

*SENATE ECONOMICS LEGISLATION COMMITTEE INQUIRY
INTO THE
INTELLECTUAL PROPERTY LAWS AMENDMENT BILL 2006*

IP AUSTRALIA RESPONSES TO QUESTIONS ON NOTICE

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1. Responses to Professor Corones' submissions

1.2 Background

1.2.1 Introduction

In September 2000, the Intellectual Property and Competition Review (IPCR) Committee released its report *Review of Intellectual Property Legislation under the Competition Principles Agreement*. This review considered the balance between competition law and intellectual property law. The Government responded to this report in 2001.

This report considered insertion of a competition ground for the grant of compulsory licenses for patents. Schedule 8 to the Intellectual Property Laws Amendment Bill 2006 (the Bill) implements the Government's response to this recommendation.

1.2.2 Compulsory licences for patents

A patent represents the grant of an exclusive right to exploit an invention. Under the current provisions of the *Patents Act 1990*, a person may obtain a compulsory licence for the use of a patent if the "reasonable requirements of the public" with respect to that patent have not been met. Section 135 of the Patents Act sets out what is meant by the "reasonable requirements of the public". For example, the reasonable requirements of the public will not have been satisfied if an existing trade or industry in Australia is unfairly prejudiced because of the patentee's failure to manufacture the patented product to a reasonable extent and to supply it on reasonable terms.

Given that the grant of a patent gives the grantee exclusive rights, the IPCR Committee pointed out that the grant of a compulsory licence to another party "is *prima facie* inconsistent with the policy purpose underpinning that grant".

In its 1984 report *Patents, Innovation and Competition in Australia*, the Industrial Property Advisory Committee, described the justification for the present compulsory licence provision in the following terms:

"... compulsory licensing and forfeiture should have the purpose in Australia of providing a mechanism by which a patentee can be prevented from misusing a patent to preclude local working which is economically desirable, in circumstances where, but for the patent, it could and would occur."

For detailed background to patent compulsory licences, see Chapter 27 of the Australian Law Reform Commission's report *ALRC 99 – Genes and Ingenuity: Gene Patenting and Human Health*: <http://www.austlii.edu.au/au/other/alrc/publications/reports/99/27.html>

Although a compulsory license has been sought in a small number of court cases, as far as is known, no compulsory licences for patented inventions have been granted in Australia to date.

Instead, the evidence indicates that the present compulsory licence provisions serve to encourage the licensing and working of inventions sooner, with the compulsory licence provisions serving as an effective incentive for patent holders to grant a licence voluntarily and on their own terms.

1.2.3 The IPCR Report

The IPCR Committee considered the compulsory licence provisions of the Patents Act, and recommended amendments to the provisions.

The Committee recognised that compulsory access to patented invention through compulsory licence provisions can affect the terms on which parties negotiate licences for the use of patents, and was informed that the existing compulsory licence provisions of the Patents Act have an impact on licence negotiations, notably between foreign rights owners and potential users of patents in Australia.

The Committee accepted that compulsory licences were warranted in some situations, such as:

- When bargaining between parties is not able to achieve an outcome; or
- When the access right acts as a pro-competitive remedy that tempers the exclusivity that the patent right primarily provides.

The Committee noted that, in other jurisdictions with compulsory licences, most notably the United States and Canada, this can lead to more efficient and immediate outcomes without harming long-term incentives to innovate, and that the threat of compulsory licensing may lead to innovations being worked sooner and more widely than they would otherwise have been.

However, the Committee noted that the current compulsory licence provisions in the Patents Act seem poorly aligned to securing these goals, but that, instead, they hark back to a period where the primary concern was the promotion of domestic industry, rather than securing the best use of resources and achieving high levels of productivity. In addition, the Committee was of the opinion that the provisions lacked an explicit competition test, and did not seem to allow for the legitimate interests of the rights owner to be adequately protected.

The IPCR Committee then recommended that section 135 of the Patents Act be repealed and that subsection 133(2) be amended to include an order requiring a compulsory license to be made if and only if all of the following conditions are met:

- (a) access to the patented invention is required for competition in the (relevant) market;
- (b) there is a public interest in enhanced competition in that market;
- (c) reasonable requirements for such access have not been met;
- (d) the order will have the effect of allowing these reasonable requirements to be better met; and
- (e) the order will not compromise the legitimate interests of the patent owner, including that owner's right to share in the return society obtains from the owner's invention, and to benefit from any successive invention, made within the patent term, that relies on the patent.

In its *Interim Report*, released in April 2000, the IPCR Committee gave its rationalisation for this form for the competition-based compulsory licence test (which reflects the test set out in Part IIIA of the Trade Practices Act):

“Overall, the Committee considers that there is merit in having provisions that can provide for third party access to IP rights along the lines provided in respect of other services by Part IIIA and Part XIC. However, the Committee is not convinced that this objective is well met by simply repealing the exception that IP rights currently have from these sections of the Trade Practices Act. Rather, it is the Committee’s view that this goal is best served by reviewing, and where appropriate amending, the relevant provisions in the intellectual property statutes themselves.”

The IPCR Committee also recommended that such orders should be obtainable on application first to the Australian Competition Tribunal, with rights of appeal to the full Federal Court.

The IPCR Committee considered that the test for a compulsory licence should be stringent, and that a licence should only be granted if there is no other option for competition in the relevant market than by having access to the patented invention. It also considered that the enhancement of competition in the relevant market that would be secured by grant of the compulsory licence would have to be material and substantial.

The IPCR Committee acknowledged that it did not seek to draft the conditions that would need to be met for the grant of a compulsory licence.

1.2.4 The Government response to the IPCR Report

The Government’s response to the IPCR Committee’s recommendation is as follows:

“Accept in part.

Compulsory licensing is one of the more contentious and politically sensitive TRIPS issues and therefore in considering this recommendation the Government has taken into account the need for consistency with international standards.

In principle, the Government supports the Committee's recommendation to make the compulsory licensing of patents subject to a competition test. However, as it stands, this recommendation would limit the grounds on which to obtain a compulsory licence to the situation where access to patented technology is required to ensure competition in the (relevant) market, rather than the broader grounds based on the 'reasonable requirements of the public.' Depending on its interpretation, this could preclude situations where compulsory licensing could be argued to be valuable from a public policy perspective.

For this reason, a competition test alone is not sufficient as:

- (a) the recommended test may be more stringent in some circumstances than the existing tests and may result in the compulsory licensing provisions ceasing to act as an incentive to negotiate a voluntary licence; and
- (b) a competition test will not cover some situations where the non-working of the invention, or other effective denial of reasonable access to it, has some negative effect on the public interest which is not dependant on competition in the market.

Accordingly, the Government believes that the existing tests should be retained and a competition test be added as an additional ground on which a compulsory licence can be obtained.

It is inappropriate that applications for compulsory licences be considered by the Australian Competition Tribunal in the first instance because the Tribunal is essentially a review body. In addition, it is not the appropriate body to hear applications for compulsory licences under the ‘reasonable requirements of the public’ test and, in view of the likely difficulties if applications under different grounds were to be heard by more than one body, the Government considers that all applications for compulsory licences should be considered by the Federal Court in the first instance.”

It is noted that the Government, in its response, did not accept the particular competition test proffered by the IPCR Committee. It is also noted that this response emphasised “consistency with international standards”.

1.2.5 The ALRC Report

In its report *ALRC 99 – Genes and Ingenuity: Gene Patenting and Human Health*, the Australian Law Reform Commission further considered the interaction between competition law and patent law – see Chapter 24 of that report. The ALRC also considered the issue of the grant of patent compulsory licences on the basis of a competition test, and reiterated the IPCR Committee’s recommendation to implement a competition based test for patent compulsory licences. See Chapter 27 of that report.

The report can be found at the following link:

<http://www.austlii.edu.au/au/other/alrc/publications/reports/99/>

The Government has not as yet finalised its response to this report.

1.2.6 International obligations and standards

1.2.6.1 International obligations

Under Article 30 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Australia can only provide limited exceptions to the exclusive rights provided by a patent, and only if these exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Under Article 31 of the TRIPS Agreement, compulsory licences may be granted, and that Article sets out procedural requirements that must be observed.

Under Article 17.9.7 of the Australia-United States Free Trade Agreement (AUSFTA), Australia is further limited as to its ability to grant compulsory licences. This Article is as follows:

“A Party shall not permit the use^{17-[22]} of the subject matter of a patent without the authorisation of the right holder except in the following circumstances:

- (a) to remedy a practice determined after judicial or administrative process to be anti-competitive under the Party's laws relating to prevention of anti-competitive practices;^{17-[23]} or
- (b) ... ”

The footnotes are as follows:

^{17-[22]} “Use” in this paragraph refers to use other than that allowed under paragraph 3 and Article 30 of the TRIPS Agreement.

^{17-[23]} With respect to sub-paragraph (a), the Parties recognize that a patent does not necessarily confer market power.”

In order to comply with our AUSFTA obligations, a compulsory licence cannot be granted in order to promote competition against a patentee – it must be confined to remedying anti-competitive practices.

1.2.6.2 International standards

In other jurisdictions in which compulsory licenses are granted on competition grounds, it is generally done so as a remedy to address anti-competitive conduct of the patent holder. Compulsory licenses are not granted in order to promote competition in the market. See Chapter 27 of the ALRC *Genes and Ingenuity* report for a comparative international summary.

1.3 The provisions of Schedule 8 to the Bill

Schedule 8 to the Bill implements the Government's response to the recommendation of the IPCR Committee's final report.

The proposed amendments to the Patents Act maintain the existing test for grant of a compulsory licence for a patent, on the ground that the “reasonable requirements of the public” with respect to the patented invention have not been satisfied. In addition to this, the amendments insert a competition-based test for the grant of a compulsory licence.

As per the IPCR Committee's recommendation, this provision has been inserted into the Patents Act rather than in the Trade Practices Act.

It is noted that the specific test proposed by the IPCR Committee, and also recommended by the ALRC, is not aimed at addressing anti-competitive practices on the part of a patentee. Rather, it is aimed at promoting competition. Indeed, the IPCR Committee considered that a compulsory licence would only be granted if the enhancement of competition in the relevant market that would be secured by grant of the compulsory licence was material and substantial. A test aimed at promoting competition would not be consistent with Australia's international obligations under the AUSFTA.

Instead, proposed amendments to the Patents Act introduce a further ground for grant of a compulsory licence, that is, that a compulsory licence is obtainable as a remedy for anti-competitive practices under Australia's law governing anti-competitive practices. This has been implemented by making a compulsory licence for a patent available as a remedy if the

patent holder has contravened or is contravening Part IV of the *Trade Practices Act 1974* or an application law. Such conduct is considered to be anti-competitive under Australia's law relating to prevention of anti-competitive practices. For example, as explained by the ALRC in its report (Chapter 24):

“24.8 Certain conduct is prohibited if it has the purpose or effect of ‘substantially lessening competition’ in a market, while other conduct is prohibited on a per se basis. Per se breaches do not involve an analysis of the impact of the conduct on competition because the conduct is presumed, by its nature, to substantially lessen competition.”

The new ground for grant of a compulsory licence for a patent relies on a breach of the competition code, and provides that, if the breach is related to a patent, then a compulsory licence is available as a remedy for that breach. The provisions therefore make it clear what the contravening conduct must be – a breach of Part IV of the Trade Practices Act or an application law.

In line with the Government response to the IPCR Committee's report, these provisions are also drafted so as to be in line with international standards, in so far as compulsory licenses are available as a remedy for anti-competitive conduct, rather than to aid in promoting competition against the patentee. The provisions are also consistent with Australia's international obligations, in particular, those under TRIPS and the AUSFTA.

1.4 The issues raised by Professor Corones

In his submission and evidence to the Senate Economics Legislation Committee, Professor Corones raises several issues with Schedule 8 to the Bill.

1.4.1 Whether section 133 of the Patents Act is intended to be a code

Professor Corones queries whether the new provisions are intended to be a code in relation to compulsory licensing, or whether the corresponding remedy under the Trade Practices Act remains available.

As explained at the hearing, the new provisions of the Patents Act are specific provisions allowing for a person to apply to the Federal Court of Australia for the grant of a compulsory licence for a patent. The Patents Act provisions specify the grounds on which a compulsory licence may be sought (paragraph 133(2)(b)), the payment that must be made to the patentee in respect of the licence (subsection 133(5)), provisions governing revocation of the licence (subsection 133(6)), and for the revocation of a patent after a compulsory licence has been granted (section 134). In contrast, the Trade Practices Act provisions are expressed very generally, and do not make a specific reference to grant of a compulsory licence.

There is a general principle of statutory interpretation under which, in the case of a conflict or inconsistency between a specific and a general legislative provision, the specific provision will prevail. Therefore in the case of any conflict or inconsistency between the proposed compulsory licence provisions of the Patents Act and the provisions of the Trade Practices Act, the former would be expected to prevail.

As a result of the application of this interpretive principle, an application for a compulsory licence could only be made under the Patents Act, and a person seeking an order for a compulsory licence for a patent would not be faced with a choice of legislative provisions under which the licence could be granted.

1.4.2 Remuneration under the Trade Practices Act

Professor Corones observes that under the remedial provisions of the Trade Practices Act, there are no pricing guidelines if a compulsory licence is granted under that Act, whereas under the Patents Act provisions, such pricing guidelines are included (subsection 133(5)). Professor Corones then observes that, if a pricing order is made under the Trade Practices Act, a court could order the grant of a licence on a completely different basis that allows the patentee to charge or to include a monopoly profit element in their royalty. Professor Corones then states that the Trade Practices Act may need to be amended to incorporate pricing principles which are the same as those under the Patents Act to avoid any conflict.

Based on the discussion in 1.4.1 above, these issues would not be expected to arise, as applications for compulsory licences would be dealt with under the Patents Act rather than under the Trade Practices Act.

It is emphasised that the amendments proposed to be made by the Bill to the Patents Act do not alter the operation of the Trade Practices Act with regard to pricing principles for remuneration for intellectual property licences.

The amendment to the Patents Act relating to the insertion of a competition test for compulsory licences has arisen as a result of extensive consultation and analysis by the IPCR Committee. The ALRC subsequently considered this issue, and made similar recommendations to those made by the IPCR Committee. Prior to these considerations, the issues have been considered in earlier reports, such as the 1984 report *Patents, Innovation and Competition in Australia* by the Industrial Property Advisory Committee.

It is noted that the issues raised by Professor Corones have not identified in any of these earlier studies, and to IP Australia's knowledge have not been raised in any other forums.

1.4.3 Whether an additional requirement is needed in the competition test

1.4.3.1 Mischief

Professor Corones raised the issue of whether there should be an additional requirement in the test for the grant of a compulsory licence – namely, that the licence seeker demonstrate that the grant of a compulsory licence is necessary to promote competition in the market. Professor Corones acknowledges in his oral evidence that this:

“is probably an unnecessary additional requirement, but if it were included it would probably make clear what the mischief is that requires the compulsory licence”.

It is noted that the mischief that the provision is addressing is set out in the Explanatory Memorandum to the Bill (see paragraphs 165 ff) and in the IPCR Committee's final report (see pages 162-3). It is also noted that both of these documents are extrinsic material that are able to be used in the interpretation of the Patents Act according to section 15AB of the *Acts Interpretation Act 1901*. Therefore the mischief this provision is addressing is already apparent from these sources. The provisions are drafted so that the legislative provisions contain the substantive legal test that must be applied. The description of the mischief sought to be cured is contained in the extrinsic material.

1.4.3.2 Promotion of competition

As explained above, it would be inconsistent with Australia's obligations under the AUSFTA for a compulsory licence to be granted for the purpose of *promoting* competition in the market. Under the AUSFTA, a compulsory licence can only be granted to remedy anti-competitive practices, and not for the purpose of promoting competition.

It is therefore not an option to insert an additional requirement along the lines suggested by Professor Corones.

In any event, in practice, it is to be expected that the grant of a compulsory licence would result in the entrance of a competitor into the marketplace, and that that would be likely to result in promoting competition in the market.

If, after grant of a compulsory licence, the patentee continues to act in breach of Part IV of the Trade Practices Act, then the patent may be revoked – paragraph 134(2)(b) as proposed to be amended. This is expected to result in the promotion of competition in the market, as continued breaches of the Trade Practices Act could lead to revocation of the patent and the patented invention subsequently being freely available to all competitors.

2. Responses to IPTA's submissions

2.2 *Schedule 1 – Revoking registration of trade marks etc.*

2.2.1 **Clarity of subsection 84A(4)**

IPTA raises concerns that new subsection 84A(4) is unclear as to when the twelve month period in which the trade mark owner can be notified of the proposed revocation of registration commences.

The wording proposed to be inserted into the Act, “within 12 months of registering the trade mark”, refers to a 12 month period commencing from when the particulars of the trade mark are entered onto the Register under the provisions of section 69 of the Trade Marks Act. This is the date that the trade mark is actually registered and becomes a registered trade mark.

Paragraphs 40 and 41 of the Explanatory Memorandum reinforce this, and remove any doubt as to when the 12 month period commences.

“41. A trade mark is considered to be registered on the day on which the particulars of the trade mark are entered onto the Register under the provisions of section 69 of the Trade Marks Act.”

2.2.2 **Uncertainty for owners of registered trade marks**

IPTA's submission asserts that the new provision gives “open slather” to the Registrar to revoke a trade mark registration, and therefore creates uncertainty for owners of registered trade marks.

A trade mark that has been registered incorrectly can affect owners of other competing trade marks, and can affect the public as a whole, as explained in the EM. The provisions are intended to balance these interests with those of the trade mark owner.

The new provisions set up a two-part test that must be satisfied before the Registrar is able to revoke the registration of a trade mark. The first part of the test requires the Registrar to be satisfied that the trade mark should not have been registered. This protects the public interest factor that invalid trade marks should not be on the Register of Trade Marks.

The second part of the test requires that, before revoking a registration, the Registrar must be satisfied that it is *reasonable* to revoke the registration, taking account of all the circumstances that existed when the trade mark became registered. The provisions provide a non-exclusive list of circumstances that must be taken into account in determining this. Paragraph 35 of the EM emphasises that the Registrar is to take account of *all* of the circumstances, and not only of the circumstances listed in this subsection.

This part of the test provides protection for the registered owner of the trade mark. It requires the Registrar to balance the inconvenience to the trade mark owner of having his or her registration revoked against the inconvenience to the public and to other affected parties of the incorrectly registered mark remaining on the Register.

The registered owner will, in each case, have an opportunity to convince the Registrar that revocation would be unreasonable in the particular circumstances. Under the provisions, the Registrar must give the registered owner an opportunity to be heard before the Registrar can revoke the registration.

One of the factors that must be taken into account includes any use that has been made of the trade mark. If, in light of such usage, the registered owner can convince the Registrar that it would be unreasonable to revoke the registration of the trade mark, then the registration would not be revoked.

In the scenario described in IPTA's submission that the trade mark owner has spent a considerable amount of money using the trade mark, including establishing licenses and authorising others to use the trade mark, the registered owner would have a strong argument that it is unreasonable for the Registrar to revoke the registration.

And if the trade mark owner would be exposed to liabilities and accusations of infringement with the potential for very expensive law suits if the trade mark was revoked, they would have a strong argument that revocation would be unreasonable.

The consequence of revocation of registration of a trade mark is *not* that the owner loses all rights to the trade mark – instead, the registered trade mark reverts to being a pending application for registration of a trade mark, as it was immediately prior to its being registered. The trade mark owner then has a further opportunity to have the trade mark examined, and once again accepted and registered.

2.2.3 Consultation on the twelve month period

IPTA raises concerns that further public consultation should be undertaken and more consideration given to whether the twelve month period is too long.

IP Australia consulted with interest groups on these provisions when they were first proposed in 2002. The response that IPTA provided at that time generally favoured the revocation of registration provisions, but IPTA preferred a time limitation of three or six months for the revocation to occur.

The trade mark system seeks to balance all of the interests that are affected by the system. The time period has been set at 12 months in order to balance the interests of the public and the owners of competing trade mark registrations with those of the trade mark owner.

In April 2006, IP Australia discussed the operation of the provisions with some interest groups, and it was agreed that practice documents would be developed, in conjunction with stakeholders, to ensure that the perspective of owners of trade marks who were likely to be affected by the provisions would be taken into account. Work on these guidelines has commenced, and it is intended that it will be progressed in consultation with stakeholders, including IPTA, before the new provisions commence.

2.3 Schedule 4 – Availability of documents about trade marks

IPTA questions the benchmark that IP Australia will apply in determining what documents are to be held confidentially within the Trade Marks Office, and believes that further

consultation on this issue is necessary. IPTA is also concerned about some operational details of the proposed new system.

IP Australia is in the process of undertaking further consultation as to how this system for availability of documents about trade marks will operate, and IPTA will be consulted in this process. This should address IPTA's concerns.

2.4 Schedule 5 – Relief from infringement of patents

IPTA notes that the option of obtaining exemplary damages appears to be only available where the plaintiff has sought an award of damages, and does not appear to be applicable where an order for an account of profits has been sought.

The Patents Act is to be amended to insert provisions for exemplary damages along the lines of subsection 115(4) of the Copyright Act. IPTA's comments apply equally to the corresponding provisions of the Copyright Act.

2.5 Schedule 6 – Exemption of continued prior use from patent infringement

2.5.1 The Government response to the IPCR report

IPTA states that, since the amendments to section 119 of the Patents Act go beyond the recommendations in the IPCRC final report, these amendments should have been available for public comment to allow the impact of them to be properly assessed.

The amendments implement the Government's response to the IPCRC report. That response went beyond the recommendations of the IPCRC report. The response was publicly released in August 2001. There has been ample time for interest groups to assess the impact of the proposed changes and to provide comments to the Government.

2.5.2 Interpretation of section 119 as proposed to be amended

IPTA considers that the amendments will create a new and broad non-infringement right that has the potential to significantly undermine the value of an Australian patent. This is based on their interpretation of how section 119 permits a prior user to do any of the actions included by the term "exploit". IPTA is also concerned that the amendments will not remove the uncertainty in section 119.

To remedy this situation, IPTA suggests that the prior use defence should be limited to the actual prior use or acts, or the uses or acts for which definite steps had been taken. Alternatively it should be made explicit that section 119 does not entitle a person to exploit an infringing product, method or process other than the specific product, method or process that was prior used.

The aim of section 119 is to provide that a person (the prior user) may do *any* act that exploits a product, method or process if, immediately before the priority date of the relevant claim, the prior user was exploiting the product, method or process (or had taken definite steps to do so).

This means that, if a person was making a product before the priority date, they may continue to make that product without infringing the patent. However, they may also do any other act that exploits *that product*, such as hiring or selling the product, without infringing the patent. This provides greater certainty for the prior user.

However, the drafting of the provision limits the prior use exemption to acts that exploit the particular product, method or process that the prior user had been exploiting previously. In other words, the prior user is *not* able to exploit other forms of the product, method or process that may be covered by the patent. The EM reinforces the limitation to the prior user's ability to exploit that particular product in paragraph 132.

Adopting the alternative approach suggested by IPTA would not remove the uncertainty in the provisions, and would be of little value to the prior user. For example, if the prior use act had been to *make* a particular product, and someone subsequently patents that product, the prior user would not be able to, for example, sell that product, as selling would be an infringement of the patent. This situation creates uncertainty for the prior user, as it is not clear what a prior user is able to do with a product he or she has made.

2.5.3 Assignment of the prior user's entitlement

IPTA is also concerned that section 119 will permit the assignment of the prior use right. In particular IPTA raises concerns that large multinational competitors will now look for and buy prior use rights, and that Australian innovators will be disadvantaged by this provision.

The Government's reason for enabling the prior use entitlement to be assignable was primarily to benefit Australian research-based organisations that do not commercialise their own inventions. It is intended to provide an incentive for further R&D to take place in Australia by allowing such organisations to profit from their work, and is expected to have the effect of stimulating innovation. It is expected to benefit consumers by providing increased choice in the market.

Australian companies will be treated in exactly the same manner as foreign companies when it comes to having a prior use exemption assigned to them – both will benefit equally. However, as only prior use within Australia is covered by the provisions, Australian innovators will benefit in this respect over foreign innovators.

Overall, the patent owner is still in a significantly better position than is the prior user. The patentee may enforce their proprietary patent rights against others, whereas the prior user will not have any such enforceable rights. In addition, the prior user will not be able to exploit any other form of the invention that is covered by the patent – their prior use right is limited to exploiting the particular product, method or process that was being exploited before the relevant priority date.

2.5.4 The corresponding UK provisions

IPTA indicates that the proposed amendments will result in the Australian legislation differing from that of our major trading partners, and cites the UK provisions which require assignment of the business when the prior user assigns their right.

Under the UK legislation, the assignment provision does not require assignment of the *entire* business. It merely requires assignment of “that part of the business in the course of which the act was done or the preparations were made”.

It would be inappropriate if a prior user exemption were only to be assignable with the *entire* business of the prior user. For example, a business may be involved in other activities in addition to the activities relating to the prior use. It should not be forced to assign its *entire* business simply in order to assign the part of the business that relates to the prior use.

If a business *does* assign its prior use entitlement under the proposed provisions, then it is no longer able to conduct that part of its business relating to that prior use. Therefore it is effectively assigning that part of its business relating to the prior use when it assigns the prior use entitlement. Therefore the proposed provision is not substantially different in this respect from the corresponding UK provisions.

Unlike the UK provisions, the prior use defence will not be limited to acts done in the course of a business, in order to allow for research institutions to benefit from the prior use defence. Therefore the Australian provisions will be quite deliberately different from the UK provisions in this respect.

2.6 Schedule 7 – Springboarding and Patents

IPTA considers that the new springboarding provisions should be restricted to patents granted on applications filed on or after commencement of the new provisions. Also IPTA believes that the proposed provisions contravene Section 51(xxxi) of the Constitution.

The application of these amendments to current patents is necessary to capture the benefits to the Australian generic industry of the current period of drug patent expiries. The Government believes that the provisions do not fall within the operation of Section 51(xxxi) of the Constitution. This issue ultimately remains for the courts to decide.

2.7 Schedule 8 – Compulsory licensing of patents

IPTA has no comments on the proposed amendment but suggests a possible clarification to the compulsory licence provisions in relation to a conflict between the “reasonable requirements of the public” test and section 136. IPTA’s submission does not relate to any provision of the Bill.

Article 17.9.7 of AUSFTA provides for the use of patents without authorisation by the right holder in the following circumstances:

- 17.9.7(a) – to remedy anti-competitive practices; and
- 17.9.7(b) – in cases of public non-commercial use, national emergency or other circumstances of extreme emergency.

In the AUSFTA, the term "anti-competitive practices" is interpreted broadly and covers the present compulsory licence provisions under the Patents Act. These provisions provide for the grant of a compulsory licence if, among other conditions, "the reasonable requirements of the public" have not been met.

As such, there is no conflict with section 136 of the Patents Act nor is there any issue of preferential or different treatment for US persons.