

177. Technological protection measures (**TPMs**) are digital locks copyright owners use to stop their material from being accessed or copied. TPMs facilitate the development of online business models for the delivery of copyright works to consumers.

178. There are two main types of TPMs:

- **TPMs that control access to copyright works:** TPMs that prevent unauthorised persons from being able to access content in order to be able to read, listen to, or watch material — for example, a payment control system such as a paywall, and
- **TPMs that protect against copyright infringement:** TPMs that allow a person to access the material to read, listen or watch, but prevent the person from making a copy of the material — for example, encryption measures stored on a DVD which prevent you from copying the movie.

179. It is possible to circumvent a TPM intended to control access to a copyright work, or a TPM intended to protect against copyright infringement, without then using the protected work in a way that infringes copyright. Simply accessing a work which is protected by copyright does not necessarily infringe copyright in that work, unless that accessing involves making an unauthorised copy of the work or constitutes another infringing act.

180. It is also possible to circumvent a TPM intended to protect against copyright infringement without infringing copyright (for example, to make a copy of a work for a use permitted under the Copyright Act).

181. Accordingly, TPMs that control access to copyright works may prevent activities that do not infringe copyright.

TPM protections under the Copyright Act 1994

182. TPMs that are protected under the Copyright Act are currently limited to TPMs that protect against copyright infringement. A combination of prohibitions and exceptions are provided for in relation to enabling circumvention of these TPMs.

183. The Copyright Act prohibits:

- Making, importing, or dealing in TPM circumvention devices with knowledge or reason to believe that the device will be used, or is likely to be used, to infringe copyright in a work protected by a TPM.
- Providing a service intended to circumvent a TPM with knowledge or reason to believe that the service will, or is likely to, be used to infringe copyright in a TPM work protected by a TPM.
- Publishing information enabling or assisting another person to circumvent a TPM if that information is intended for use in infringing copyright in a TPM work.[6]

[6] Section 226A of the Copyright Act

184. Unless an exception is provided for, the issuer of a work protected by a TPM (the copyright owner or the licensee) has the right to take civil proceedings against a person who carries out any of the above conduct. Civil remedies include forfeiting the profits made as a result of the prohibited conduct and compensation for the damage caused.

185. People engaging in the above conduct in the course of business may also be liable to criminal penalties (a fine not exceeding $150,000 or a term of imprisonment not exceeding five years, or both).

186. Alongside the current prohibition against providing a device, service or information to enable circumvention of a TPM, the Copyright Act provides exceptions for specific permitted acts (such as fair dealing with a work for the purposes of criticism or review) and for encryption research. This combination of prohibitions and exceptions balances the rights of copyright owners to protect copyright works with the ability of users to use content for legitimate purposes.

187. The Copyright Act does not explicitly prohibit a person circumventing a TPM. However, if in circumventing a TPM a person is infringing copyright (e.g. making an unauthorised copy of the work), they may separately be liable for copyright infringement.[7]

188. The Copyright Act only prohibits providing services or devices to enable circumvention of TPMs if those TPMs protect against copyright infringement and the provider knows (or has reason to believe) the service or device would likely be used to infringe copyright. Services and devices can currently be provided for circumventing TPMs that solely control access to a copyright work.

Status quo and problem definition

189. Article 18.68 of TPP requires New Zealand to provide for civil remedies against any person who:

- circumvents a TPM that controls access to a copyright work, or
- provides devices or services that enable the circumvention of a TPM that:
    - protects against infringement of copyright or of performers' rights in sound recordings, or
    - controls access to a copyright work.

190. Criminal penalties will also apply if a person is found to have engaged wilfully and for commercial purposes or advantage.

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7 Note that the Crimes Act 1961 contains criminal prohibitions against crimes involving computers (sections 249 to 252), including accessing a computer system for a dishonest purpose. The Crimes Act provisions apply irrespective of whether the material protected by the TPM is protected by copyright. There may be circumstances where acts involving the circumvention of a TPM relate to criminal activities regulated under the Crimes Act, but this kind of activity is beyond the scope of this analysis.

191. However, the obligation provides some flexibility for New Zealand to provide exceptions and limitations to these prohibitions (discussed below). Exceptions and limitations can be provided for both TPM prohibitions (both those relating to the act of circumvention, and enabling circumvention) provided the following conditions are met:

    a. the exception or limitation enables a use that does not infringe copyright or performers' rights in sound recordings;

    b. the prohibition has an actual or likely negative impact on a use that does not infringe copyright or performers' rights in sound recordings

    c. the limitations and exceptions do not undermine the adequacy of New Zealand's legal system for the protection of TPMs, or the effectiveness of legal remedies against the circumvention of such measures; and

    d. any limitations or exceptions in relation to enabling circumvention enable the legitimate use of the exception only by its intended beneficiaries.

192. Non-profit libraries, museums, archives, educational institutions, and public non-commercial broadcasters can also be exempted from criminal liability, and from civil liability if the relevant act was done in good faith without knowing the conduct was prohibited.

Implications for New Zealand

193. Implementing these obligations without any exceptions and limitations, would result in a significant shift from the status quo, disrupting the balance between protection and access currently provided for in the Copyright Act. Without exceptions, the new prohibitions will apply regardless of whether the TPM circumvention amounted to copyright infringement or a breach of a performer's rights in a sound recording.

194. New Zealand is not a notable exporter of TPM works or exporter of online services providing access to copyright works. We are, however, a significant net-importer of works protected by TPMs. If the enhanced TPMs protections prevent use of copyright works or public domain content in a way that is currently lawful, users of copyright works may face additional costs in obtaining permission to get around the TPM to maintain their current use.

195. In determining what exceptions and limitations should be provided under the Copyright Act, this analysis examines options for the scope and type of exceptions that might be provided for each prohibition:

- **Issue 1:** providing any exceptions and limitations to the prohibition on circumventing TPMs which control access to copyright works.
- **Issue 2:** providing any exceptions and limitations to the prohibition on providing devices and services to circumvent TPMs.

Objectives

196. To meet the overarching objectives, the new TPM prohibitions required by TPP should be implemented in a manner that:

- meets New Zealand's obligations under Article 18.68 of TPP
- strikes an appropriate balance between the rights of copyright owners and performers to protect their copyright works and performances and the ability of users to make use of content for legitimate purposes.

Options and impact analysis

Issue 1: Providing any exceptions and limitations to the prohibition on circumventing TPMs that control access to copyright works

197. In determining whether New Zealand should provide any exceptions and limitations to the prohibition required by TPP against circumventing TPMs that control access to copyright works, this RIS examines the following options:

- **Option 1:** Provide no exceptions or limitations to the new prohibitions relating to TPMs that control access to copyright works.
- **Option 2:** Amend the Copyright Act to provide the exceptions and limitations referenced in TPP relating to non-profit entities.
- **Option 3 (preferred option):** Amend the Copyright Act as under Option 2 and provide for further exceptions and limitations appropriate to New Zealand's domestic circumstances.

Option 1: Provide no exceptions or limitations to the new prohibitions relating to TPMs that control access to copyright works

198. Under this option, TPP prohibitions would be adopted without exceptions — there would be a blanket prohibition on the circumvention of TPMs which control access to copyright works, and civil and criminal remedies would apply.[8] No exceptions or limitations would be provided for.

Option 2: Amend the Copyright Act to provide the additional exceptions and limitations referenced in TPP relating to non-profit entities

199. Article 18.68 allows non-profit libraries, museums, archives, educational institutions, or public non-commercial broadcasters (**non-profit entities**) to be exempt from criminal liability, and from civil liability if the relevant act was done in good faith without knowing the conduct was prohibited.

[8] Criminal remedies will not apply to individuals accessing for personal use.

200. Under this option non-profit entities would be:

a. Exempt from criminal liability when circumventing a TPM that controls access to copyright works in respect of anything done in performing their functions.

b. Exempt from civil liability when circumventing a TPM that controls access to copyright works:

i. in respect of anything done in performing their functions

ii. provided that the relevant act was done in good faith, without knowledge that the conduct was prohibited.

Option 3 (preferred option): Amend the Copyright Act as under Option 2 and provide for further exceptions and limitations appropriate to New Zealand's domestic circumstances

201. Under this option, in addition to the exceptions outlined under Option 2, the Copyright Act would provide further exceptions and limitations appropriate to New Zealand's domestic circumstances in cases where copyright and performers' rights in sound recordings are not infringed. The exceptions and limitations include existing "permitted acts" under Part 3 of the Copyright Act, the exceptions and limitations that are being included in relation to the new regime relating to property rights for performers, as well as exceptions for activities which are inherently non-infringing.

202. Part 3 permitted acts include:

- "Fair dealing" for the purpose of criticism, review, news reporting, research, or private study.
- Various educational purposes — for example, performing or showing work in the course of activities of an educational establishment.
- Time shifting of TV programmes for viewing at a later time.
- Back up of computer programmes.
- Braille copies of literary or dramatic works.

203. The Part 3 permitted acts will apply to the new regime relating to performers property rights.

204. Alongside the permitted acts, this option would establish further exceptions as set out in Table 1.

Table 1

Proposed exceptions	Examples of when the exception would apply
To allow access to computer programmes that are embodied in a machine or device and restrict the use of goods (other than the work) or services in relation to the machine or device.	For example: • enabling use of a generic (rather than manufacturer-approved) printer cartridges; • "unlocking" a device to enable connection to an alternative wireless network (e.g. mobile or wifi) provided there is authorisation to do so; • "jailbreaking" a legitimately purchased device to install legitimately purchased, non-infringing, apps or other software; and • to allow for the diagnosis, repair, or lawful modification of a vehicle.

To enable circumvention of a TPM to the extent that it controls geographic market segmentation by preventing the playback of legitimate physical copies of a copyright work in New Zealand.	For example, to view or use legitimate, non-infringing copies of physical works, such as DVDs for films or computer games, where regional zone protection is included.
To enable interoperability of an independently created computer programme with the original programme or other programme.	For example to allow for the playback of legitimate non-infringing purchased movies or sound recordings on devices running software other than that supplied by the distributor of the movie or sound file.
To enable encryption research.	To allow study or employment in the field of encryption technology for the purpose of identifying and analysing flaws and vulnerabilities of encryption technology.
To enable good-faith security research.	To allow for the good-faith testing, investigating, or correcting the security of a computer, computer system, or computer network
To enable online privacy.	For example, by allowing the circumvention of a TPM to remove unwanted programmes on a device that are collecting personal information.
To enable law enforcement and national security.	To allow anything lawfully done for the purposes of law enforcement, national security, or performing a statutory function, power or duty.
To enable the use of legitimate computer programmes for which outside server support has been discontinued.	For example, where a developer decommissions support for a legitimately purchased game that is no longer popular, rendering it entirely unplayable.
For any other purpose that does not infringe copyright or performers' right sin sound recordings.	To enable any other use that does not infringe copyright or performers' rights in sound recordings where there is an actual or likely negative impact on that non-infringing use. It is proposed that, subject to a consultation process, the Minister of Commerce and Consumer Affairs should have the ability to recommend regulations that narrow this exception – for example, by excluding specific activities.

Analysis

205. We are of the view that all of the options outlined for Issue 1 would enable us to meet our obligations under TPP in terms of providing prohibitions against circumvention of TPMs that control access to copyright works.

206. However, proceeding with Option 1 would significantly weaken the ability of users to access content for legitimate purposes. Providing prohibitions without any exceptions would disrupt the balance between the rights of copyright owners and performers to protect their works and performances and the ability of users to make use of content for legitimate purposes. For this reason, we do not recommend proceeding with Option 1.

207. We consider that non-profit entities play an important role in enabling the consumption of copyright material. While Option 2 would protect the legitimate activities of non-profit entities, we are of the view that this option would not go far enough to protect the ability of users to access content for legitimate purposes.

208. As well as enabling us to meet our obligations under TPP, Option 3 would:

- define the specific circumstances where the benefits of providing access are clearly justified and where circumvention would be permitted
- protect the legitimate activities of non-profit entities.

209. By doing so, Option 3 would appropriately balance the rights of copyright owners and performers to protect their works and performances and the ability of users to make use of content for legitimate purposes. For these reasons, we recommend proceeding with Option 3.

Consultation

210. 32 submitters commented on the TPMs section of the targeted consultation document (which covers both TPM issues canvassed in this RIS) and the proposals were also discussed at workshops.

211. The targeted consultation document did not explicitly reference the need to prohibit the provision of devices or services that enable the circumvention of a TPM that protects against infringement of performers' rights in sound recordings. However, following further consideration, officials consider that it is necessary to clarify that this is captured by the TPMs protections, and that the above exceptions and limitations should apply to these provisions as well. While submitters did not have the opportunity to comment on this specific aspect, this only represents a change to the scope of the TPMs protections and exceptions, not a departure from the proposed implementation approach.

212. Many submitters (including museums, libraries, educational institutions and user groups and individuals), were supportive of the proposed exceptions, noting their importance to promoting innovation and enabling the legitimate use of copyright works. Some rights holders had concerns about certain aspects of the exceptions framework (discussed below) and three rights holders submitted that the entire exceptions framework was too broad.

213. The majority of submitters did not provide any specific comments on the proposed exceptions for non-profit entities. However, libraries, archives, museums and galleries strongly supported these proposed exemptions and stressed the importance of the exceptions in performing their functions.

214. Submitters were supportive of providing exceptions for permitted acts under Part 3 of the Copyright Act, with a number of rights holders submitting that the current exceptions framework (which is confined to Part 3 and a few specific exceptions) works well and should be retained. One submitter did not consider that the inclusion of all Part 3 permitted acts was allowed for under TPP. Some submitters noted that without these TPM exceptions, the copyright exceptions under Part 3 would not be workable.

215. Submitters were also generally supportive of the specific exceptions for situations where copyright was not infringed. While a few submitters questioned the compliance of the proposed exceptions generally, the Law Society submitted that, subject to how the exceptions were drafted, these all could comply with TPP.

216. Several submitters recommended alternative wording or broadening of some of the exceptions. Two exceptions have been broadened in terms of applicable subject matter as a result:

- the geographic market segmentation exception to apply to all physical goods (rather than just films, sounds recordings, or computer games)
- the exception relating to video games for which outside server support has been discontinued be broadened to cover all software

217. We expect that a number of other comments are likely to be addressed by the framing of the exceptions in the TPP Implementation Bill.

218. However, some of the proposals were more complex and will require further consideration to consider potential impacts and reduce the risk of any unintended consequences. It is also likely that further proposals will be made once the TPP Implementation Bill is introduced and further detail on how the exceptions will be expressed is publicly available. Officials will further consider the matters raised by submitters in preparation for the select committee process.

219. There was a difference of views around the proposed exception "for any other purpose that does not infringe copyright". Rights holders and industry groups argued that this is too broad, does not comply with TPP obligations, might undermine investment in new content and content delivery services and will create uncertainty. One submitter also considered it would undermine the exclusive rights of copyright owners and would undermine the Crimes Act provisions. However we note that there is currently no prohibition at all against the act of circumvention and the proposed exceptions framework only applies to non-infringing activities (so will not undermine rights of copyright owners).

220. On the other hand, user groups, educational institutions, libraries, individuals, and the Institute of Patent Attorneys all strongly supported the inclusion of this exception. Reasons provided included ensuring the regime is flexible enough to allow for the development of innovative non-infringing uses, maintaining balance, ensuring that TPMs do not restrain user behaviour and uses of technology and that liability for circumventing a TPM should follow only where there is a copyright infringing act or purpose.

221. Many submitters were confused regarding the purpose of the regulation making power and expressed concern that it may be misused. We expect that these submissions are likely to be addressed by the framing of the power in the TPP Implementation Bill, which provides further detail, including specific criteria to take into consideration in exercising the power and a consultation process.

222. Some submitters proposed additional exceptions, however, many of these related to broader copyright matters (for example, adding exceptions for personal use, amending provisions relating to preservation of copyright works, and extending the exceptions relating to persons with a print disability to cover a wider range of activities). There were calls for museums and galleries to be captured under the current definition of archives, and a number of submitters advocated for the adoption of fair use. Officials consider these matters to be better considered as part of a broader review of New Zealand's copyright regime.

Issue 2: Providing any exceptions and limitations to the prohibition on providing devices and services to circumvent TPMs

223. In determining whether New Zealand should provide any exceptions and limitations to the prohibition required by TPP against providing devices and services to circumvent TPMs, this RIS examines the following options:

- **Option 1:** Provide no exceptions or limitations to the new prohibitions relating to providing devices and services that enable circumvention of TPMs that control access to copyright works.
- **Option 2:** Amend the Copyright Act to provide the additional exceptions and limitations referenced in TPP relating to non-profit entities.
- **Option 3 (preferred option):** Amend the Copyright Act as under Option 2 and provide for further exceptions and limitations appropriate to New Zealand's domestic circumstances.

Option 1: Provide no exceptions or limitations to the new prohibitions relating to providing devices and services that enable circumvention of TPMs that control access to copyright works

224. Under this option, TPP prohibitions would be adopted without any exceptions — there would be a blanket prohibition on providing devices and services that enable the circumvention of TPMs that control access to copyright works.

225. The current exceptions relating to the provision of devices and services that enable circumvention of a TPM that protects against copyright infringement (see paragraph 183 above) would remain in effect.

Option 2: Amend the Copyright Act to provide the additional exceptions and limitations referenced in TPP relating to non-profit entities

226. As noted above, Article 18.68 allows non-profit entities to be exempt from criminal liability, and from civil liability if the relevant act was done in good faith without knowing the conduct was prohibited.

227. Under this option, in addition to the exception in option 1, non-profit entities would be:

- exempt from criminal liability when providing a device or service to enable circumvention of a TPM in respect of anything done in performing their functions.
- exempt from civil liability when providing a device or service to enable circumvention of a TPM:
  i. in respect of anything done in performing their functions, and
  ii. provided that the relevant act was done in good faith, without knowledge that the conduct was prohibited.

Option 3 (preferred option): Amend the Copyright Act to provide for further exceptions and limitations appropriate to New Zealand's domestic circumstances

228. Under Option 3, in addition to the exceptions outlined under Options 1 and 2, the Copyright Act would be amended to provide further exceptions and limitations appropriate to New Zealand's domestic circumstances in cases where copyright is not infringed. The exceptions and limitations would be the same as those provided for in relation to Issue 1, Option 3.

229. In other words, Option 3 would allow any person to provide a device or service enabling circumvention of a TPM to exercise a permitted act under Part 3 of the Copyright Act, or permitted act to be included in relation to the new regime relating to property rights for performers, or to enable any of the non-infringing uses specified in table 1 above[9].

230. An exception will not apply if the provider knows or has reason to believe that the device or service will, or is likely to, be used for infringing uses.

Analysis

231. We are of the view that all of the options outlined for Issue 2 would enable us to meet our obligations under TPP in terms of providing prohibitions in relation to assisting people to circumvent TPMs.

232. Option 1 would significantly restrict the ability of users of a work who do not have the skills or tools to circumvent a TPM for a legitimate purpose. Proceeding with Option 1 would fail to strike an appropriate balance between the rights of copyright owners to protect works protected by copyright and the ability of users to use content for legitimate purposes. For this reason, we do not recommend proceeding with Option 1.

233. We consider that non-profit entities play an important role in enabling the consumption of copyright material. While Option 2 would protect the legitimate activities of non-profit entities, we are of the view that this option would not go far enough to protect the ability of users to be assisted to access content for legitimate purposes.

234. As well as enabling us to meet our obligations under TPP, Option 3 would:

- define the specific circumstances where the benefits of providing access are clearly justified and where assistance to allow circumvention would be permitted
- ensure that users of a work who do not have the skills or tools to circumvent a TPM for a legitimate purpose are able to be assisted to do so
- protect the legitimate activities of non-profit entities.

235. By doing so, Option 3 would appropriately balance the rights of copyright owners and performers to protect their copyright works and performances and the ability of users to make use of content for legitimate purposes. For these reasons, we recommend proceeding with Option 3.

Consultation

236. General comments on the TPM exceptions are contained in the consultation section on issue one above. Submitters were divided on whether the exceptions should also apply to the prohibitions on the supply of circumvention devices and services.

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9 This exception would capture the current exceptions relating to Part 3 and encryption research, and remove the need for current exception allowing a qualified person to circumvent a TPM that protects against copyright infringement to exercise a Part 3 permitted act on behalf of another person (as any person would now be able to provide a TPM circumvention device or service to another person to enable the exercise of a permitted act).

237. The majority of submitters supported the exceptions applying to both prohibitions, citing the importance of maintaining balance and ensuring that TPM rules benefit all users, not just the technically able. One submitter noted that "allowing supply of circumvention tools or services for permitted purposes does not undermine copyright enforcement because general supply for any purpose, or unqualified supply which would be likely to undermine the rights of copyright owners would still be actionable."

238. Rights holders argued that this would amount to permitting trafficking in TPM devices and services which would in turn increase piracy rates. Some also submitted that they do not consider the proposed approach would then meet the requirement that exceptions do not undermine the adequacy of New Zealand's legal system for the protection of TPMs. However we note that providers of TPM circumvention devices and services would still be liable for a breach of the TPMs prohibitions, and potentially copyright infringement, if they are providing devices and services for non-permitted uses. We also consider that it is important that users of a work that do not have the skills or tools are not prevented from being able to exercise a TPM exception.

New Performers' rights

Background

239. TPP requires New Zealand to join the World Intellectual Property Organisation Performers and Phonograms Treaty (WPPT), which provides for certain rights to be given to performers (for example, someone who sings a song) and producers of phonograms ("**sound recordings**").

240. The WPPT requires that performers are given a set of rights in relation to their live aural performances and performances fixed in sound recordings. These include:

- the right to be identified as the performer and the right to object to any derogatory treatment of such performances (**moral rights**)
- the right to authorise live aural communication (e.g. live broadcasting of the performance) and the right to authorise the making of sound recordings from their performances (**non-property rights**)
- the right to authorise the exploitation (including reproduction and distribution) of any such recording (**property rights**).

241. The WPPT also requires that producers of sound recordings are given the right to authorise the exploitation (including reproduction and distribution) of those sound recordings.

242. In effect, the WPPT requires performers of aural performances be provided with a set of rights similar to those already provided to authors of copyright works.

243. Articles 5 and 16 permit parties to the WPPT to provide exceptions and limitations to the rights given to performers and producers under their domestic law.

244. Neither the WPPT nor TPP require that performers are given rights in relation to the visual aspect of their performance, such as the recording of a performance on film. These latter issues are dealt with under a separate international treaty, the *Beijing Treaty on Audiovisual Performances*. TPP does not require New Zealand to join this treaty and no decision has been taken on whether New Zealand should join it.

Existing authors' (producers') rights

245. "Authors" include producers of sound recordings, but not performers. As authors of copyright works, producers have both moral rights and property rights in relation to their sound recordings — including the right to be identified as the author of their sound recordings and the right to object to derogatory treatment of their sound recordings.

246. The Copyright Act includes certain exceptions and limitations in respect of the rights given to producers. For example:

- "fair dealing" in respect of a work for the purposes of news reporting is not an infringement of a producer's property rights
- any act that would not infringe copyright in the work will not infringe a producer's right to be identified
- communication of a work for the purposes of news reporting will not infringe a producer's right to object to derogatory treatment.

247. The Copyright Act already gives producers of sound recordings the rights required by WPPT.

Existing performers' rights

248. Part 9 of the Copyright Act provides performers with certain rights in relation to their performances. Performers are given the non-property right to consent to the recording of their performances or the communication of their performances (e.g. via broadcast). In this context, a recording means a sound recording or film made directly from the performance (or from a broadcast that includes the performance). Any recording made without the performer's consent is referred to as an **illicit recording**.

249. Where the performer has consented to the recording or communication of their performance, only the person communicating or recording the performance (i.e. the "author" / producer) has rights to control the exploitation of the communication or recording. However, where a recording is an illicit recording, any exploitation of that recording will continue to infringe the performers' rights.

250. Included in the Copyright Act are a number of exceptions and limitations to performers' rights. These exceptions and limitations seek to ensure that a person can continue to perform any act which does not amount to an infringement of copyright in the recording (such as those set out under Part 3 of the Copyright Act).

251. Performers are not currently given any moral rights in respect of their performances.

Status quo and problem definition

252. Article 18.7(2)(f) of TPP requires New Zealand to join the WPPT.

253. In order to join the WPPT, the Copyright Act needs to provide:

- moral rights for performers to be identified and to object to the derogatory treatment of their live aural performances (Article 5)
- property rights to performers to authorise the reproduction, distribution and rental of sound recordings made from their performances (Articles 7, 8 and 9).

254. The WPPT allows parties to put in place appropriate exceptions and limitations to these rights (Articles 5 and 16).

Performers' moral rights

255. The WPPT requires that performers are given the right to be identified as the performer and to object to derogatory treatment only in relation to their live aural performances. There is no requirement to provide a parallel right for the visual aspects of the same performance.

256. However, the majority of live performances are made up of both audio and visual aspects. The visual aspects of a performance can be just as important, and in some cases more important, than the audio aspects.

257. Additionally, the non-property rights given to performers under the current Copyright Act do not distinguish between the audio and visual aspects of a performance.

258. This paper analyses options for implementing the new moral and property rights for performers as required by the WPPT.

Exceptions and limitations

259. As noted above, the obligation provides some flexibility for New Zealand to implement appropriate exceptions and limitations to performers' rights. The WPPT allows for exceptions and limitations to be provided under domestic law provided that they are limited to special cases which do not conflict with the normal exploitation of a performance or sound recording and do not unreasonably prejudice the interests of the performer.

260. While the Copyright Act provides producers with moral rights and property rights in relation to sound recordings and communication of works to the public, it also permits certain acts to be undertaken without infringing producers' rights under the Act. The exceptions and limitations to producers' rights enable the interests of the producer to be balanced against the wider interests of the public to be able to use those works.

261. Introducing new moral rights and property rights for performers without exceptions could undermine the current balance between authors' (producers') rights and wider interests of the public to be able to use the copyright works. This paper analyses options relating to the scope of any exceptions and limitations to the new performers' rights.

Objectives

262. To meet the overarching objectives, the new performers' rights required by TPP should be implemented in a manner that:

- meets New Zealand's obligations under Article 18.7.2(f) of TPP
- keeps amendments to the minimum necessary, where reasonable and practical to do so, to comply with all WPPT obligations
- appropriately balances:
    i. the rights of performers and authors (producers) in relation to the live communication of, and recordings made from, performances, and
    ii. the interests of users and the public to use and receive such communications and recordings
- minimises any regulatory and business compliances costs for performers, authors, users and consumers.

Options and impact analysis

Issue 1: Application of performers' moral rights

Option 1 (preferred option): Moral rights apply to both the audio and visual aspects in respect of a performance, and to the live communication of a performance

263. Under this option, a performer would have the right to be identified whenever they produce or put on a performance, and for any live communication of that performance, irrespective of the medium used to communicate their performance (e.g. by radio, television or streaming over the internet).[10] Similarly, a performer would have the right to object to derogatory treatment of their performance for any live communication of that performance, irrespective of the medium used.

Advantages

264. Most performances comprise an audio aspect and visual aspect, and the two aspects are intended to be received simultaneously by the audience. For some performances, the visual aspect is as important as the audio aspect. Under this option, performers would be given similar moral rights in relation to their live performances and the live communication of those performances to those currently given to authors of copyright works.

265. Extending moral rights to the visual aspect of a performance, and any communication of that live performance, would assist to simplify the moral rights regime. It would be easier for performers, broadcasters, users and consumers to implement and understand if no distinction had to be made between the audio and visual aspects of a live performance.

266. This approach mirrors that taken in the UK.[11]

267. Ultimately, this option is likely to reduce regulatory and business compliance costs inherent in providing a moral rights regime for performers.

Disadvantages

268. The disadvantage is that this option does not meet the objective of keeping the amendments to the minimum necessary, where reasonable and practical to do so, to comply with WPPT obligations. The WPPT only requires performer's moral rights to be provided in relation to audio aspects of any performance or live communication of any performance.

Option 2: Moral rights apply only to the audio aspect of a performance and the audio aspect of any live communication

269. Under this option, a performer would have the right to be identified whenever they produce or put on a performance, and for any live communication of that performance, only in relation to the audio aspects of a performance. Similarly, a performer would have the right to object to derogatory treatment of their performance for any live communication of that performance, only in relation to the audio aspects.

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10 To comply with TPP, we are required to provide moral rights in respect of performances which are fixed in sound recordings.

11 Sections 205C and 205F of the UK Copyright, Designs, and Patents Act 1988.

Advantages

270. The amendment would meet the objective of keeping amendments to the Copyright Act to a minimum to comply with the WPPT.

Disadvantages

271. This option would result in an imbalance in the treatment of different aspects of a live performance. This option is likely to be difficult and confusing for performers, communicators of live performances (such as broadcasters) and copyright users to understand and apply.

272. This option would also be difficult to implement as the Copyright Act does not currently distinguish between aural performances and visual performances.

Consultation

273. Submissions received on the the targeted consultation document broadly supported Option 1.

Conclusion and Recommendation

274. We recommend that the new performers' moral rights should apply to both the audio and visual aspects of a performance whenever a person produces or puts on a performance and for any live communication of that performance (Option 1).

Issue 2: Exceptions and limitations to performers' moral rights

Option 1 (preferred option): Provide certain exceptions and limitations to performers' moral rights

275. Under this option, the Copyright Act would provide certain exceptions and limitations to performers' moral rights.[12] Exceptions and limitations would apply to acts that did not involve copyright infringement, or where it would be impractical, or otherwise unreasonable, for a performer to be able to enforce their moral rights. The exceptions and limitations would be modelled on existing exceptions and limitations on authors' moral rights (currently provided under Part 4 of the Act).

276. In relation to the right to be identified, three additional exceptions would be provided — the right would not apply:

- where it would be reasonably impractical to identify the performer (or where identification of a group is permitted)
- in relation to any performance given for the purpose of advertising any good or service
- when a recording appears incidentally in another recording, and it is not a substantial part of the other recording.

277. These additional exceptions are provided for the equivalent rights under the UK legislation.[13]

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12 For the purposes of this analysis, we are assuming that moral rights will apply to both the audio and visual aspects in respect of a performance, and to the live communication of a performance (as recommended above), as well as to the communication and distribution of performances which are fixed in sound recordings (as required by WPPT and TPP).

13 Section 205E of the UK Copyright, Designs, and Patents Act 1988.

278. In relation to the right to object to derogatory treatment, an additional exception would be provided for modifications made to a performance which are consistent with normal editorial or production practice. This additional exception is provided for the equivalent rights under the UK legislation.[14]

Advantages

279. By providing exceptions and limitations to performers' moral rights which are modelled on existing exceptions and limitations to authors' moral rights, the moral rights regimes would be consistent.

280. Providing for exceptions and limitations to performers' moral rights would contribute to the objective of ensuring that the Copyright Act appropriately balances the new rights being given to performers with the interests of users and consumers. This option would also ensure that we are compliant with Article 18.66 of TPP, which requires parties to endeavour to achieve an appropriate balance in their copyright regime by, among other things, means of exceptions and limitations.

281. This option would also assist to reduce regulatory and business compliance costs associated with live performances and the use of applicable communication works.

Option 2: Provide no exceptions and limitations

282. Under this option, no exceptions or limitations would be provided for performers' moral rights.

Advantages

283. This option would be easy for performers, communicators and copyright users to understand — those rights would need to be respected in every instance. Not providing any exceptions or limitations would still comply with WPPT requirements, because the provision of exceptions and limitations under domestic law is discretionary.

Disadvantages

284. Providing for performers' moral rights without providing for exceptions and limitations would create an imbalance in the Copyright Act between the rights of performers and the interests of users and consumers. It would also mean that the moral rights of performers and authors would not be aligned.

285. Failing to provide for any exceptions and limitations to performers' moral rights at all is an approach some may argue would not be consistent with our obligation under Article 18.66 of TPP to endeavour to achieve an appropriate balance within our copyright system.

Consultation

286. Submissions received on the targeted consultation document broadly supported Option 1. Some submitters suggested that new exceptions could be provided for other uses of sound recordings (such as an exception for uses which amount to parody, or a broad exception for uses which are reasonable in all the circumstances). Undertaking a wider review of exceptions and limitations for using copyright works would not be consistent with the objectives for implementing TPP, but is a matter that could form part of a wider review of the Copyright Act.

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14 Section 205G(3) of the UK Copyright, Designs, and Patents Act 1988.

Conclusion and Recommendation

287. We recommend that the Copyright Act be amended to provide exceptions and limitations to performers' moral rights that mirror the existing exceptions and limitations to authors' moral rights, and additional specific exceptions where it would be impractical or unreasonable for the rights to apply (Option 1).

Issue 3: Exceptions and limitations to performers' property rights in sound recordings

Option 1 (preferred option): Provide certain exceptions and limitations to performers' property rights in sound recordings

288. Under this option, the Copyright Act would provide exceptions and limitations to performers' new property rights in sound recordings. Exceptions and limitations would apply to acts that do not currently infringe copyright in sound recordings. The exceptions and limitations would be modelled on existing exceptions and limitations on producers' copyright in sound recordings, set out in Part 3 and elsewhere in the Copyright Act.

Advantages

289. This option would align performers' new property rights in sound recordings with producers' copyright in sound recordings. Providing exceptions and limitations is consistent with the objective of providing an appropriate balance between the rights of performers and the interests of users and consumers. We expect that alignment would also facilitate cooperation between performers and authors over the licensing of sound recording to users and consumers.

290. Providing exceptions and limitations to performers' property rights in sound recordings would ensure that users and consumers are able to continue to use sound recordings in circumstances that currently do not involve an infringement of the producer's copyright in the same sound recording.

291. Providing alignment between the exceptions and limitations for the two sets of property rights would also make it easier for users and consumers to understand when they may be permitted to use sound recordings without first seeking licences from performers and producers.

292. We would expect alignment of exceptions and limitations to ultimately reduce the regulatory and business compliance costs arising from giving performers a property right over sound recordings.

Disadvantages

293. Providing exceptions and limitations to performer's new property rights in sound recordings may constrain a performer's ability to maximise their returns from licensing the use of sound recordings. This is because certain uses of the sound recording would not require the authority of (i.e. licence from) the performer.

Option 2: No exceptions and limitations to a performer's property rights in sound recordings

294. Under this option, no exceptions and limitations would be provided to a performer's new property rights in sound recordings.

Advantages

295. Because performers would have the authority to exercise complete control over the use of sound recordings by intermediaries and users of sound recordings, especially over actions that the Copyright Act does not permit producers to authorise control over, performers would be able to maximise their returns in respect of licensing of sound recordings — effectively, every use of a sound recording would require a licence from the performer.

Disadvantages

296. Failing to provide exceptions and limitations to performers' property rights in sound recordings would create imbalance in the Copyright Act and result in a performer's property rights not being aligned with a producer's copyright in the same sound recording.

297. This is likely to result in an increase in regulatory and business compliance costs associated with licensing the use of sound recordings by users, which may in turn reduce incentives for users to use sound recordings for legitimate purposes. The licensing of sound recordings would likely become more complex because of the mismatch between a performer's property rights and those of the producer. In turn, this could hinder the efforts of performers and producers to cooperate in the licensing of sound recordings, which both would have rights in.

298. Under this option, the non-alignment of performers' property rights and producers' copyright would likely increase regulatory and business compliance costs associated with using sound recordings.

299. The differences between the scope of performers' property rights and producers' copyright could lead to unnecessary tensions in the copyright system.

300. Lastly there could again be a question of whether New Zealand was complying with it's obligations to endeavour to achieve an appropriate balance in our copyright system.

Consultation

301. Submissions received on the targeted consultation document broadly supported Option 1, emphasising the importance of aligning of exceptions and limitations for performers' property rights in sound recordings with those currently provided for producers' copyright in sound recordings. While some submissions suggested additional exceptions and limitations should be provided under Part 3 of the Copyright Act, such amendments would go beyond the requirements of TPP and not meet our implementation objectives. A broader review of the Copyright Act could consider whether additional exceptions and limitations under Part 3 should be provided and, if so, whether they would also be included in the performers' rights regime.

302. Some submitters suggested that performers' new moral and property rights should also apply to films (i.e. visual recordings of performances), rather than being limited to sound recordings. These submitters claimed that there was no rational reason for differentiating between audio and visual recordings. However, we do not consider that it is appropriate to go beyond the requirements of WPPT and TPP without evidence that there is a clear need to do so. A number of submitters outlined the likely costs and complexities arising from extending the rights. We note that this issue could form part of a wider review of the Copyright Act.

Conclusion and Recommendation

303. We recommend that the Copyright Act be amended to provide exceptions and limitations to the new performers' property rights that mirror the existing exceptions and limitations provided to producers of sound recordings (Option 1).

Consultation

304. The detailed implementation proposals were tested through a public consultation process and a series of workshops targeted at key stakeholder groups. MBIE received 55 submissions during the consultation period, ranging from individuals and user groups to rights holders.

305. Submissions were received on all areas of the targeted consultation document. The majority of submitters' comments were focused on technological protection measures. A significant number of submitters also commented on performer's rights and patent term extensions. A summary of submitters' views on the respective areas is addressed above in the corresponding sections, but overall there was support for the approach taken in the targeted consultation document.

306. The targeted consultation document was published on the MBIE website and key stakeholders were informed by email. To assist in information on the consultation process being widely distributed, a notice was also placed on Rauika (the Te Puni Kokiri website for online events and opportunities of interest to Maori whanau throughout Aotearoa) and Te Puni Kokiri also distributed an email to their business and regional networks.

307. Officials will further consider the matters raised by submitters in relation to suggested TPM proposals, including meeting with submitters, in preparation for the select committee process.

Conclusions and recommendations

308. Based on our assessment of the options, we conclude that:

- The Patents Act 2013 should be amended to make term extensions available for delays in the grant of a patent only if they are more than three years from the date of a request for examination or five years from the date of filing, disregarding delays not directly attributable to IPONZ. This is the minimum requirement under TPP. The Act should provide for regulations to be made prescribing the delays that are deemed to be not attributable directly to IPONZ.
- The Patents Act 2013 should be amended to make term extensions available for pharmaceuticals:
    i. only for patents disclosing a pharmaceutical substance per se, where products consisting of, or containing, the substance have been approved for marketing by Medsafe
    ii. if the time period between filing of the application approval, and the grant of approval is more than three years for small molecule pharmaceuticals and five years for biologics, these time periods excluding time periods not attributable to Medsafe.
- The Copyright Act 1994 and Trade Marks Act 2002 should be amended to provide a procedure for Customs to invite notices from rights holders to provide ex officio powers to Customs (similar to the approach taken in the EU).
- In relation to TPMs, the Copyright Act 1994 should be amended to:
    i. prohibit the circumvention of a TPM that controls access to a copyright work
    ii. prohibit providing devices or services to circumvent TPMs that control access to a copyright work

iii. provide exceptions for situations where copyright is not infringed

iv. provide that civil remedies and criminal procedures and penalties do not apply to non-profit libraries, museums, archives, educational institutions and public non-commercial broadcasting entities in appropriate circumstances.

- In relation to the rights of performers, the Copyright Act 1994 should be amended to provide for:

  i. new performers' moral rights that apply to both the audio and visual aspects of a performance whenever a person produces or puts on a performance and in any live communication of that performance

  ii. exceptions and limitations to the new performers' moral rights which mirror the exceptions and limitations to authors' moral rights already provided in the Copyright Act, and additional exceptions where it would be impractical or unreasonable for the rights to apply

  iii. exceptions and limitations to the new performers' property rights which mirror the exceptions and limitations to producers' copyright already provided in the Copyright Act.

Implementation plan

309. Final policy decisions will be reflected in the TPP implementation bill.

310. Once the resulting bill comes into effect:

- The provision of patent term extensions will be administered by IPONZ.
- The new powers for Customs will be administered by Customs, in consultation with MBIE, which has responsibility for intellectual property policy.

311. The changes to protections for technological protection measures and performers' rights will be administered by MBIE.

312. The changes in this RIS will only be brought into effect on entry into force of the TPP for New Zealand.

Monitoring, evaluation and review

313. It is intended that review of the effects of the amendments to the Copyright Act implementing the requirements of TPP will take place three years after their introduction. Information collection for monitoring purposes will be organised as a specific project under MBIE's Regulatory Management Strategy, with a full evaluation in 2019. In the meantime monitoring and reporting on the amendments will take place through MBIE's Regulatory Management Strategy.

314. The effects of the amendments to the Patents Act 2013 providing for patent term extension will be monitored by checking the number and length of extensions granted each year. The data will be collected from the IPONZ online case management system. Because of the timeframes associated with the patent term extension provisions, it is likely to be 2021 at the earliest before any extensions could be granted (for Medsafe delays) and 2023 (for IPONZ delays).