



Licensing Executives Society of Australia and New Zealand Inc (LESANZ)

Executive summary of briefing notes in respect of the
Patent Amendment (*Human Genes and Biological Materials*) Bill 2010

These notes take into account the extent of jurisprudential and other support for the existing provisions within the Patents Act on Crown use, compulsory licensing, compulsory acquisition by Government and competition law.

This information is provided in support of LESANZ's position that existing mechanisms render the Bill unnecessary.

In February 2011 LESANZ made submissions to the Senate Legal and Constitutional Affairs Committee in opposition to the proposed Patent Amendment (*Human Genes and Biological Materials*) Bill 2010 (the Bill).

While LESANZ did not comment on the substantive detail of the Bill, LESANZ supports the views outlined in submissions from organisations directly involved in clinical, medical and scientific research such as WEHI, the Group of Eight, AusBiotech and the Murdoch Children's Research Institute to name but a few.

LESANZ believes that the proposed amendments to the Patents Act are unnecessary for the following reasons:

1. There are *existing provisions* contained in the Patents Act and in the Competition and Consumer Act 2010 which, if properly utilised, are entirely capable of providing access to patents for genes and other biological materials by Commonwealth or State healthcare providers in situations where the patented technologies are of national importance or where access is being inappropriately prevented by the patent owner.

2. The Intellectual Property Laws Amendment (*Raising the Bar*) Bill 2011, proposes two new exemptions to the Patents Act which again, if properly utilised, will operate to provide clinicians, researchers and the wider community appropriate access to patents for biological materials.

Existing provisions

CROWN USE (s 163 of the Patents Act)

The Patents Act currently provides that at any time after a patent application has been lodged or a patent granted, the Commonwealth or a State, or a person authorised in writing by the Commonwealth or a State, may exploit the invention without infringement provided the exploitation is for the services of the Commonwealth or State.

- Crown Use has been upheld in two Australian and two UK decisions.
 - *Stack v Brisbane City Council*
 - *General Steel Industries Inc v Commissioner for Railways (NSW)*
 - *Pyrene and Autogene*
 - *Pfizer Corporation v Ministry of Health*

The patent owner is entitled to just and equitable compensation for Crown use as may be agreed mutually or fixed by the court under s 163 of the Patents Act.

LESANZ's views on Crown Use align with

(i) the ALRC 2004 report on "*Genes and Ingenuity: Gene Patenting and Human Health*" which recommended that the Patents Act be amended so that "for the services of the Commonwealth or of a State" includes provision of healthcare services or products to members of the public¹ in order, for example, to facilitate access to patented inventions for public healthcare or where patented biotechnology products are required for public research purposes. The ALRC additionally recommended the Commonwealth to amend the Patents Act to provide prompt, reasonable and just remuneration when a patent is exploited under Crown Use provisions; and

(ii) the findings of the ACIP 2005 Review of Crown Use Provisions for Patents and Designs²

LESANZ considers generally that if the recommendations of the ALRC and ACIP reports are implemented by Government they will provide a relevant and effective solution to ensure ongoing access of clinicians, researchers, industry and the public to innovative therapeutics and devices.

COMPULSORY LICENSING (s 133 of the Patents Act)

Although a compulsory licence has never been granted in Australia, the existing compulsory licensing provisions nonetheless operate as an incentive to patent holders to make their inventions available to the public or enter into licensing arrangements.

The compulsory licensing scheme allows the Federal Court to grant a licence where the applicant establishes that all of the conditions under sub-s 133(2) exist or the patent owner has contravened Part IV of the *Competition and Consumer Act 2010* ("CCA").

Once a court finds that the reasonable requirements of the public have not been satisfied, it should order the licence or revocation of the patent unless there is a sound reason for not doing so.³ Sound reasons have been found to include unsuitability of the proposed licensee and good reasons for delays in establishing local manufacturing.

The threat of compulsory licences is not to be underestimated, particularly where negotiations break down between IP holders and potential licensees. The presence of compulsory licensing provisions operates to facilitate negotiations, and where negotiations fail, courts have the expertise to determine reasonable compensation⁴.

COMPULSORY ACQUISITION BY GOVERNMENT (s 171 of the Patents Act)

Section 171 of the Patents Act allows the Commonwealth to acquire a patent and for compensation to be paid to the patent owner and all compensable persons.

To date there have not been any acquisitions of patents by the Australian government using this provision.

COMPETITION LAW (Competition and Consumer Act 2010)

Part IV of the CCA deals with anti-competitive conduct, and proscribes contracts, arrangements or understandings which restrict dealings or affect competition.

Among the types of anti-competitive conduct proscribed under Part IV is the misuse of market power (s 46). Although sub-section 51(3) of the CCA provides certain exemptions for intellectual property licences and assignments, to the extent that they 'relate' to the subject matter of the IP right, that provision does not exempt activity in relation to a patent that contravenes section 46 of the CCA, misuse of market power.

Accordingly, a patent owner may contravene s 46 of the CCA by refusing to grant a licence under the patent if the owner has a substantial degree of market power and is taking advantage of that power to establish barriers to entry into the relevant market.

¹ ALRC, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99, June, 2004 p. 21

² Australian Government Advisory Council on Intellectual Property (ACIP) Review of Crown Use Provisions for Patents and Designs, November 2005

³ *Ibid* at [20,270]

⁴ *Ibid* Yosick at 1298

LESANZ contends that the existing provisions of the CCA whereby a complainant can take action against patent owners that misuse market power are adequate and sufficient and thus add further weight to the argument that the proposed amendments to the Patents Act are unnecessary.

International Perspectives on Compulsory Licensing

TRIPS regulates compulsory licences under Article 31 (Other Use Without the Authorization of the Right Holder). The requirements include an attempt to obtain a licence from the patent holder, use of the patented invention primarily for the domestic market and adequate remuneration to the patent holder for the compulsory licence.

Governments may also impose compulsory licences under TRIPS as remedies for anti-competitive practices⁵. Most major industrial nations have the power to grant compulsory licences, subject to the limitations imposed by the Paris Convention for the Protection of Industrial Property, Stockholm, 1967, amended 1979 and TRIPS and usually allow an initial period of three to five years for exploitation of the patented invention before a compulsory licence may be granted⁶.

Overseas arguments in favour of compulsory licensing emphasise that in addition to the first three to five year window, licences are not able to be granted unless the invention is for domestic use or it is blocking a dependent patent and the inventor is entitled to reasonable royalties⁷.

One of the traditional arguments against compulsory licensing is that it discourages innovation. However, surveys in the US have concluded that reasonable compulsory licensing would have little adverse impact on the patent system⁸.

The threat of compulsory licences is not to be underestimated, particularly where negotiations break down between IP holders and potential licensees. Another traditional argument put forward against compulsory licensing is the difficulties of setting appropriate royalty rates. The presence of compulsory licensing provisions operates to facilitate negotiations, and where negotiations fail, courts have the expertise to determine reasonable royalty rates⁹.

⁵ TRIPS art 31(k)

⁶ Yosick, J at 1292

⁷ Ibid Yosick, J at 1292

⁸ Ibid Yosick, J at 1293, citing F. M. Scherer, *The Economic Effect of Compulsory Patent Licensing* 84 (Ctr. For the Study of Fin, Inst. N. Y. Univ., Monograph No. 1977-2, 1977) at 51

⁹ Ibid Yosick at 1298



background briefing paper

Licensing Executives Society of Australia and New Zealand, Inc (LESANZ) submissions in response to the proposed *Patent Amendment (Human Genes and Biological Materials) Bill 2010*

INTRODUCTION AND PURPOSE

This background briefing note provides information for your assistance with presenting LESANZ's position to members of Federal Parliament in respect of the proposed amendments to s 18 of the *Patents Act 1990* (Cth) ("Patents Act") by the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* ("the Bill").

This note discusses the extent of jurisprudential support and other support (such as recommendations by the Australian Law Reform Commission or the Trade Practices Commission where appropriate) for the existing provisions within the Patents Act on Crown use, compulsory licensing, compulsory acquisition by Government and competition law. Where appropriate, reference has been made to overseas jurisdictions. The information is intended to support LESANZ's position that these existing mechanisms render the Bill unnecessary.

BACKGROUND

LESANZ made submissions to the Committee Secretary of the Senate Legal and Constitutional Affairs Committee dated 25 February 2011 (**Doc 1**) in opposition to the proposed amendments to s 18 of the Patents Act by the Bill (**Doc 2**).

The purpose of the Bill is set out in the Explanatory Memorandum (**Doc 3**), namely to enable doctors, clinicians, medical and scientific researchers to have "*free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature.*"¹⁰

LESANZ does not make submissions on the substantive detail of the Bill and supports the positions taken by those organisations directly involved in clinical, medical and scientific research, such as the response by AusBiotech (**Doc 4**).

Rather, LESANZ considers that the proposed amendments to s18 of the Patents Act are unnecessary. There are two reasons for this.

There are existing provisions in the Patents Act, discussed below which provide mechanisms for Government to have access to technologies of national importance or to which access is inappropriately prevented by the patentee. These provisions, if properly utilised, are capable of providing access to gene patents by Commonwealth or State healthcare providers in preference to the fundamental changes proposed to s 18.

The *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011*, introduced into the Senate on 22 June 2011, proposes two new exemptions to the Patents Act, being s 119B (regulatory approval (non-pharmaceuticals) and s 119C (experimental purposes) (**Doc 5**). Again, if these mechanisms are properly utilised, they should also operate to provide appropriate access to gene patents.

CROWN USE (s 163 of the Patents Act)

The operation of s 163 is discussed on page 5 of the LESANZ submission (**Doc 1**).

¹⁰ Purpose of the Bill, *Explanatory Memorandum Patent Amendment (Human Genes and Biological Materials) Bill 2010* p. 2

Sub-section 163(1) provides that at any time after a patent application has been lodged or a patent granted, the Commonwealth or a State, or a person authorised in writing by the Commonwealth or a State, may exploit the invention without infringement provided the exploitation is for the services of the Commonwealth or State.

Crown use has been upheld under the exemption in s 163 of the Patents Act in the following Australian and UK decisions.

Stack v Brisbane City Council (1995) 131 ALR 333 (**Doc 6**)

- Brisbane City Council's use of a patented invention for water meter assemblies was held to be use within the scope of the Crown use exemption. Cooper J considered Brisbane City Council was an authority of a State for the purpose of s 163. The focus is to be on government and its functions, whether the functions of the relevant authority have the 'stamp' of government and whether the authority has been given the power to direct or control the affairs of others on behalf of the State.

General Steel Industries Inc v Commissioner for Railways (NSW) (1964) 112 CLR 125

- Barwick CJ upheld Crown use under the predecessor to s 163 of the Patents Act for the use of an invention for central bearing structures for railway carriage construction by a State Commissioner for Railways. In considering the phrase 'for the services of the State', Barwick CJ had regard to the UK decisions in *Pyrene Company Limited v Webb Lamp Company Ltd* (1920) 37 RPC 57 ("Pyrene") and *Aktiengesellschaft Fur Autogene Aluminium Schweissung v London Aluminium Co. Ltd* (No. 2) (1923) 40 RPC 107 ("Autogene") (see below).

Pyrene and Autogene

- The two UK decisions of *Pyrene* and *Autogene* considered by Barwick CJ in *General Steel* both upheld the relevant uses as Crown use under the equivalent predecessors to s 163.
- *Pyrene* (UK) concerned the supply of fire extinguishers by the Ministry of Munitions during the First World War and *Autogene* (UK) concerned Government use of patents relating to the welding of aluminium articles.

Pfizer Corporation v Ministry of Health [1965] AC 512 ("Pfizer")

- *Pfizer* concerned the use of tetracycline in the National Health Services. The Minister for Health had attempted to outsource the supply of tetracycline by tender from firms to manufacture the drug in Italy and re-supply to patients under the Crown use exemption.
- The majority of the court considered the re-supply to patients was a use for the services of the Crown. The dissenting judges considered that the re-supply to patients went beyond the scope of the Crown use exemption as having the effect of withdrawing from the benefit of the patent a large part of the customers (the general public) who were not part of a Government department or Crown service.

Just and equitable compensation for Crown use

The patent owner is entitled to be compensated for Crown use under s 163 of the Patents Act. If there is no agreement with the patent owner on exploitation terms or appropriate compensation, a court may fix those terms or compensation.

Compensation is to be just and equitable and may include compensation which any person interested in the invention or patents has received directly or indirectly from the Commonwealth or a State but does not include loss of the opportunity to manufacture or manufacturing profits: *Patchett's Patent* (CA) [1967] RPC 237.

ALRC recommendations on Crown use provisions

The ALRC in its 2004 report on “*Genes and Ingenuity: Gene Patenting and Human Health*” (Doc 7 – relevant extracts), recommended practical options including encouraging Commonwealth, State and Territorial health departments to exercise existing legal options to facilitate access to patented inventions and clarification of the Crown use and compulsory licensing provisions of the Patents Act.

Where gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or healthcare, the ALRC has recommended that Commonwealth, State and Territory health departments consider existing legal options to facilitate access to those inventions, which include:

1. obtaining advice on the validity of the patent;
2. challenging a patent application or granted patent through opposition proceedings;
3. seeking re-examination of a patent or revocation;
4. exploiting or acquiring a patent under the Crown use and acquisition provisions in the Patents Act;
5. applying for a compulsory licence under the Patents Act; and
6. notifying the ACCC of conduct which is perceived to be anti-competitive.

The ALRC recommended that s 163(1) of the Patents Act be amended so that “*for the services of the Commonwealth or of a State*” includes provision of healthcare services or products to members of the public¹¹ in order, for example, to facilitate access to patented inventions for public healthcare or where patented biotechnology products are required for public research purposes.

An additional recommendation made by the ALRC, in light of there being no guidance on the quantum of remuneration payable for Crown use, was that the Commonwealth should amend the Patents Act to provide that:

“when a patent is exploited under the Crown Use provisions the remuneration that is to be paid by the relevant authority must be paid promptly and must be just and reasonable having regard to the economic value of the patent.”¹²

ACIP recommendations on Crown use provisions

The ACIP 2005 Review of Crown Use Provisions for Patents and Designs¹³ (Doc 8) made recommendations which included:

1. the need for prior consent to be obtained before actual use by “hybrid public/private organisations” operating with a view to profit as this type of use should not qualify as ‘public non-commercial’ use¹⁴;
2. authorisation for access to the Crown use provisions be given by the appropriate Minister¹⁵; and
3. an express statutory standard of remuneration (just and reasonable) in the interests of the World Trade Organisation’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS) (and AUSFTA) compliance, assisting with negotiations and courts in determining remuneration¹⁶.

ACIP noted that the UK and NZ have Crown use models similar to Australia, with requirements for notification and remuneration and the ability for the patent holder to dispute the exercise of the Crown use provisions in court.¹⁷

¹¹ ALRC, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99, June, 2004 p. 21

¹² *Ibid* p 608

¹³ Australian Government Advisory Council on Intellectual Property (ACIP) Review of Crown Use Provisions for Patents and Designs, November 2005

¹⁴ *Ibid* ACIP, Executive Summary at p. 2

¹⁵ *Ibid* ACIP at p. 2

¹⁶ *Ibid* ACIP at p. 2

¹⁷ *Ibid* ACIP at p. 13

Canada requires the Government to apply for a compulsory licence and to pay compensation to the patent holder as determined by the Commissioner of Patents, subject to appeal to the Federal Court¹⁸.

The US does not have Crown use provisions as such, but section 1498 (a) of Title 28 of the US Code entitles the owner of IP used by the Government to 'reasonable and entire' compensation¹⁹.

None of the overseas jurisdictions ACIP surveyed provided limitations on the circumstances under which patented inventions may be exploited (save for a non-exhaustive list in the UK) or the types of patents that may be subject to Crown use²⁰.

Submission to ACIP's Discussion Paper included those by the Institute of Patent and Trade Mark Attorneys Australia ("IPTA") (**Doc 9**). IPTA's submissions referred to the COD case 1980²¹ as providing guidance on the types of entities (those which are "conducted in the interest and for the profit of its members"²²) which should be excluded from having access to the Crown use provisions. This issue has been reflected in the ACIP recommendations, as has the issue of Ministerial approval being made contingent on an assessment of whether the relevant entity would gain a commercial advantage.

IPTA also recommended that court processes to recover compensation for Crown use should not be necessary. IPTA suggested that an independent tribunal be established or an expert appointed by the Commissioner of Patents with access to mediation or ADR. This submission was not reflected in ACIP's final recommendations. ACIP recommended that assistance should be sought from the relevant State or Commonwealth Ombudsman. If this fails to resolve the matter, orders would then need to be sought from the appropriate court. ACIP considered that its recommendations dealing with the standard of remuneration and process for determining disputes regarding remuneration would greatly reduce the need to apply to courts²³ for a determination.

LESANZ considers generally that each of the ALRC and ACIP recommendations provides a preferable solution to the suggested amendment proposed by the Bill.

COMPULSORY LICENSING (s 133 of the Patents Act)

The operation of s 133 is discussed on page 6 of the LESANZ submission.

Although a compulsory licence has never been granted in Australia, the compulsory licensing provisions nonetheless operate as an incentive to patent holders to make their inventions available to the public or enter into licensing arrangements.

A competition-based test was inserted into the compulsory licensing provisions by the *Intellectual Property Law Amendments Act 2006* (IPLAA), to give the Federal Court power to grant a compulsory licence if the patentee contravenes Part IV of the *Competition and Consumer Act 2010* ("CCA"). This is discussed under Competition Law below.

The compulsory licensing scheme allows the Federal Court to grant a licence where the applicant establishes that all of the conditions under sub-s 133(2) exist or the patentee has contravened Part IV of the CCA.

The requirements of ss 133(2) of the Patents Act include the 'reasonable requirements of the public' test and that the patentee has given no satisfactory reason for failing to exploit the invention.

Menzies J in *Fastening Supplies Pty Ltd v Olin Matheson Chemical Corp* (1969) 119 CLR 572 observed that the object of the compulsory licensing provisions (in the equivalent sections of the 1952 Patents Act) may dictate that in some circumstances a compulsory licence should be confined to the use of the patented invention for local manufacture and

¹⁸ Ibid ACIP at p. 14

¹⁹ Ibid ACIP at p. 14

²⁰ Ibid ACIP at p. 14

²¹ (1980) 144 CLR 577, cited in the Institute of Patent and Trade Mark Attorneys, Australia Submissions to ACIP – Review of Crown Use Provisions in Patents and Design Legislation, at paragraph 3.2.2

²² Ibid IPTA Submissions to ACIP at paragraph 3.2.2

²³ ACIP at p. 35

sale of products of manufacture, and should not afford the licensee the right to import and sell patented articles.²⁴

Once a court finds that the reasonable requirements of the public have not been satisfied, it should order the licence or revocation of the patent unless there is a sound reason for not doing so.²⁵ Sound reasons have been found to include unsuitability of the proposed licensee and good reasons for delays in establishing local manufacturing.

Sound reasons were found for refusing a compulsory licence for a patented fastener driving bolt tool in *Fastening Supplies* as the exclusive licensee in Australia had good reasons for failing to supply to the public and had acted reasonably in trying to develop the tool for manufacture. The proposed sub-licensee was also not considered to be a suitable company to exploit the invention in Australia.

In *Amrad Operations Pty Ltd v Genelabs Technologies Inc* [1999] FCA 633 (12 May 1999) an application was successfully made for leave to serve an application requesting a compulsory licence overseas on the patentee Genelabs Technologies Inc in the United States (**Doc 10**). The application concerned two diagnostic assay kits for Hepatitis E Virus in Australia, one of which (the IgM diagnostic assay) was confined to use in the Westmead Hospital in Sydney. It appears that Amrad did not continue with its application after it obtained leave to serve the application outside of the jurisdiction.

COMPULSORY ACQUISITION BY GOVERNMENT (s 171 of the Patents Act)

The operation of s 171 of the Patents Act is discussed on page 7 of the LESANZ submission.

Section 171 of the Patents Act allows the Commonwealth to acquire a patent and for compensation to be paid to the patent owner and all compensable persons.

There have not been any acquisitions of patents by the Australian government using this provision. However, any acquisition would need to be on just terms within the meaning of s 51(xxix) of the Constitution, which allows laws to be made with respect to “*The acquisition of property on just terms from any State or person for any purpose in respect of which the Parliament has the power to make laws*”.

In *Smith Kline French Laboratories (Australia) Ltd v Secretary to the Department of Community Services & Health* (1991) 20 IPR 643 it was argued that use of confidential information supplied by SK&F to a government department, where it was used for administrative purposes was an acquisition of property not on the just terms required under s 51(xxix). The Federal Court dismissed this argument because the use of confidential information by the relevant department was administrative and did not amount to an ‘acquisition’ of property.

COMPETITION LAW (Competition and Consumer Act 2010)

Part IV of the CCA deals with anti-competitive conduct, and proscribes contracts, arrangements or understandings which restrict dealings or affect competition.

The types of anti-competitive conduct proscribed under Part IV include:

1. exclusionary provisions
2. misuse of market power (s 46)
3. exclusive dealing
4. resale price maintenance
5. conduct and/or acquisitions likely to have the effect of substantial lessening competition in a market.

Sub-section 51(3) of the CCA provides certain exemptions for intellectual property licences and assignments, to the extent that they ‘relate’ to the subject matter of the IP right. However, that provision does not exempt activity in relation to a patent that contravenes section 46 of the CCA, misuse of market power.

²⁴ Lahore, J and Dufty, ‘*Patents, Trade Marks and Related Rights*’, The interpretation of Chapter 12, Service 146 – May 2011 at [20,270]

²⁵ Ibid at [20,270]

Accordingly, a patent owner may contravene section 46 of the CCA by refusing to grant a licence under the patent if the owner:

1. has a substantial degree of market power; and
2. is taking advantage of that power for one of the anti-competitive proscribed purposes set out in s 46 of the CCA, being:
 - (i) eliminating or damaging a competitor in the market or any other market;
 - (ii) preventing entry to the market or any other market; or
 - (iii) deterring or preventing competitive conduct in the market or any other market.

The existence of IP rights is a relevant factor in establishing whether a corporation has the necessary degree of market power²⁶: Market power may be able to be demonstrated by barriers to entry into the relevant market. The ALRC in its 2004 Genes and Ingenuity report confirmed that “*in certain circumstances, intellectual property rights could create significant barriers to entry into a market*”.²⁷

The High Court in *NT Power Generation*²⁸ has stated that a refusal to grant an IP licence could amount to a misuse of market power under s 46 of the CCA:

*“The fact that s 46 can apply to intellectual property rights, and hence to market power which they can give, suggests that it can apply to the use of market power derived from other property rights not specifically mentioned in the Act. It follows that, provided the notoriously difficult task of satisfying the criteria of liability can be carried out, s 46 can be used to create access regimes.”*²⁹

In its 2000 Review of Intellectual Property legislation under the Competition Principles Agreement, the Trade Practices Committee recommended that the “*imposing of conditions in a licence, or the inclusion of conditions in a contract, arrangement or understanding, should also clearly mean the refusal by the owner of an IP right to enter into a licence, contract, arrangement or understanding.*”³⁰

In its 2004 Genes and Ingenuity report the ALRC also referred to the Trade Practices Commission’s background paper on Misuse of Market Power³¹. In that paper, the Commission considered that a misuse of market power is most likely to occur in relation to an IP right where an advantage is sought which is greater than that conferred by statute or the corporation attempts to extend the monopoly conferred into markets other than those protected by the statutory grant³².

Finally, it is notable that the Patents Act also already contains other provisions (ss 144 and 145) to prevent a patentee seeking to gain such an advantage. Section 144 renders “tying” conditions in a patent licence void and also provides an absolute defence to infringement if the patent is the subject of a contract containing such a provision (A “tying” provision is one which fetters the licensee’s freedom to acquire or use a product or process not protected by the patent). Section 145 provides a statutory right to terminate a patent licence on three months notice after expiry (and thus prevents the patentee seeking to require payment of royalties after such expiry).

²⁶ *Queensland Wire Industries v BHP* (1989) ATPR 40-925 (1989) CLR 177, per Mason CJ and Wilson J at pg 584.

²⁷ ALRC Report *Genes and Ingenuity*, 2004, Chapter 24 Competition Law and Intellectual Property at p. 558

²⁸ *NT Power Generation v Power and Water Authority* [2004] HCA 48

²⁹ *NT Power* per McHugh, Gummow, Callinan and Heydon JJ at 85

³⁰ Intellectual Property Competition Review, *Review of intellectual property under the Competition Principles Agreement*, Final Report (September 2000) at p. 213

³¹ Trade Practices Committee, *Misuse of Market Power: Section 46 of the Trade Practices Act 1974 (Background Paper)* (1990), Commonwealth of Australia, 35 as quoted by the ALRC in its Genes and Ingenuity Report, 2004 at p. 560

³² *Ibid* at p. 560

OVERSEAS EXAMPLES

EC anti-trust law and IP rights

The traditional position in the EC was that a refusal to license could not of itself constitute an abuse of a dominant position³³.

However, in *Radio Telefis Eireann v EC Commission*³⁴, an EC copyright case, abuse of a dominant position was found under Article 86 (EC anti-trust law) against the copyright owners, who were the only sources of basic information on programme scheduling used for compiling a weekly television guide. The refusal to provide this basic information by relying on national copyright provisions prevented a new weekly guide to television programmes, which the appellants did not offer and for which there was a potential consumer demand.

More recently in another copyright case, a compulsory licence was granted in 2007 by the European Court of First Instance (CFI) against Microsoft³⁵. Microsoft was found by the CFI to have infringed Article 82 EC³⁶ (EC anti-trust law) as a result of failing to license interface information of its working group server to competing software companies to ensure interoperability³⁷.

The CFI applied the 'incentives balance test' formulated by the EU Commission, which compared the impact of a compulsory licence on the incentives for the innovation of new software for Microsoft and for its competitors on the market for application software³⁸.

European commentators consider that the use of compulsory licensing in this way is a clear limitation on intellectual property rights through the application of Article 82 EC³⁹.

US IP and antitrust unilateral refusals to deal

Refusals to license patents have not been considered actionable under US antitrust laws⁴⁰. US Courts are far less likely to interfere with intellectual property rights in the manner of the CFI decision in *Microsoft* on compulsory licensing in the EC.

However, whilst US judicial decisions have generally upheld the absolute rights of patent holders, there are instances where compulsory licenses have been ordered. In *United States v Glaxo Group Ltd*⁴¹ the Supreme Court used compulsory licensing against a group of drug companies which had entered into a patent pooling arrangement to “‘*pry open to competition*’ the particular drug market that has been “closed by defendants’ illegal restraints.”⁴²

In *Image Technical Services Inc v Eastman Kodak Co*⁴³ a compulsory licence was ordered, however the decision has been severely criticised as creating instability for patent holders and for being “*the first time that a court has forced a patentee to license a valid patent*”⁴⁴. Kodak was ordered to license patented parts in the equipment service market for photocopying machines (a market it monopolised) for a period of ten years.

In practice, US courts have only used compulsory licensing for anti-trust violations. Refusals to grant licences have only resulted in compulsory licences being granted “*where the patent*

³³ *Volvo v Veng* [1989] 4 CMLR 122

³⁴ [1995] 4 CMLR 122 at para

³⁵ European Commission Case COMP/C-3/37,792 Microsoft, C(2004) 900 final and Judgment of the Court of First Instance in Case T-201/04, 17.09.2007, cited by Schmidt C and Kerber W “*Microsoft, Refusal to License Intellectual Property Rights, and the Incentives Balance Test of the EU Commission*”, <http://ssrn.com/abstract=129739>

³⁶ Art 82 EC refers to article 102 of the Treaty on the Functioning of the European Union (as renamed by the Treaty of Lisbon, which entered into force on 1 December 2009).

³⁷ Schmidt and Kerber above note 5, p. 2. It is also noted that in Australia, there are provisions in Div 4A, s 47D of the Copyright Act 1968 (Cth) which provide limited exemptions to the reproduction of computer software programs where reproduction is necessary to determine interoperability provided the reproduction or adaptation is only to the extent necessary for interoperability.

³⁸ *Ibid* p. 2

³⁹ *Ibid* p. 32

⁴⁰ *SCM Corp v Xerox Corp.* 645 F. 2d 1195 (2d Cir. 1981)

⁴¹ 410 U.S. 52 (1973) cited in *Compulsory Patent Licensing for Efficient Use of Inventions*, Yosick, Joseph. A., University of Illinois Law Review, Vol 2001, 1276 – 1304 at 1282

⁴² *Ibid* at 62, cited by Yosick, J. at 1282

⁴³ 125 F.3d 1195 (9th Cir. 1997)

⁴⁴ Yosick. J. at 1283

was obtained fraudulently, the litigation was a sham, or there was an illegal tying arrangement⁴⁵.

International Perspectives on Compulsory Licensing

TRIPS regulates compulsory licences under Article 31 (Other Use Without the Authorization of the Right Holder). The requirements include an attempt to obtain a licence from the patent holder, use of the patented invention primarily for the domestic market and adequate remuneration to the patent holder for the compulsory licence.

Governments may also impose compulsory licences under TRIPS as remedies for anti-competitive practices⁴⁶. Most major industrial nations have the power to grant compulsory licences, subject to the limitations imposed by the Paris Convention for the Protection of Industrial Property, Stockholm, 1967, amended 1979 and TRIPS and usually allow an initial period of three to five years for exploitation of the patented invention before a compulsory licence may be granted⁴⁷.

Overseas arguments in favour of compulsory licensing emphasise that in addition to the first three to five year window, licences are not able to be granted unless the invention is for domestic use or it is blocking a dependent patent and the inventor is entitled to reasonable royalties⁴⁸.

One of the traditional arguments against compulsory licensing is that it discourages innovation. However, surveys in the US have concluded that reasonable compulsory licensing would have little adverse impact on the patent system⁴⁹.

The threat of compulsory licences is not to be underestimated, particularly where negotiations break down between IP holders and potential licensees. Another traditional argument put forward against compulsory licensing is the difficulties of setting appropriate royalty rates. The presence of compulsory licensing provisions operates to facilitate negotiations, and where negotiations fail, courts have the expertise to determine reasonable royalty rates⁵⁰.

DOCUMENTATION

1. LESANZ submissions to the Committee Secretary of the Senate Legal and Constitutional Affairs Committee dated 25 February 2011.
2. Patent Amendment (Human Genes and Biological Materials) Bill 2010 and current version of proposed amendments to the Bill as of July 2011.
3. Explanatory Memorandum to Patents Amendment (Human Genes and Biological Materials) Bill 2010.
4. AusBiotech submissions to the Committee secretary of the Senate Legal and Constitutional Affairs Committee dated 25 February 2011.
5. Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (extract of Sections 119ZB and 119C)
6. *Stack v Brisbane City Council* (1995) 131 ALR 333
7. Chapter 24 'Competition Law and Intellectual Property, Genes and Ingenuity Report, Gene Patenting and Human Health, ALRC Report 99, 2004
8. Australian Government Advisory Council on Intellectual Property (ACIP) Review of Crown Use Provisions for Patents and Designs, November 2005
9. Submission to ACIP's Discussion Paper by the Institute of Patent and Trade Mark Attorneys (IPTA), Australia
10. *Amrad Operations Pty Ltd v Genelabs Technologies Inc* [1999] FCA 633 (12 May 1999)

⁴⁵ Ibid Yosick. J. at 1284

⁴⁶ TRIPS art 31(k)

⁴⁷ Yosick, J at 1292

⁴⁸ Ibid Yosick, J at 1292

⁴⁹ Ibid Yosick, J at 1293, citing F. M. Scherer, *The Economic Effect of Compulsory Patent Licensing* 84 (Ctr. For the Study of Fin. Inst. N. Y. Univ., Monograph No. 1977-2, 1977) at 51

⁵⁰ Ibid Yosick at 1298