Law Council
OF AUSTRALIA

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Secretary-General

15 October 2012

Compulsory Licensing of Patents
Productivity Commission
LB2 Collins Street East
Melbourne Vic 8003
**Via email: patents@pc.gov.au**

Dear Sir or Madam,

The Intellectual Property Committee of the Business Law Section of the Law Council of Australia (IPC) makes the following submission and observations in relation to the Commission's inquiry into Compulsory Licensing under the *Patents Act 1990* (*Patents Act*). The IPC has not sought to address every question posed in the Issues Paper, but only those matters of particular relevance.

## 1. Summary

### Compulsory Licensing - Product Not Available in Australia

Where a patented product or process is not available in Australia at all, the current licensing scheme appears to work. While there are relatively few cases which have gone to a final hearing, there are examples of cases noted in this submission where the threat of using the compulsory licensing provisions has led to a negotiated outcome. Part of the reason why there are relatively few cases may be that, ordinarily, the patentee will have an incentive to maximise revenue by selling the product or using the process in Australia.

### Compulsory Licensing - Price Dispute Only

A compulsory licensing scheme directed to situations where the patented product is readily available in Australia, but there is a dispute between the users and the patentee about price, is at risk of diverging from Australia's treaty obligations. The submission elaborates on the reasons.

### Court Determination of Licence Terms and Conditions

There is no reason to think that a court cannot determine appropriate royalty rates and conditions for a licence based on expert accounting and commercial evidence. Experience of compulsory licensing decisions in the UK and Canada provide many examples where courts have done so. The patents office in the UK has dealt with determination of compulsory licensing issues, but the IPC's view is that the Australian

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Patent Office, as it stands, would not be so well equipped to make such assessments. The assessments are predominantly accounting and commercial assessments and are likely to require determination of the credibility of witnesses, better handled by judges with experience of determining commercial disputes.

Experience of tribunals, such as the copyright tribunal, disclose no particular benefit (nor particular disadvantage) whether in terms of time, cost or otherwise, arising from using a tribunal rather than a court.

The cases are likely to be insufficiently frequent to justify establishing a tribunal. The cases also seem to be insufficiently frequent to enable the development of a specific body of expertise at the Australian Patent Office.

**Technology Neutral**

The IPC's view is that any compulsory licensing provision should be technology neutral as a matter of general principle. Attempts to distinguish between technologies lead to attempts to find exceptions and loopholes. The Australian Government's obligations under international agreements are also relevant - separate treatment of a specific field of technology may be an unjustifiable discrimination against a field of technology.

**Crown Use**

The Crown use provisions are limited to cases of "necessity", which are unlikely to apply when the product is in fact available, albeit at a higher price.

Also, where the dispute is one about price, it cannot be assumed, without reviewing the facts, that it is the case that users are right about the reasonable price. For example, a user might wish to pay $200 for a genetic test for which the patentee wishes to charge $10,000. A consideration of matters such as the cost of the research (including failed research attempts) undertaken to invent and develop the test, the benefit to the users (and/or the public) from the test and the comparative cost of competing methods or technologies might, in appropriate cases, justify the higher figure rather than the lower.

**Collecting Schemes**

Collecting schemes are unlikely to have any useful place in the context of patents. While there are examples of industries (including aspects of computer technology) where widespread non-exclusive licensing, including bulk pricing of patents, is known, the IPC is not aware of any examples of a successful collecting scheme for patents. It is likely that the reason for that is quite fundamental. In particular, the variable nature and value of patent rights would mean that the determination of price to users and the distribution of royalties to patentees would frequently need to be assessed on a case by case basis. The ability to determine a standard general charging mechanism and a fair general method of splitting the revenue among IP owners, which are the key to collecting schemes, are not present. Administrative costs and disputes at both levels are likely to consume any return.

**Compulsory Licensing Statistics**

The IPC has identified some references on compulsory licensing statistics globally which may be of assistance.

**General**

The IPC is concerned that the Commission considers the full impact of compulsory licensing proposals.

Members of the IPC have observed that, in relation to products such as pharmaceuticals, which require clinical trials and marketing approval, patent protection is a necessary prerequisite to a product being brought onto the market in Australia. Manufacturers would not have the incentive to incur the extremely high costs necessary to develop products, conduct trials and obtain marketing approvals unless they had an opportunity to recover those costs. Recovery of costs is normally achieved through a period of exclusivity as provided for under the *Patents Act*.

Widespread compulsory licensing is likely to result in the reduction of these incentives.

The IPC has prepared a brief commentary on the points above. It would be happy to elaborate further if that would assist.

## 2. Compulsory Licensing - Product Not Available in Australia

Where a patented product or process is not available in Australia at all, the current licensing scheme appears to work. While there are relatively few cases which have gone to a final hearing, the examples of cases below show the threat of using the compulsory licensing provisions can lead to a negotiated outcome. Part of the reason why there are relatively few cases may be that, ordinarily, the patentee will have an incentive to maximise revenue by selling the product or using the process in Australia.

Examples of experience in practice involving compulsory licences follow. Because licence agreements are usually on confidential terms, it is not possible to list all such agreements, or to provide full details of those listed in a general way below.

1. A licence of bauxite processing technology was negotiated after proceedings were commenced seeking orders for a compulsory licence. A negotiated outcome was achieved before the proceedings progressed beyond pleadings.

2. After discussions stalled in relation to a licence to a patent covering a hepatitis E assay kit, an application and statement of claim pursuant to section 133 (1) of the *Patents Act* were prepared. The pleadings were given to the patentee and a licence was subsequently granted without the need for the proceeding to be issued.

3. In a claim in relation to another assay kit, proceedings were commenced in which the cross-claimant alleged invalidity, or in the alternative, sought a compulsory licence. A negotiated licence was ultimately agreed prior to trial.

It is also relevant that in most cases a patent licence entered into includes access to know-how. Proceeding on the assumption that the words "licence to work the patented invention" in section 133 do not extend to cover know-how, the compulsory licensing provisions do not deal with this potential obstacle to an agreement being reached to exploit a patent. To that extent, the solution to the availability of access to technology

requires a commercial negotiation between a patentee/owner of know-how and a prospective licensee in any event.

## 3. Compulsory Licensing - Price Dispute Only

Australia is a signatory to several international agreements which, in addition to establishing patentability criteria, impose conditions on Australia's right to authorise non-voluntary access to patents (including compulsory licences). The most significant international agreements are the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS) and the *Australia-United States Free Trade Agreement* (AUSFTA).

Section 136 of the *Patents Act* directs the Federal Court not to make an order under the compulsory licensing provisions that is inconsistent with Australia's international treaties. Hence, Australia's multilateral and bilateral international obligations, such as those under TRIPS and AUSFTA respectively, have limited the types of provisions that the Australian Government has been, and is, able to introduce into Australia's patent legislation.

### 3.1 TRIPS

On 1 January 1995 Australia became a World Trade Organisation (WTO) Member State, and thereby a signatory of WTO Agreements including TRIPS. As such, Australia must comply with the minimum standards specified in TRIPS. TRIPS aims to establish a common global standard for the protection of intellectual property rights, including patents.[1] The common global standard of patent protection extends to a common approach to compulsory licensing in domestic intellectual property law.[2]

Article 31 of TRIPS, "Other Use Without Authorization of the Right Holder", allows, under certain conditions, the use of a patent without the authorisation of the patent holder. TRIPS does not specify the grounds for allowing non-voluntary access, but it does impose conditions on the circumstances in which use may be authorised, namely:

- authorisation shall be considered on its individual merits[3];
- the proposed user has sought authorisation from the patentee on reasonable commercial terms and conditions and has not been successful within a reasonable period of time (waived during times of national emergency or situations of extreme urgency or in the case of public non-commercial use)[4];
- the authorisation has a limited scope and duration[5];
- such use[6] is non-exclusive[7], non-assignable[8] and predominantly for supplying the domestic market[9];

[1] World Trade Organization (2011) Intellectual property: protection and enforcement. Available: http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm. Accessed 17 September 2012.
[2] World Health Organization Briefing note: access to medicines—country experiences in using TRIPS safeguards (February 2008). Available: http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf. Accessed 17 September 2012.
[3] Article 31(a).
[4] Article 31(b), however, Members are not obliged to apply the conditions set forth in subparagraph (b) where such use is permitted to remedy a practice determined after judicial or administrative process to be *anti-competitive*. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases: Article 31(k).
[5] Article 31(c).

- the authorisation will be terminated if the circumstances which led to the initial authorisation of non-voluntary access cease to exist, with the competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances[10];
- the patentee/rights holder receives adequate remuneration, taking into account the economic value of the authorisation[11]; and
- decisions related to use[12] and remuneration[13] are subject to judicial review.

The *Declaration on the TRIPS Agreement and Public Health* (the Doha Declaration) affirmed that TRIPS "does not and should not prevent Members from taking measures to protect public health"[14] and that Members are free to determine the grounds upon which compulsory licences are issued, which can include public health crises.[15]

Further agreement was reached on 30 August 2003 (the August 2003 Decision)[16] to allow Members to issue compulsory licences for export to countries that lack manufacturing capacity in circumstances of national emergency or other circumstances of extreme urgency. Paragraph 11 of the 2003 Decision expressly envisages a permanent amendment to TRIPS based on the 2003 Decision. On 6 December 2005 the WTO General Council agreed to the *Protocol Amending the TRIPS Agreement*[17] to amend TRIPS to incorporate the waiver provision permanently by addition of "Article 31bis" as an Annex to TRIPS. The amendment will take effect when it is ratified by two-thirds of WTO Members,[18] which has failed to occur to date. Canada, India, Norway, Switzerland, the EU, India, China, Korea and the Netherlands have implemented domestic legislation allowing for compulsory licensing of generic drugs in accordance with the 2003 Decision. However, a large number of developed countries that have failed to do so include the United States, Japan and Australia. Australia accepted the Protocol on 12 September 2007,[19] but has not amended the *Patents Act* to provide an appropriate legal environment

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[6] Article 30: Exceptions to Rights Conferred: Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such 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.

[7] Article 31(d).

[8] Article 31(e).

[9] Article 31(f), however, Members are not obliged to apply the conditions set forth in subparagraph (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be *anti-competitive*. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases: Article 31(k).

[10] Article 31(g).

[11] Article 31(h).

[12] Article 31(i).

[13] Article 31(j).

[14] *Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (2001), art 4. See also, *TRIPS Agreement,* opened for signature 15 April 1994, 1867 UNTS 3, annex 1C, art 8 (entered into force 1 January 1995).

[15] *Declaration on the TRIPS Agreement and Public Healt*h, WTO Doc WT/MIN(01)/DEC/2 (2001), art 5.

[16] *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 and Corr 1 (2003) ('Decision of the General Council of 30 August 2003') <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm> at 17 September 2012.

[17] *Amendment to the TRIPS Agreement*, WTO Doc WT/L/641 (2005) (General Council).

[18] As of 21 August 2012 only 44/155 Member States have accepted the amendment.

[19] WTO, *Members Accepting Amendment of the TRIPS Agreement* (2008)

<http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> at 17 September 2012.

for the export of pharmaceuticals under Protocol conditions.[20] It is arguable that the types of uses intended under the Protocol are permissible under AUSFTA since the permitted uses without authorisation in article 17.9.7(b) of AUSFTA include national emergency, or other circumstances of extreme urgency, subject to certain limitations that would have to be included in the enabling legislation.

### 3.2 AUSFTA

AUSFTA came into effect on 1 January 2005, and primarily ensures greater access to the United States of America market for Australian products. The implications for Australia from entering this bilateral agreement is that not only does any domestic patent legislation have to comply with the minimum standards set by TRIPS, but it must also comply with the much higher standards agreed to under AUSFTA, "TRIPS-plus provisions"[21], which limit the grounds for use without authorisation to the special categories mentioned in TRIPS.

Hence, while article 31 of TRIPS imposes no limitations on the grounds for compulsory licensing or Crown use, both Australia and the United States of America have agreed to limit the grounds in their legislation to the specific matters identified therein. Use without authorisation in Australia is now limited to the situations provided under section 17.9.7 AUSFTA.

Section 17.9.7 of AUSFTA limits the use[22] of a patented invention without authorisation of the patentee to:

- remedying a practice determined to be anti-competitive — after judicial or administrative process — under either country's laws relating to prevention of anti-competitive practices;[23]
- cases of public non-commercial use, national emergency, or other circumstances of extreme urgency, provided that:
    - use is limited to use by the government or third persons authorised by the government;[24]
    - the patent owner is provided with reasonable compensation for such use;[25] and
    - the patent owner is not required to provide undisclosed information or technical know-how related to a patented invention.[26]

It is not clear from the text of AUSFTA whether it is intended to restrict the national emergency and other circumstances provision to situations solely within Australia. If this

[20] J Nielsen and D Nicol, 'Whither Patent Use Without Authorisation in Australia?' (2008) 36(3) *Federal Law Review* 331.
[21] Frankel, 'Challenging TRIPS-Plus Agreements' (2009) 12(4) *Journal of International Economic Law* 1023, 1025.
[22] "Use" in this paragraph refers to use other than that allowed under paragraph 3 and Article 30 of the TRIPS Agreement.
[23] Section 17.9.7(a).
[24] Section 17.9.7 (b)(i).
[25] Section 17.9.7(b)(ii).
[26] Section 17.9.7(b)(iii).

were the case, it would prevent Australia from implementing the 2003 Decision under TRIPS.[27]

The ALRC Report on Gene Patenting concluded that AUSFTA restricts the "reasonable requirements of the public test" to matters related to competition within a market or public non-commercial use.[28] However, section 17.9.7(b)(i) restricts public non-commercial users to the government or third parties authorised by the government, suggesting that this provision concerns Crown use rather than compulsory licensing. Given that a new anti-competitive conduct test has been added to section 133 *Patents Act* (and is apparent in AUSFTA at (a)), it is unclear whether there is any genuine scope for issuing a compulsory licence under the "reasonable requirements test". However, the Australian Government has advised that it does not intend to amend the existing test in light of AUSFTA. The approach preferred by the Australian Government is that the term “anti-competitive practices” addressed in AUSFTA should be interpreted broadly so as to cover the existing compulsory licence provisions under the *Patents Act*, and this will include “the grant of a compulsory licence if, among other conditions, 'the reasonable requirements of the public’ have not been met”.[29]

## 4. Court Determination of Licence Terms and Conditions

Case law of the United Kingdom demonstrates that courts and relevant authorities (Comptroller-General of the Patents Office, and Patents Court) in that jurisdiction have been able to determine licence terms and reasonable royalty rates for compulsory licences under legislation analogous to that in Australia.

*In the Matter of an Application by McKechnie Bros Ltd's for a Compulsory Licence in respect of certain Letters Patent* (1934) 51 RPC 461 concerned a patent granted to a German company in respect of improvements in the manufacture of lithopone. The assignees and their licensees of the patent appealed against the decision of the Comptroller who had allowed McKechnies' application for a compulsory licence under section 27 of the *Patents and Design Acts 1907 to 1932*. Justice Luxmoore of the High Court of Justice upheld the decision of the Comptroller to order a compulsory licence and found that the reasonable royalty be determined by looking at the royalty reserved in the original licence agreements between the patentee and the original licencees, which was assumed to have been fixed on a fair commercial basis from the point of view of the patentee.

*In the Matter of an Application by A. Hamson & Son (London) Limited for a Licence under No 635,123* [1958] RPC 88 concerned a compulsory licence application under section 37 of the *Patents Act 1949*. Having determined that the grounds under section 37 had been made out by the applicants, the Superintending Examiner (acting for the Comptroller-General) granted a compulsory licence and ordered that the terms of the licence, including the royalty rate, be determined at a subsequent hearing following the applicants' submission of a draft licence agreement (with supporting financial and commercial evidence), upon which the patentee could comment (with supporting financial and commercial evidence). The applicants submitted a draft compulsory licence agreement,

[27] J Nielsen and D Nicol, 'Whither Patent Use Without Authorisation in Australia?' (2008) 36(3) *Federal Law Review* 331.
[28] Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health* (Report No 99, 2004) chs 26, 27, p 615.
[29] Charles Lawson, 'Compulsory Licensing under the Patents Act 1990 to remedy anticompetitive conduct under the Trade Practices Act 1974' (2008) 36 *Australian Business Law Review* 369.

which the patentee did not oppose, and which was ultimately granted by the Superintending Examiner.

*Penn Engineering and Manufacturing Corp's Patent* [1972] FSR 533 was heard before the Patents Appeal Tribunal (on appeal from the decision of Superintending Examiner, acting for the Comptroller-General) and concerned an application for a compulsory licence under section 37 of the *Patents Act 1949* in relation to a patent covering self-anchoring studs. The Superintending Examiner, having found that a demand for the patented article in the United Kingdom was being met solely by importation, went on to decide that a non-exclusive compulsory licence should be granted to the applicants. After hearing expert evidence, the Superintending Examiner further determined the rate of royalty at five per cent of the licensees' net selling price by reference to royalties in comparable licence agreements relating to engineering components, and that this rate was sufficient to ensure the patentees' reasonable remuneration.[30] Justice Graham of the Patents Appeal Tribunal upheld the Superintending Examiner's decision to grant a compulsory licence, the terms of that licence and the associated royalty rate.[31]

The Court of Appeal's decision in *Allen & Hanburys Limited's (Salbutamol) Patent* [1987] RPC 327 has been considered by later courts as laying down the current guidelines for determining the royalty rate for a compulsory licence.[32] In that case, the patent in suit related to salbutamol, a pharmaceutical used in the treatment of asthma. The applicants for a "licence of right" under section 46 of the *Patents Act 1977*[33], having been unable to agree on a royalty and certain other terms with the patentees, sought to have them settled by the Comptroller. The majority of the Court held that the powers of the Comptroller when settling the terms of a licence were to be exercised with a view to ensuring, among other general purposes, that the patentee received reasonable remuneration having regard to the nature of the invention (as per section 50(1)(b) of the *Patents Act 1977*[34]).

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[30] ps 539-540.

[31] p 545.

[32] See, for example, *In the Matter of the Patents Act 1977 and In the Matter of Smith Kline & French Laboratories Limited's Letters Patent Nos. 1,338,169 and 1,397,436 v In the Matter of the Application of Generics (UK) Limited for Settlement of Terms of a Licence of Right Thereunder* [1989] EWCA Civ J1214-7, and *In The Matter of the Patents Act 1977 v In The Matter of an Application Under Section 46(3) Of The Patents Act 1977 By Generics (UK) Limited For Settlement of Terms of a Licence of Right In Respect Of Letters Patent No 1,291,631 in the Name of the Upjohn Company* [1988] EWCA CivJ1201-2.

[33] Licences of right are granted under section 46 of the *Patents Act 1977*. While licences of right are not strictly compulsory licences under section 48 of the *Patents Act 1977,* sections 46 and 48 are part of a group of sections, sections 46 to 54, headed 'Licences of Right and Compulsory Licences', which require similar considerations in determining licence terms: Lord Justices Lord Lloyd, Nicholls and Butler-Sloss in *In the Matter of the Patents Act 1977 and In the Matter of Smith Kline & French Laboratories Limited's Letters Patent Nos. 1,338,169 and 1,397,436 v In the Matter of the Application of Generics (UK) Limited for Settlement of Terms of a Licence of Right Thereunder* [1989] EWCA Civ J1214-7; Justice Dillon at p 368 in *Allen & Hanburys Limited's (Salbutamol) Patent* [1987] RPC 327.

In fact one of the ways by which a patent might come to be the subject of a licence of right is by an application under section 48(1)(b): Justice Dillon at p 368 in *Allen & Hanburys Limited's (Salbutamol) Patent* [1987] RPC 327.

The link between sections 46 and 48 is particularly strong, because where an application is granted under section 48, the Comptroller has alternative powers, one of which is to order the compulsory registration of the patent under section 46. The other power is to grant a licence either to the applicant or, where the applicant is a government department, to the person specified in the application, but in each case "in such terms as the Comptroller thinks fit.": per Lord Justice Woolf at p 384 in *Allen & Hanburys Limited's (Salbutamol) Patent* [1987] RPC 327.

[34] Section 50(1)(b) provides that, in exercising his power to order a compulsory licence under the Act, the Comptroller must secure, among other things, that "the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the nature of the invention." Section 50(1) had been previously acknowledged as providing guidance on the objects which Parliament intended to be

The effect of this was that a court had to consider what a willing licensor and a willing licensee would have agreed upon as a reasonable royalty to be paid for the rights granted to the applicant under the proposed licence.[35] The elements required to be taken into account when considering what amounted to "reasonable remuneration" included those under section 41 of the *Patents Act 1949*,[36] namely allowances for the recovery by the patentee of the costs of discovering the drug and establishing its efficiency (research and development costs), allowances for the recoupment to the patentee of the promotional expenses incurred in creating and maintaining the market for it (promotional costs), and a reward to the patentee for his contribution to the art secured by an appropriate measure of profit upon the capital invested (profit uplift).[37] Finally, the Court held that the patentee's position as manufacturer was an irrelevant consideration in fixing the royalty.[38]

The most recent of the five cases analysed is *In the Matter of the Patents Act 1977 and In the Matter of Smith Kline & French Laboratories Limited's Letters Patent Nos. 1,338,169 and 1,397,436 v In the Matter of the Application of Generics (UK) Limited for Settlement of Terms of a Licence of Right Thereunder* [1989] EWCA Civ J1214-7. The two appeals in this case concerned the terms of licences of right to be granted to the applicants Generics (UK) Limited and Harris Pharmaceuticals Limited who wished to manufacture, import and sell Smith, Kline and French Laboratories Limited's patented product, cimetidine. Specifically, the Court of Appeal, on appeal from the Patents Court, determined the appropriate royalty rate for the previously granted licences of right. In affirming its earlier approach in *Allen & Hanburys Limited's (Salbutamol) Patent* [1987] RPC 327, the Court held that determination of a fixed royalty rate per unit quantity of the patented product used was primarily a matter of fact and discretion of the Patents Office and Patents Court (on appeal), based on expert evidence such as that from expert economists and accountants, and that the principle of "reasonable remuneration" can be determined by analysing the nature of the invention, comparable licence royalty rates, and section 41 of the *Patents Act 1949* considerations.[39]

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achieved by the Comptroller when exercising his discretion regarding the terms of a licence, whether the licences of right entry is made voluntarily or compulsorily, as confirmed in *Allen & Hanbury's Limited v. Generics (U.K.) Limited* [1986] RPC 203.

[35] p 376.

[36] Section 41 of the *Patents Act 1949*, now repealed, provided that the Comptroller was empowered to grant a compulsory licence in respect of, inter alia, medical patents. In settling terms he was obliged to secure that medicines should be available to the public at the lowest price consistent with the patentee deriving a reasonable advantage from his patent rights. A practice grew up of taking three elements into account in settling terms under the old section 41: (i) an allowance for the patentee's research and development costs, (ii) an allowance for his promotional costs, and (iii) an appropriate uplift. The first and second elements are classed together as the compensation element in the calculation; the third is the reward element. This practice was recognised in *Geigy's Patent* [1964] RPC 391 and was approved by the Court of Appeal in *Allen & Hanburys Limited's (Salbutamol) Patent* [1987] RPC 327, 376 in the context of section 50(1)(b) of the *1979 Act*.

[37] p 376.

[38] p 378.

[39] per Lord Justice Nicholls (majority judgment): "In my view the judge's conclusion on the royalty rate was justified on the evidence before him. 45 per cent is a very high royalty rate but, generally speaking, in these cases the best evidence will be that of close comparables if there are any. Here there was one: the atenolol licences. There was also the Rhone-Poulenc agreement, although this cannot be regarded as close a comparable as the atenolol licences. When one adds to the two figures of 47 per cent and 42 per cent, the figure of 42 per cent from the section 41 calculation and notes that the latter figure takes no account of the nature of the invention, the judge's conclusion of 45 per cent speaks for itself. To use the "profits available" approach as a crosscheck: a royalty rate of 45 per cent on SKF's selling price would represent a division of the 64 per cent "profits available" between the patentee and the licensees in the approximate proportions of five-sixths and one-sixth, the one-sixth equalling a return of about 11 per cent on the licensees' likely selling price. This is a small share for the licensees. But given that the licensees are entering a very large,

Australian courts could seek guidance from the jurisprudence of the United Kingdom in applying the current compulsory licence provisions under the *Patents Act*.

## 5. Technology Neutral

The compulsory licensing provision should remain technology neutral as a matter of general principle and in accordance with the Australian Government's obligations under international agreements.

The separate treatment of a specific field of technology such as health, pharmaceuticals or gene technology is likely to lead to legislative complexity, the use of loopholes, inconsistency, and the need for judicial intervention to resolve issues, and therefore should not be implemented.

Furthermore, the separate treatment of a specific field of technology may be an unjustifiable discrimination against a field of technology that is offensive to TRIPS and AUSFTA-defined international patent norms and other treaties or agreements to which Australia is a party.[40]

This is consistent with the general scheme of the *Patents Act* and in particular Sections 119B and 119C of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012,* which is technology and industry neutral. Section 119A of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012,* which is an exception, deals with a minor and very specific issue.

## 6. Crown Use

The Crown use exception in the *Patents Act* should not be used as a general, substantial alternative to the compulsory licence exception. Section 163(3) of the *Patents Act* allows for exploitation of an invention by the Commonwealth or a State "for the services of the Commonwealth or a State" provided that the exploitation is "necessary" for the proper provision of those services. Hence, the Crown use exception is more limited in scope compared to the compulsory licensing provisions in sections 133 and 135 of the *Patents Act* which have a broader focus on meeting the "reasonable requirements of the public" and addressing anti-competitive conduct.

The scope of the Crown use exception has been further limited by the inclusion of section 165A into the *Patents Act* which provides that a court can declare that the Commonwealth's or State's exploitation of the invention is not, or is no longer, "necessary" for the proper provision of services of the Commonwealth or State, and can further order the Commonwealth or the State to cease exploiting the invention. Section 165A of the *Patents Act* was introduced in the context of the *Patents (World Trade Organization Amendments) Act 1994* (Cth). The Explanatory Memorandum to the *Patents (World Trade*

established market with a proven product which costs comparatively little to manufacture, and given also the risks taken by SKF in discovering and proving the product and establishing the market, I do not think this division is so manifestly unreasonable as to cause me to disturb the judge's conclusion."

[40] TRIPS article 27.1, and generally, article 31 (reference to 'a patent' without discrimination based on field of technology); Australia-United States Free Trade Agreement section 17.9.1.

*Organization Amendments) Act 1994* does not clarify the intended operation of section 165A, however, it states that "the purpose of this Bill is to amend the *Patents Act* to bring it in line with the standards and principles prescribed for patents in the agreement establishing the World Trade Organisation". The international Crown use provisions contemplated by the Australian Government are provided in TRIPS (article 31(g)) and AUSFTA (section 17.9.7(b)(i)). Notably, article 31(g) of TRIPS refers to the termination of the authorised use of a patent where the circumstances which led to the authorised use no longer exist.

There has been no judicial authority on the interpretation of "necessary" to date, but it is the view of the IPC that "necessary" is likely to be interpreted as "substantially more than convenient" or "reasonably required to achieve the benefits of economy and efficiency" in line with the term's judicial interpretation in other legislation and case law. Under such an interpretation, it is unlikely that the Crown use exception could be applied in a situation where price negotiations for a voluntary licence are on foot or where the patented product is in fact available, albeit at a higher price. It is possible that the Crown use exception could be applied in situations where the price of the patented product is greater than what is reasonable, where the patented product is urgently needed and there is no time to negotiate a voluntary licence, and where the patented product is not available for licence (in which case the current compulsory licensing provisions could be utilised).

However, the IPC submits that the Productivity Commission's specific concern for compulsory licensing of gene patents, as opposed to patents generally, can be more appropriately addressed through the experimental use exception. In particular, section 119C of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* effectively addresses one of the criticisms of gene patenting by providing a research and development exemption titled "acts for experimental purposes". This exemption permits genuine research to continue despite the presence of gene patents covering, for example, diagnostic type products.

## 7. Collecting Schemes

Collecting schemes are unlikely to have any useful place in the context of patents. While there are examples of industries (including aspects of computer technology) where widespread non-exclusive licensing, including bulk pricing of patents, is known, we are not aware of any examples of a successful collecting scheme for patents anywhere in the world. It is likely that the reason for that is quite fundamental. In particular, the variable nature and value of patent rights would mean that the determination of price to users and the distribution of royalties to patentees would frequently need to be assessed on a case by case basis. The ability to determine a standard general charging mechanism and a fair general method of splitting the revenue among IP owners, which are the key to collecting schemes, are not present. Administrative costs and disputes at both levels are likely to consume any return.

While a collecting scheme arrangement could be implemented on a voluntary basis, there is no present need for a statutory-based scheme.

## 8. Compulsory Licensing Statistics

World Intellectual Property Organisation resources indicate that as of March 2011 the following number of compulsory licences had been granted for patents in the named regions: 36 in Africa, 25 in Central and Latin America, 34 in Asia and Oceania, 39 in

Europe, and 30 in OECD countries. In the Asia and Oceania region 85.2% of the licences granted were for reasons involving non-working of the patent, 70.5% were for reasons involving public interest, 55.8% were for reasons involving correction of patent abuse, and 55.8% were for reasons involving government use.[41]

The article by Reed Beall and Randall Kuhn, 'Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis' (2012) 9(1) *Public Library of Science* e1001154, concludes that there have been 24 instances where compulsory licences relating to pharmaceuticals have been publicly entertained or announced by 17 WTO Member states following the Doha Declaration between 1 January 1995 and 6 June 2011. Twelve out of 24 compulsory licence instances resulted in the announcement of a compulsory licence, but the great majority ended in a price reduction for the potential issuing nation, whether via a compulsory licence, voluntary licence, or discount.[42] Most of these instances occurred between 2003 and 2005 involving drugs for HIV/AIDS, and occurred in upper-middle-income countries. The article and the supporting information annexed to the article contain useful summary tables and a compilation of case summaries of the 24 instances of compulsory licensing.

## 9. General

As noted in the summary, the IPC is concerned that any scheme relating to compulsory licensing should balance the positive and negative affects of compulsory licensing.

A useful summary of the potential negative economic effects of domestic compulsory licensing, which the Productivity Commission should consider, is contained within Dr Richard P Rozek's article, 'The Effects of Compulsory Licensing on Innovation and Access to Health Care' (2000) 3 *Journal of World Intellectual Property* 889. Dr Rozek's article is based on the Canadian experience under Canada's former compulsory licensing scheme.

In the pharmaceutical context, a party wishing to gain access to the pharmaceutical market can be assisted by section 119A of the *Patents Act* which exempts from infringement acts done solely for the purpose, or connection with, obtaining regulatory approval for a pharmaceutical. Similarly, section 119B of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* exempts from infringement acts done solely for the purpose, or connected with, obtaining regulatory approval for agro chemicals, veterinarian medicines, medical devices, diagnostics and any other non-pharmaceutical subject matter for which there is a legally established regulatory approval regime. Section 119B is not prescriptive and is intended to cover both the current regulatory approval regimes and those that may be established in the future. Finally, section 119C of *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* exempts genuine acts of research and development from infringement provided that the experimental activities are related to the subject matter of the invention. Therefore, inability to negotiate a

[41] Marco Aleman (Deputy Director, Patents and Innovation Division and Head, Legislative and Policy Advice, World Intellectual Property Organisation), 'Topic 3: Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels' (Presentation delivered at the Regional Seminar on the Effective Implementation and Use of Several Patent-Related Flexibilities, Bangkok , 29-31 March 2011) http://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_bkk_11/wipo_ip_bkk_11_ref_topic3.pdf> at 10 September 2012.

[42] Reed Beall and Randall Kuhn, 'Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis' (2012) 9(1) *Public Library of Science* e1001154, p 3.

licence is not an impediment to undertaking certain steps in relation to subject matter covered by a patent.

The matters identified in the headings above assist to maintain the delicate *equipoise* between stimulating investment and innovation on the one hand, and general public, competitor and researcher access to new technology on the other hand that underpins the *Patents Act*.

The IPC would be happy to discuss any aspects of this submission.

Due to time constraints, this submission has not been considered by the Directors of the Law Council of Australia.

Yours faithfully

**Professor Sally Walker**
**Secretary-General**