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12 October 2012

Ms Alison McClelland
Commissioner
Productivity Commission
Compulsory Licensing of Patents
LB 2 Collins Street East
MELBOURNE VIC 8003
Email: patents@pc.gov.au

Dear Commissioner

Submission on compulsory licensing provisions in Australia

Alphapharm appreciates the opportunity to provide comments to the Productivity Commission's Review of compulsory licensing provisions in Australia. We are grateful for the extension of time granted to make our submission.

Yours sincerely.
Alphapharm Pty Limited

Dr Martin Cross
Managing Director

ALPHAPHARM

COMPULSORY LICENSING SUBMISSION

PRODUCTIVITY COMMISSION INQUIRY

Can the current compulsory licensing provisions be invoked efficiently and effectively in the Australian health care sector?

Executive Summary:

1. There is scant anecdotal evidence regarding the use of compulsory licensing provisions in Australia and their efficiency and effectiveness. There is no empirical evidence.
2. The potential for success of a compulsory licensing application is negligible.
3. The normal rule applicable to court costs acts as a powerful disincentive for applicants.
4. There is no temporal immediacy between the alleged abuse of the patent system and the relief from such abuse that a compulsory licence may bring an applicant.
5. The prerequisites are legally complex, ambiguous and, therefore, onerous.
6. The provisions are not directed towards dealing with the adverse impact on the Australian economy of modern kinds of patent abuses, e.g. evergreening.
7. The Australian patent system, and how it is currently performing is so suboptimal that it is undermining the Australian economy and, particularly in regard to Australia's health care system, is doing more harm than good.

Recommendations:

1. That the compulsory licensing provisions in the *Patents Act, 1990 (Cth),* be repealed;
2. That the *Office of the Intellectual Property Regulator* be established and be empowered to, among other things, oversee the operation of the intellectual property system in Australia and provide appropriate intervention and relief in cases of abuse on such terms as it deems fit taking into account the nature of the intellectual property right in issue and its importance to and impact on the Australian economy or any sector within the economy; and,
3. That the *Patents Act, 1990 (Cth),* be amended to insert:
   a) an objects clause that sets out, with sufficient particularity, the role and function of the Australian patent system within the Australian economy and its economic objectives;
   b) a provision defining abuses of the Australian patent system;
   c) a provision providing civil and criminal remedies for abuses of the Australian patent system; and
   d) a provision providing market based incentives to encourage third parties to challenge granted patents.

Submission

Introduction

Alphapharm is a key contributor to the Australian economy.

Alphapharm is Australia's leading supplier by volume of prescription medicines to the Pharmaceutical Benefits Scheme (PBS). One in seven prescriptions for PBS medicines is dispensed with an Alphapharm product. Our specialty is bringing patent-expired medicines to market, which contributes to the sustainability of the PBS by providing timely access to quality, safe, efficacious and affordable medicines. Alphapharm medicines are made to the highest global quality standards and have the same effect on the body as initial brands.

Alphapharm pioneered generic medicines in Australia in 1982, setting up as a small pharmaceutical manufacturer in Queensland with 12 staff and four products. Today, we have more than 680 employees nationally, including 500 at our state-of-the-art manufacturing plant at Carole Park, Queensland. This year, the plant will produce 3.1 billion doses of which about 1.7 billion will be exported to some 50 countries around the world.

Alphapharm is part of US-based Mylan. Mylan is a global pharmaceutical company committed to setting new standards in health care. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service a habit, do what's right, not what's easy and impact the future through passionate global leadership. We offer a growing portfolio of more than 1,100 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately one-third of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 150 countries and territories. Our workforce of more than 18,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world.

Pharmaceuticals are Australia's leading export of manufactured goods. Generating about $4 billion a year, pharmaceutical exports are more significant to the economy than the exports of cars, wine or information technology. We are pleased to be a major contributor to Australia's balance of trade.

Historical

The first patents legislation to create a national Australian patent system was the *Patents Act, 1903 Cth*. Compulsory licensing provisions were contained in that Act.[1] Subsequently, compulsory licensing provisions were contained in the *Patents Act, 1952*

[1] s.87.

Cth[2] and the *Patents Act, 1990 Cth*.[3]

The *Patents Act, 1903 Cth* was modelled on the *Patents, Designs and Trade Marks Act, 1883 UK* (as amended in 1902) and the compulsory licensing protections which were pioneered in that legislation have been carried over in both the subsequent Acts.

The first formal consideration of compulsory licensing in the context of patents of invention under British patent law was undertaken by a British *Royal Commission into the Working of the Law Relating to Letters Patent for Inventions*. Under the Letters Patent establishing the Royal Commission, the Commissioners were given the "full power and authority to call" any person and also "to call for, have access to, and examine all such Books, Documents, Registers, and Records as may afford the fullest Information on the subject, and to inquire of and concerning the premises by all other lawful ways and means whatsoever." The Commissioners were also empowered to have witnesses give their evidence "touching or concerning the premises" under oath. The Royal Commissioners travelled to various cities throughout the United Kingdom, taking evidence between November 1862 and June 1864. Witnesses included Bennet Woodcroft, the Superintendent of [Patent] Specifications (an office established by the *Patent Law Amendment Act, 1852 UK* and the predecessor to the office of Commissioner of Patents established by the *Patents, Designs and Trade Mark Act, 1883 UK*), the Duke of Somerset and Rear-Admiral of the British Navy, Robert Robertson, General John Lefroy, from the British War Office and Sir John Romilly, Master of the Rolls (as he was at the time). Having completed their extensive review, the Commissioners provided their Report[4] in 1865 containing this recommendation among the other seven:[5]

> That the granting of licences to use patented inventions ought not to be made compulsory.[6]

The Commissioners were of the opinion that the "practical difficulties" for introducing compulsory licensing provisions into British patent law were "insuperable", particularly when "no rule" could be "laid down for estimating the value of a Patent, or the amount of charge which may reasonably be imposed for those using it." While on the one hand "a prohibitory price would render the law inoperative", on the other hand "unless some provision be made to determining the price to be paid" it would be "manifestly futile to require the inventor to grant a [compulsory] licence". In their view no "system of arbitration would prove satisfactory, when neither precedent, nor custom, nor fixed rule

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[2] s.108.

[3] s.133.

[4] *Report of The Commissioners appointed to inquire into the Working Of The Law relating to Letters Patent For Inventions* (UK), 1865.

[5] There were eight recommendations including recommendations against the preliminary examination of patent applications, and, against the extension of the patent term beyond 14 years.

[6] Ibid, xiii.

of any kind could be appealed to on either side."[7]

Regardless, by the time the British patent system was significantly overhauled some 20 years later, the *Patents, Designs and Trade Marks Act, 1883 UK* contained provisions providing for the compulsory licensing of patents.[8] There are a number of reasons to explain this turnaround.

First, in 1873, at the suggestion of the U.S. government, the Austro-Hungarian government agreed to host an international patent congress during the *Weltausstellung*, an international trade fair held in Vienna between May and November. The international patent congress was held in August and was well attended by representatives of governments from all over the world. One of the objectives of the congress, according to John Thacher, the U.S. Assistant Commissioner of Patents and the U.S. Government's representative, was "to discuss the propriety of establishing a uniform patent law in Europe ... and also to suggest, to the several governments, the general principles and features which such a law ought to embrace."[9] At its conclusion resolutions were agreed upon providing a set of common principles designed to lead to greater international harmonisation of the various patent and trade mark systems. Among these principles, which included "a system of preliminary [patent] examination", was the establishment of "legal rules to which the patentee may be induced, *in cases in which the public interest should require it*, to allow the use of his invention to all suitable applicants, for adequate compensation."[10] This was clearly a reference to compulsory licensing. This international patent congress became known as the Vienna Convention.

Second, between the time of the Vienna Convention and the passage of the *Patents, Designs and Trade Marks Act* in 1883, a number of precursor Bills related to that Act were introduced in the British Parliament. In 1875, Hugh Cairns, The Lord Chancellor, in introducing the first of these Bills to the House of Lords explained that while "nothing was done in consequence of the Report of [the Royal] Commission", a subsequent Select Committee of the House of Commons in 1871 and 1872 was "appointed to inquire into the same subject" and that as a result of that Committee's report and "the Universal Exhibition at Vienna" there not only existed "a large body of evidence on the subject" but also "great landmarks as to the direction in which any alteration of the laws as to patents ought to proceed". These two events combined with what Lord Cairns described as the "loud and continuous demand from those persons who are engaged in manufactures" and provided the British Government with an encouragement to make "some alterations [to British patent system]... in order to give

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[7] Ibid, xi.

[8] s.22.

[9] *Scientific American*, 6 September 1873.

[10] Resolution II "An effective and useful patent law should be based on the following principles: ... (f) It is advisable to establish legal rules, according to which the patentee may be induced, in cases in which the public interest should require it, to allow the use of his invention to all suitable applicants, for an adequate compensation. ...". *Resolutions adopted by the patent congress, Vienna, Austria, August 5-10, 1873.*

effect to those various recommendations which have been made from time to time."[11] In taking their Lordships through the Bill, which included provisions providing for the preliminary examination of patents, a feature consistent with the "same conclusion" reached at the Vienna Convention and which, according to Lord Cairns, would "if your Lordships only think of the matter for a moment ... [be] absolutely necessary", he eventually raised "a question of deep interest" and one, which he acknowledged, was "surrounded with difficulty - I mean the subject of [compulsory] licences." He then provided the government's justification for supporting the compulsory licensing of patents saying:

> If your Lordships consider the question of licences, I think you will arrive at the conclusion that there may be a considerable difference between one kind of invention and another as regards the subject of requiring licences to be granted. It may well be that the manufacturer of a particular patented article could manufacture that article to such an extent and in such quantities as to supply the whole community, and without any interruption of trade arising from any want of supply. *But it is altogether different when the patented invention is part of a process.* Let me illustrate what I mean by a reference to a patent of that kind. Your Lordships probably observed, as I did the other day, in one of the ordinary sources of information, mention made as to a discovery in the manufacture of glass. The discovery was said to have been made by a person who was not a glass manufacturer;—and I believe few of those discoveries are made by persons in the trade or art itself. A farmer found out that glass could be made much less brittle in the course of its manufacture by cooling it in oil in place of water, and the consequence, it is said, is that glass can be manufactured much more tough or less brittle than it was before. Now, assuming that to be so —I do not know whether it is or not—and a patent taken out for an invention of that kind, what would be the consequences? It is an invention connected with a process in a particular trade carried on in all parts of the country. If such an invention were made and were found to be as valuable as is suggested, the consequence would be that practically no person would desire to have glass of any other manufacture, and yet no one manufacturer could possibly supply the whole country. Not only that, but if he were able to do so it would suspend the operations of the whole glass manufactories throughout the country—assuming that the patentee insisted on manufacturing himself, and refused to grant licences for the use of the process. *That is a case in which a whole trade would be injured and crippled if licences to use the invention were not granted.* **These considerations, my Lords, have led us to the conclusion that the recommendation which has been made ought to be acceded to; and we propose that there should be a condition upon all patents granted after the commencement of the Act,** in consequence of which they should be liable *at any time after the expiration of two years from their date to be recalled upon either of two grounds*—either *that the patentee fails to use or put in practice, either by himself or his licencees in this country, the patented article to a reasonable extent—proof to the contrary lying on him—so that the*

[11] HL Deb 12 February 1875 vol 222 cc241-68 (UK).

> *patent may not lie dormant, unused, and unexercised, or be a patent which, having been taken out here, he puts in practice abroad*; and, secondly, *if it is made to appear to the Tribunal that in order to insure a proper supply of the article to the public, or proper means for using the invention by the public licences are necessary, and the patentee fails to grant licences on terms which the Tribunal under all the circumstances may think reasonable*. I am aware that that provision casts upon the Tribunal a task of some difficulty—namely, the ascertaining of what are reasonable terms; but persons best competent to judge of that matter are of opinion that it is a difficulty which can be surmounted, and that if we provide a system of licences it will go far to remove one of the present objections to the granting of patents.[12]

In other words, the British government was not persuaded to the view, as the Royal Commissioners had been some ten years earlier, that the question of the calculation of "adequate compensation" to the patentee in the event of the grant of a compulsory licence was "insuperable". Indeed, even if such a calculation was difficult, of overriding importance if the British patent system was to continue to be relevant to the British economy going forward, was that a patentee (a) "use or put in practice" the invention in the United Kingdom, and, (b) "insure a proper supply" of the invention, or article made by the use of an invented process, within the United Kingdom.[13]

It must be appreciated that serious consideration was being given at the time to the complete repeal of the patent system in Britain. Calls for the repeal of patent laws had been made since the 1850s both within and outside of the British Parliament.[14] Lord Cairns acknowledged the tension caused by "what I may call a twofold controversy - a controversy conducted, on the one hand, by those who think there ought to be no Patent Laws at all; a controversy, on the other hand, pressed forward by those who, while desiring to retain the protection of patents, seek a considerable alteration in the Patent Laws as they now exist."[15]

That the British government had by 1875 come to the view that the British patent system should be retained, albeit only if it were subjected to a "considerable alteration", is relevant to the current Inquiry given that there is a sense of déjà vu with

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[12] Ibid (emphasis added).

[13] Ibid.

[14] "The privileges granted to inventors by patent laws are prohibitions on other men, and the history of inventions accordingly teems with accounts of trifling improvements patented, that have put a stop, for a long period, to other similar and much greater improvements. It teems also with accounts of improvements carried into effect the instant some patents had expired. The privileges have stifled more inventions than they promoted, and have caused more brilliant schemes to be put aside than the want of them could ever have induced men to conceal. Every patent is a prohibition against improvements in a particular direction, except by the patentee, for a certain number of years; and, however beneficial that may be to him who receives the privilege, the community cannot be benefited by it. . . . On all inventors it is especially a prohibition to exercise their faculties; and in proportion as they are more numerous than one, it is an impediment to the general advancement, with which it is the duty of the Legislature not to interfere, and which the claimers of privileges pretend at least to have at heart." *The Economist*, 1 February 1851.

[15] Ibid.

many of the criticisms that were being made of the patent systems in the mid-nineteenth century, being raised today with those "considerable alterations" having been put in place.[16]

It should therefore be recognised in the context of the present Inquiry, that the insertion of provisions for the grant of compulsory licensing of patents was seen in the 1870s to be one of the many important changes needed to provide checks and balances against, what patent critics believed was, the potential for patentees to abuse the British patent system.[17] These checks and balances were not included to merely appease the critics, but were regarded by the British Government to be essential and novel features of a new and improved British patent system designed to ensure that it made a positive contribution to the British economy.

It is noteworthy that in coming to this view the British Government discredited the idea that a patent is property "in the sense that everybody understands the word". Describing it as "a palpable fallacy"[18] Lord Cairns elaborated as follows:

> A man's invention is his own, and he may proceed to use it; but it is wholly another thing when he seeks to prevent anybody else from using it. *The question of allowing him to do this is not one of property or of abstract right, but one of expediency, respecting which the State is quite entitled to make a*

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[16] F List, (1841) *The National System of Political Economy*, translated by Sampson S. Lloyd MP, 1885 edition; Vaughan, F.W. (1919), 'Suppression and Non-Working of Patents, With Special Reference to the Dye and Chemical Industries', *The American Economic Review*, 9 (4), 693-700; Kronstein, H. and Till, I. (1947), 'A Reevaluation of the International Patent Convention', *Law and Contemporary Problems*, 12 (4), 765-781; Machlup, F and Penrose, E. (1950) 'The Patent Controversy in the Nineteenth Century', *The Journal of Economic History*, Vol 10 No 1, 1-29; E Schiff (1971), *Industrialization without National Patents: The Netherlands, 1869-1912, Switzerland, 1850-1907*, Princeton, New Jersey, US: Princeton University Press; *Industrial Property Advisory Committee Report into the Australian Patent System* (1984), dissenting report of Professor Lamberton; Merges, R.P. and Nelson, R.R. (1990), 'On the Complex Economics of Patent Scope', *Columbia Law Review*, 90 (4), 839-916; Owens, L. (1991), 'Patents, the "Frontiers" of American Invention, and the Monopoly Committee of 1939: Anatomy of a Discourse', *Technology and Culture*, 32 (4), 1076-1093; Heller, M. and Eisenberg, R.S. (1998), 'Do Patents Deter Innovation? The Tragedy of the Anticommons in Biomedical Research', *Science*, New Series, 280: 698-701; Verspagen, B. (1999), 'Large Firms and Knowledge Flows in the Dutch R&D System: A Case Study of Philips Electronics', *Technology Analysis & Strategic Management*, 11 (2), 211-233; P Drahos, with Braithwaite J (2002), *Information Feudalism*, London UK: Earthscan Publications Ltd; A B Jaffe and Lerner, J (2004), *Innovations and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to do about it*, Princeton, US: Princeton University Press; P Drahos (ed) (2005), *Death of Patents*, London UK: Lawtext Publishing and Queen Mary Intellectual Property Law Institute; Maskus, K.E. (2006), 'Reforming US Patent Policy: Getting the Incentive Right', *Innovations*, 1 (4), 127-153; L Palombi, (2009) *Gene Cartels Biotech Patents in the Age of Free Trade*, London UK: Edward Elgar.

[17] In the Second Reading speech of the final version of the Bill which was passed into law as the *Patents, Designs and Trade Marks Act, 1883 (UK)*, Lord Selborne, The Lord Chancellor, explained to the House of Lords: "A compulsory licence might also be granted, in certain cases, if the patentee did not take proper means for bringing the patent into use."

[18] Ibid.

bargain, and the only consideration is on what terms an exclusive right of user should be allowed to him.[19]

Therefore, while an invention made by an inventor is his or her 'property' in a sense, the patent rights conferred on an inventor by the State in return for the full and complete disclosure of the invention and how to make and use it, being a "bargain" and constituting what has been called a *social contract*, do not give the patentee *carte blanche* over that 'property'. There are conditions and the ability of the State to exercise some form of control over the patentee's exploitation of the invention through compulsory licensing is one example of the "expediency" to which Lord Cairns referred.

Finally, it is worth noting that the views expressed by Lord Cairns as Lord Chancellor in the government of Benjamin Disraeli at the beginning of the legislative review process in 1875 were supported by his successor, Lord Selborne as Lord Chancellor in the government of William Gladstone at the end of that process in 1883.[20]

Compulsory licensing in the modern Australian context - the reasonable requirements of the public.

The Australian patent system, if it is to legitimately and properly operate within the Australian economy, must not only make a positive contribution to the functioning and health of the Australian economy overall but also it must meet *all* of the terms of the social contract, including providing third party access to an invention so that the "reasonable requirements of the [Australian] public" are met. This approach was reinforced recently in 2006 when the Australian Parliament passed legislation amending the compulsory licensing provisions.[21]

In 2001 the Australian Government rejected [22] the recommendation [23] contained in the Intellectual Property and Competition Review Committee's Report[24] that compulsory licensing be restricted to instances where the patentee's "invention is required for

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[19] Ibid (emphasis added).

[20] HL Deb 9 August 1883 vol 282 cc2034-6 (second reading of the *Patents, Designs and Trade Marks Bill*) (UK).

[21] Intellectual Property Laws Amendment Act, 2006 (Cth).

[22] *Government Response to Intellectual Property and Competition Review Recommendations* (IP Australia, 2001).

[23] The Report recommended "that s.133(2) be amended to include an order requiring a compulsory licence 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."

[24] *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000)

[maintaining] competition in the (relevant) market". According to the government, the recommended threshold was too "stringent" and could, therefore, negate the "incentive to negotiate a voluntary licence".[25] Furthermore, it believed that by restricting compulsory licensing only to instances where competition in a specific market was impeded, other relevant considerations such as the adverse impacts produced on the Australian economy by "the non-working of the invention" or by the "effective denial of reasonable access to it" would be overlooked.[26] Importantly, the Australian Government drew a distinction between the requirement of competition on the one hand and the requirement to meet the public interest on the other, which, in its opinion were "not dependent"[27] on each other. Therefore, the Australian Government recognised, much as the British governments of Benjamin Disraeli and William Gladstone had done some 130 years earlier, that compulsory licensing provides an important check and balance to guard against the potential for patent abuse.

The efficiency and effectiveness of Australia's compulsory licensing provisions.

There is scant anecdotal evidence regarding the use of compulsory licensing provisions in Australia and their efficiency and effectiveness. There is no empirical evidence.

According to IP Australia, in the 109 years of the Australian patent system, only three applications for a compulsory licence have been made.[28] Under the *Patents Act, 1903* there were none. Under the *Patents Act, 1952* there were two. And under the current Act there has only been one so far. Two of the applications were made to a court, the first,[29] in 1968, to the High Court of Australia exercising its original jurisdiction (as it did at that time) and the second,[30] in 1998, to the Federal Court of Australia (which assumed original jurisdiction in patent cases on its formation in 1975). Only one,[31] in 1987, was made to the Commissioner of Patents. In each instance the application failed.

On the basis of these three failed applications, producing a zero success rate for the applicants, it is tempting to conclude that the compulsory licensing provisions have been a complete failure, and indeed, this much has been asserted in at least one

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[25] *Government Response to Intellectual Property and Competition Review Recommendations* (IP Australia, 2001), n40, 8

[26] Ibid.

[27] Ibid.

[28] Answer to Question on Notice: Question 4 (Senator Boyce): Senate Community Affairs Committee on Community Affairs: Senate Inquiry into gene patents: Letter from IP Australia to Senate Standing Committee on Community Affairs, 4 June 2009.

[29] *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation* (1969) 119 CLR 572.

[30] *Amrad Operations Pty Ltd v Genelabs Technologies Inc and Others* (1999) 45 IPR 447.

[31] *Wissen Pty Ltd v Kenneth Mervyn Lown* (1987) 9 IPR 124.

learned paper.[32] Having undertaken a study of the compulsory licensing provisions, Dr Lawson maintains that their underlying rationale, to meet the "reasonable requirement of the public", has been undermined by the courts which have "narrowly consider[ed] the circumstances when they might consider a compulsory licence appropriate within the bounds of the existing [provisions]."[33] And coupled with the "uncertain meanings [of key phrases in the provisions], evidentiary requirements and likely expense [given likelihood of legal costs being ordered against the applicant] with no certainty of success", Dr Lawson argues that "a potential applicant would have to be very brave to lodge an application."[34] In regards to their "incentive effects", he believes the evidence shows that they are "very weak".[35]

Taking the contrary position, however, is the Licensing Executive Society of Australia and New Zealand (LESANZ). In a response to the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*, a private members bill that sought to exclude from patentability isolated but otherwise naturally occurring biological materials, one of the arguments made in opposition to the bill by LESANZ was the existence of compulsory licensing provisions with respect to which it argued:

> ... operate as an incentive to patent holders to make their inventions available to the public or enter into licensing arrangements.[36]

LESANZ is not alone. The Institute of Patent and Trade Mark Attorneys of Australia (IPTA) expressed a similar opinion in its submission to the Senate's Legal and Constitutional Law Committee's Inquiry into the same legislation.[37] Under the heading 'safeguards' IPTA asserted that an:

> ... application [for a compulsory licence] can be made where the applicant believes the reasonable requirements of the public are not being met with regard to access to the technology and has been unable to negotiate a licence on reasonable terms with the patentee."[38]

The submission went on to suggest that "the spectre of their existence" has "forced" patentees to "responsibly exercise their patent rights" in Australia. Indeed, IPTA believes that, even in the absence of a "public health crisis based on inappropriate monopolistic behaviour of patentees or exclusive licensees in Australia", steps should be taken to "review the existence and accessibility of these safeguards and ensure that

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[32] Lawson, C (2008), 'Public interest compulsory licensing under the Patents Act, 1990 (Cth): A real incentive or a barrier to working?', *Australian Intellectual Property Journal*, Vol 19, No 3, 129-147.

[33] Ibid, 147.

[34] Ibid.

[35] Ibid.

[36] LESANZ, Executive summary of briefing notes in respect of the Patent Amendment (Human Genes and Biological Materials) Bill 2010, 2; Submission 95: Senate Legal and Constitutional Affairs Committee: Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill, 2010: 3, 6-7.

[37] Submission 49: Senate Legal and Constitutional Affairs Committee: Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill, 2010: 18.

[38] Ibid.

they are optimal."[39]

Both LESANZ and IPTA are associations that together represent the majority of lawyers, patent attorneys and IP licensing executives in Australia.

The Australian Law Reform Commission both in its report into gene patents[40] and in its submission to the Senate's Legal and Constitutional Law Committee's Inquiry, in which it opposed the same Bill, argued that compulsory licensing could be used as one of a number of measures that "are likely to be more effective in promoting the Bill's stated purpose."[41]

The Walter and Eliza Hall Institute, also in opposing the Bill, referred positively to compulsory licensing as being one of a number of "rights under law" available to governments to "intervene when patent rights are inappropriately exercised."[42]

Likewise, CSIRO made reference to "existing mechanisms of compulsory licensing"[43] in its submission and the Victorian Government, in an indirect reference, to compulsory licensing advocated that the use of the relevant provisions were:

> ... alternatives, which aim to enhance Australia's patent system whilst promoting research and the translation of innovations to the benefit of the community, provide a means to achieve a balance between commercial investment and public health and wellbeing.[44]

AusBiotech, an association describing itself as "Australia's biotechnology industry organisation" representing "over 3,000 members, encompassing medicines, medical devices and diagnostics, agricultural, environmental and industrial sectors in biotechnology",[45] referred very positively to compulsory licensing as being one of the "safeguards existent in the patents system". In its opinion these "safeguards" protect "the community" from "patent owners (be they universities, companies or individuals) when they act unethically or unreasonably ...".[46] Indeed, it went further in its submission by suggesting that there is a need to reform and strengthen them:

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[39] Ibid.

[40] ALRC Report 99, recommendation 27-1.

[41] Submission 30: Senate Legal and Constitutional Affairs Committee: Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill, 2010: 4.

[42] Submission 59: Senate Legal and Constitutional Affairs Committee: Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill, 2010: 25.

[43] Submission 78: Senate Legal and Constitutional Affairs Committee: Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill, 2010: 8.

[44] Submission 112: Senate Legal and Constitutional Affairs Committee: Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill, 2010: 4.

[45] Submission 97: Senate Legal and Constitutional Affairs Committee: Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill, 2010: 1.

[46] Ibid, 7.

> The interests and needs of the Australian public can be protected via the safeguard mechanisms that already exist in the law. AusBiotech believes that a review of the Crown Use and compulsory licensing provisions that allow the government of the day or third parties to exploit a patent in certain circumstances *is required followed by an effective legislative response to ensure these safeguards are adequate, efficient and accessible to all Australians.*[47]

Finally, a joint submission by the Department of Industry and Innovation and IP Australia referred to the compulsory licensing provisions as one of the "powerful safeguards ... which can be invoked where the public interest is not served through restrictive licensing practices that block access to important medical or other technologies."[48]

Although these submissions were made in the context of a Bill seeking to outlaw gene patents, what they demonstrate for present purposes is the existence of a widely held perception by patent lawyers, patent attorneys, medical and scientific research institutes, industrialists, the responsible federal government department and IP Australia that the compulsory licensing provisions, even in the absence of any empirical or anecdotal evidence to support this perception, play an important role in mediating patentee behaviour. Described variously as "safeguards" or "powerful safeguards" working within the Australian patent system, the clear and unambiguous thrust of these submissions is that the existing compulsory licensing provisions function efficiently and effectively to prevent abuses of the Australian patent system. Only IPTA, the Department of Industry and Innovation and IP Australia went further to suggest the need for a review of these safeguards to ensure that they are either "optimal" or "adequate, efficient and accessible to all Australians."

The question, however, is this: do the compulsory licensing provisions work as they are perceived to?

First, on the basis of what little anecdotal evidence there is, it seems reasonable to conclude that they do not. Apart from the fact that no compulsory licences have ever been granted, Dr Lawson's comprehensive review of the Australian cases together with some of the relevant United Kingdom cases, suggest that with the potential for success being almost negligible, there is little or no incentive for anyone to make an application for a compulsory licence in Australia.[49]

Second, even if, as suggested by LESANZ and IPTA, the reason why there has been no grant of compulsory licences in the health sector is that there has been no "health crisis" in Australia, and irrespective of the accuracy of this statement, it must be noted that the criteria for the grant of a compulsory licence is not a 'health crisis', whatever that means, but is, in accordance with s.133, either:

(i) ***all*** of the three conditions in s.133(2)(a) being satisfied [s.133(2)(a)]; or

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[47] Ibid, 8.

[48] Submission 94: Senate Legal and Constitutional Affairs Committee: Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill, 2010: 24.

[49] Op cit, 32.

(ii) the patentee has or is contravening Part IV of the *Competition and Consumer Act, 2010* [s.133(2)(b)]; or

(iii) if the applicant is a patentee or exclusive licencee of a patent being subservient to another patent which is the subject of the application, only if the applicant satisfies the court that the subservient patent "involves an important technical advance of considerable economic significance" with respect to which the "other patent relates", is it possible for the application to be further considered in accordance with s.133(3B) [s.133(3B)].

In regard to item (i) not only must the applicant have first "tried for a reasonable period, without success, to obtain a licence to "work the invention on reasonable terms and conditions" from the patentee, but also he or she must "satisfy the court" that: (a) "the reasonable requirements of the public with respect to the patented invention have not been satisfied",[50] and, (b) "the patentee has given no satisfactory reason for failing to exploit the patent."

To be sure, while a patentee's denial of reasonable access to an essential medicine or diagnostic at a reasonable price may amount to a 'health crisis', this eventuality does not of itself satisfy the prerequisite criteria in s.133(2)(a).

According to Dr Lawson the prerequisites set out in s.133 are legally complex, ambiguous and, therefore, onerous. This coupled with the normal rule regarding legal costs which acts as a further disincentive as the unsuccessful applicant is burdened with paying the patentees legal costs, suggests that abuses of the Australian economy caused by the gaming of Australia's patent system are being ignored.

This precise situation was the subject of a study in the United Kingdom. In a report prepared by the Chief Scientific Adviser and delivered to the British government of Margaret Thatcher in 1983.[51] Dr Nicholson found:

> There are several procedures for correcting various forms of patent monopoly abuse such as non-working, keeping prices high by deliberately restricting production, obstructing licensing deals. But these are virtually never used. *We do not believe that this is because no abuse takes place but because the chances of first getting adequate redress and then turning it into a commercial success are heavily weighted against potential applicants.*[52]

Third, there is no temporal immediacy between the alleged abuse and the relief from such abuse that a compulsory licence may bring. This is because s.133(1) quarantines such abuse from an application for a compulsory licence for a period of three years.[53] Dr Nicholson found that such a temporal quarantine, which is identical under the *Patents Act, 1977 (UK)*, negated the use of compulsory licences because: "three years later the market has often moved on and a compulsory licence will not help."[54]

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[50] s.135 defines the "reasonable requirements of the public".

[51] *Intellectual Property Rights and Innovation* (December 1983, Cmnd 9117).

[52] Ibid, 27 (emphasis added).

[53] Reg. 12.1(1) *Patent Regulations, 1991 (Cth)*.

[54] Op cit 51, 28.

Fourth, despite the generally held perception that the compulsory licensing provisions act to mediate patentee behaviour against abusing the Australian patent system, there is absolutely no anecdotal evidence of this being the case in Australia. None of the parties that filed submissions to the Senate Inquiry into the *Patent Amendment (Human Genes and Biological Materials) Bill, 2010* and who relied upon the compulsory licensing provisions in arguing that the current Australian patent system is able to cope with the patent abuses that may be occurring around the patenting of genes and other naturally occurring biological materials, such as proteins, provided a single unequivocal example in support.

While it may be true that the original trigger for that Senate Inquiry,[55] being the threat of patent infringement proceedings made by the exclusive licensee against all Australian laboratories providing BRCA genetic testing (related to breast and ovarian cancers in women with families histories of these forms of cancers), was eventually withdrawn, this was not attributable to the compulsory licensing or crown use provisions. In fact no application for a compulsory licence was made, nor did any government in Australia threaten to invoke its Crown use powers. It would seem, rather, that it was the adverse media and public reaction[56] and the Senate's decision to order an Inquiry into gene patents[57] that motivated the decision to withdraw the threat. In an announcement made to the Australian Stock Exchange by the exclusive licensee concerning its decision "to allow other laboratories in Australia to freely perform BRCA testing" no reference was made to the provisions having played a role.[58]

Compulsory licensing reform - is it possible?

The generally held perception, apparent from various submissions to the Senate's Inquiry into the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*, is that compulsory licensing acts as a safeguard against abuses of the Australian patent system. Unfortunately this perception is unsupported by any empirical or anecdotal evidence, and the little anecdotal evidence there is demonstrates it to be neither an efficient nor effective safeguard. This does not, however, mean that it cannot be made to be.

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[55] The Senate Legal and Constitutional Affairs Committee's Inquiry was into the *Patent Amendment (Human Genes and Biological Materials) Bill, 2010*. This Bill was introduced into the Senate by Senators Heffernan, Coonan, Xenophon and Siewert in anticipation of the tabling of a Report into gene patents conducted by the Senate's Community Affairs References Committee. Although separate inquires the two are associated and linked to the threat of patent infringement proceedings over the unauthorised use of BRCA genetic tests.

[56] Canberra Times (16 July 2008) *Fears patent will make breast cancer gene tests too expensive*; The Australian (16 July 2008) *Patent bid sparks fear of price hike for cancer test*; New Zealand Herald (17 July 2008) *Cancer tests will continue despite patent wrangle*; Sydney Morning Herald (21 July 2008) *Lawyer looks at breast gene patent*; The Australian (30 July 2008) *A price on your genes*; The Australian (17 October 2008) *Alarm sounds on cancer test monopoly*.

[57] Senate, 11 November 2008, 29 (Hansard).

[58] Genetic Technologies Media Release (2 December 2008).

If compulsory licensing is to safeguard the Australian patent system, and this is seen by patent attorneys, patent lawyers, industrialists, the Department of Industry and Innovation and IP Australia to be very desirable, then it is in need of a major overhaul. This much has been alluded to by LESANZ, IPTA, the Department of Industry and Innovation and IP Australia. Dr Lawson, in his paper, goes further, unequivocally making the case for a review of the provisions. The question is: how to go about it?

The **first problem** was first recognised by the Royal Commissioners in their Report in 1865. In their opinion the "practical difficulties", which they believed were "insuperable", revolved around the fact that there was "no rule ... for estimating the value of a Patent, or the amount of charge which may reasonably imposed on those using it."

However, eleven years later the British Government rejected this advice and decided to include a compulsory licensing provision[59] in the substantial redesign of the British patent system, arguing that although the provision "casts upon the Tribunal a task of some difficulty—namely, the ascertaining of what are reasonable terms" it believed that "it is a difficulty which can be surmounted, and that if we provide a system of licences *it will go far to remove one of the present objections to the granting of patents*." Both the British Government in 1875, and its successor in 1883, were of the opinion that if the concerns of the patent system's critics were to be met safeguards against the potential for patent abuse were indispensable. And successive British governments have taken the same approach ever since.[60] That approach was also followed in Australia. Indeed, both the *Patents Act, 1903 (Cth)* and the *Patents Act, 1952 (Cth)* were modelled on the *Patent, Designs and Trade Marks Act, 1883 (UK)* and *Patents Act, 1949 (UK)* respectively.

Internationally, specific reference to "the right to take the necessary legislative measures to prevent the abuses which might result from the exclusive rights conferred by the patent, for example, failure to work"[61] was incorporated into the *Paris Convention for the Protection of Industrial Property, 1883* at The Hague Conference in 1925. Specific reference to "the grant of compulsory licences", being one of the "necessary legislative measures", was also introduced in the context of the "forfeiture" of a patent, a penalty that was no longer to be available unless the grant of a compulsory licence "is insufficient to prevent such abuses."[62] Further revisions to Article 5A were made at the London Conference in 1934, the Lisbon Conference in 1958 and the Stockholm Conference in 1967.[63] The current Art 5A in regard to compulsory licensing is as follows:

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[59] s.22 *Patent, Designs and Trade Marks Act, 1883 (UK).*

[60] Compulsory licensing provisions are contained in the *Patents Act, 1977 (UK).*

[61] Article 5A(2).

[62] Article 5A(3).

[63] Reichman J and Hasenzahl C (2002) , 'Non-voluntary Licensing of Patent Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America', *UNCTAD/ICTSD* Capacity Building Project.

> Art 5A(2): Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.
>
> Art 5A(3): Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licences would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory licence.
>
> Art 5A(4): A compulsory licence may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory licence shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-licence, except with that part of the enterprise or goodwill which exploits such licence.

A **second problem** is that the incorporation of compulsory licensing as a mechanism to prevent "abuses which might result from the exercise of the exclusive rights conferred by the patent" did not address the original concerns of the 1864 Royal Commissioner[64] of how to estimate "the value of a Patent, or the amount of charge which may be reasonably imposed on those using it" nor, since 1925 has there been any definition of the word "abuses" in this context other than by reference to the example in Art 5A(2) of a "failure to work" the invention. And while this example clearly suggests that a relevant 'abuse' is a patentees use of patent rights to suppress the production of the patented invention in the patent granting country, as Dr Lawson points out in his paper, it is unclear what the relevant threshold is and how to measure it.[65]

This in turn raises a **third problem**. While the original concern of the British governments in 1875 and 1883 was to create a mechanism to check against the possibility of a foreign patentee simply importing the British patented invention into Britain without making any attempt to manufacture it there (i.e., producing no jobs nor transferring relevant skills and know-how to British workers), as can be seen by the changes made to Art 5A at the 1925 Hague Conference on the Paris Convention, the scope of compulsory licensing had broadened so as to prevent "abuses" of the economies of countries that were members of the Paris Union. The example of a "failure to work" was therefore merely a reference back to that original objective. Even so, an examination of the relevant criteria set out in s.133, *Patents Act, 1990 (Cth)* seems fixated on the "failure to work" example and this is, more than anything, probably a consequence of the original British approach to compulsory licensing and

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[64] There is no Australian court authority that provides any guidance in regard to determining the amount "to be paid" to the patentee pursuant to s.133(5).

[65] Lawson, C (2008), 'Public interest compulsory licensing under the Patents Act, 1990 (Cth): A real incentive or a barrier to working?', *Australian Intellectual Property Journal*, Vol 19, No 3, 129-147, 141-143.

the language used in the original s.22, *Patent, Designs and Trade Marks Act, 1883 (UK)* rather than an attempt to create a compulsory licensing scheme that truly meets the criteria set out in Art 5A(2).

Section 135, *Patents Act, 1990 (Cth),* defines the term, "the reasonable requirements of the public with respect to a patent invention", not by reference to "abuses" of the Australian economy, but by reference to a "failure to work" the invention in Australia. To fully comprehend this point it is important to reproduce s.135(1) in full:

> (1) For the purposes of sections 133 and 134, the reasonable requirements of the public with respect to a patented invention are to be taken not to have been satisfied if:
>
> (a) an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee's failure:
>
> (i) to manufacture the patented product to an adequate extent, and supply it on reasonable terms, or
>
> (ii) to manufacture, to an adequate extent, a part of the patented product that is necessary for the efficient working of the product, and supply the part on reasonable terms; or
>
> (iii) to carry on the patented process to a reasonable extent; or
>
> (iv) to grant licences on reasonable terms; or
>
> (b) a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee (whether before or after the commencing day) to the purchase, hire or use of the patented product, the use or working of the patented process; or
>
> (c) if the patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia.

Apart from the ambiguities in s.135(1) which Dr Lawson identifies and discusses in his paper, including such terms as "an existing" or the "establishment of a new", "trade or industry",[66] "unfairly prejudiced ... trade or industry",[67] "reasonable terms",[68] "adequate extent",[69] "unfairly prejudiced by conditions",[70] "not being worked", "commercial scale" and "capable of being worked"[71], there are other ambiguities in the provisions, such as, with regard to the term "satisfactory reason" in s.133(2)(A)(ii). This term is used to

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[66] Lawson, C (2008), 'Public interest compulsory licensing under the Patents Act, 1990 (Cth): A real incentive or a barrier to working?', *Australian Intellectual Property Journal*, Vol 19, No 3, 129-147, 133.

[67] Ibid, 134.

[68] Ibid, 135.

[69] Ibid, 138.

[70] Ibid, 140.

[71] Ibid, 141.

raise the threshold for the "failure to work" by providing that a compulsory licence can only be granted under s.132(2)(A) if the patentee can provide "no satisfactory reason for the non-working". Again Dr Lawson provides a learned examination of the implications.[72]

This is probably the most significant failing of the compulsory licensing provisions in regard to patents operating in the healthcare sector. The provisions are completely ineffective in ameliorating the negative impact that these patents, many of them being of very poor quality, are having on the higher-than-normal prices of patented medicines, diagnostics and therapeutics in Australia. It is noteworthy that no application for a compulsory licence has been brought by a generic pharmaceutical company or a diagnostic laboratory operating in Australia in spite of the fact that 'evergreening' patents[73] are being used inappropriately to create barriers to generic entry. The rise in both the number of pharmaceutical related patents and the extraordinary length and scope of the patent monopolies[74] seriously challenges the viability of the generic pharmaceutical industry in Australia. The problem for generic pharmaceutical companies in this country is that the cost of mounting patent challenges in the Australian courts is very high and the outcome is very risky. While in the past this may not have been an issue given the reasonable market conditions that then applied, today, due to a series of government policies combined with the readiness of the Australian Federal Court to grant preliminary injunctions enjoining the supply and sale of generic medicines during a patent challenge, it has become very difficult for generic pharmaceutical companies to justify commercially the cost of challenging the validity of such patents. Indeed, so hostile is the current business environment that unless a feasible solution is found to restore balance, there is a real likelihood that the manufacture of generic medicines in Australia and the availability of generic medicines to Australians will cease. Just as problematic is the imported supply of generic medicines to Australia which is also being threatened by international efforts designed to extend extraterritorial jurisdiction for alleged patent infringement through various international treaties and agreements such as the *Anti-Counterfeiting Trade*

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[72] Ibid, 143-145.

[73] There are many examples of evergreening pharmaceutical patents in Australia. Two of the most recent concern secondary patents over the pharmaceutical compounds, clopidogrel and venlafaxine. The estimated costs of the relevant evergreening patents to the PBS, both of which were invalidated after generic pharmaceutical companies challenged the patents all the way to the High Court of Australia, is in the order of $1.5 billion.

[74] Most biotechnology-pharma patents claim patent monopolies over 'isolated' genetic materials that are identical to those found in nature. They also contain claims to the use of these materials in virtually any conceivable and speculative way, such as in genetic therapies, vaccines and other therapeutics with respect to which the patents fail to disclose sufficiently to enable a person of ordinary skill in the relevant field to reproduce the 'invention' so claimed. This kind of activity impedes the development of biologic and biosimilar pharmaceuticals because it claims a monopoly over the actual genetic material which is often the key to the commercial scale production of these kinds of medicines.

Agreement[75] and the *Trans-Pacific Partnership Agreement.*[76]

While acknowledging the positive contribution that a properly calibrated patent system may make to the Australian economy, Alphapharm is of the view that the Australian patent system, and how it is functioning, is so suboptimal that it is undermining the Australian economy and, particularly in regard to Australia's healthcare system, is doing more harm than good.

Unfortunately, generic pharmaceutical companies operating in Australia cannot use compulsory licensing as a means of seeking redress. This is because the provisions are, as Dr Lawson points out, outdated, poorly conceived and riddled with legal ambiguities. Simply put, the provisions are not directed to redressing the damage that 'modern' kinds of abuses are inflicting on the Australian economy and the Australian healthcare system. A patentee's "failure to work" an invention in Australia is not necessarily the issue when it comes to ameliorating the negative impact that the practice of 'evergreening' has on the healthcare sector, just as it is irrelevant to facilitating access to 'isolated' genetic materials coming within the scope of the *Patent Amendment (Human Genes and Biological Materials) Bill, 2010*. Yet, the practice of 'evergreening' or the grant of patents over naturally occurring biological materials on the pretext that they have been isolated from their natural environments are two kinds of modern 'abuses' that are unlikely to come within the scope of s.133. And the problem is not merely confined to competition law as provided in s.133(2)(b), although it is possible that these practices in certain circumstances could conceivably be relevant contraventions of the *Competition and Consumer Act, 2010 (Cth)*. But even so, this is the precise point of distinction made by the Australian Government in its rejection[77] of the Intellectual Property and Competition Review Committee's recommendation to make a 'competition test' a prerequisite for a compulsory licence.[78] The point being that the kinds of modern abuses that are being perpetrated on the Australian economy and healthcare system through the patent system cannot be remedied through competition law alone for the reason that a patent monopoly cannot by itself violate competition principles. It is, after all, a statutory monopoly. Furthermore, invoking the Part IV provisions of the *Competition and Consumer Act, 2010 (Cth)* is not straightforward. Unlike the European Commission's Competition Divisions investigation into potential anti-trust abuses of the healthcare sector in the European Union, the Australian Competition and Consumer Commission has failed to simply act.

A **fourth problem**, and closely related to the third problem, is the unresolved policy tension between two arms of government over the role patents play in the Australian

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[75] Senate Joint Standing Committee on Treaties, *Anti-Counterfeiting Trade Agreement* Report 126 (June 2012)

[76] The Canberra Times, *Trade agreement threatens health in Australia and Pacific* (3 August 2011).

[77] *Government Response to Intellectual Property and Competition Review Recommendations* (IP Australia, 2001), n40, 8

[78] *Report of the Review of Intellectual Property Legislation under Competition Principles Agreement* (IP Australia, 2000).

economy. On the one hand is the Department of Industry and Innovation which seeks to promote innovation through the patent system. On the other is the Department of Health and Ageing which seeks to fund Australia's healthcare system. And while the two departments appear to be operating within two separate and distinct policy spheres, the fact is that the operation of the Australian patent system impacts directly upon the cost of funding the Australian healthcare system.

A relevant example of this policy tension is highlighted by the Reports of two British committees, one established by the Minister for Health in May 1965 "to examine the relationship of the pharmaceutical industry in Great Britain with the National Health Service" (better known as the Sainsbury Committee), the other established by the British Board of Trade in May 1967 to "examine and report with recommendations upon the British patent system" (better known as the Banks Committee). The Committees presented their respective reports to the British Government in 1967[79] and 1970[80]. Both discussed compulsory licensing in the context of the impact of the British patent system on the British economy.[81] Interestingly, the Banks Committee Report recommended the abolition of compulsory licensing.[82] The Sainsbury Committee Report, however, found it both relevant and desirable, suggesting that what was "required" was the "considerable simplification and hastening of existing procedures."[83] While compulsory licensing had "been little used", the Sainsbury Committee attributed this to, first, the "procedures for obtaining compulsory licences" which it believed were "time-consuming and inefficient" and, second, to the "considerable reluctance on the part of most business firms to apply for compulsory licences."[84]

The division of opinion between the Sainsbury Committee and the Banks Committee over what to do about compulsory licensing had much to do with their respective terms of references which in themselves exemplified the policy tensions existing between the Ministry of Health, charged with funding the NHS, and, the Board of Trade, charged with facilitating the harmonisation of the British patent system with the then much anticipated European patent system. Most interestingly, the British Government rejected the Banks Committee's recommendation on compulsory licensing, but also failed to act on the Sainsbury Committee's suggestion.

Unfortunately this unresolved policy tension continues to exist today, not only in Britain, not only in Australia, but in just about every country that is a member of the World trade Organisation with Brazil, India and China being notable exceptions.

A consequence of the inability of policymakers to diffuse this policy tension became

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[79] Committee of Inquiry, Lord Sainsbury, (1967), *Relationship of the Pharmaceutical Industry with the National Health Services, 1965-1967*, [Cmd 3410],

[80] Committee of Inquiry, M. A. L. Banks, (1970), *The British Patent System* [1970-71 Cmd 4407].

[81] Sainsbury, 45-46; Banks, 118-119.

[82] Banks, 119.

[83] Sainsbury, 45.

[84] Ibid.

apparent in the European Union in 2008 after the European Commission's Competition Division simultaneously raided the headquarters of proprietary pharmaceutical companies across Europe[85] in an attempt to uncover evidence of their manipulation of the European patent system to obstruct, hinder and delay legitimate generic pharmaceutical competition. In July 2009 the European Commission published its final report.[86]

The Report stated:

> The pharmaceutical sector is one of the main users of the patent system. The number of pharmaceutical-related patent applications before the EPO nearly doubled between 2000 and 2007. Patents concerning the active substances are also referred to by the industry as 'primary patents' because they relate to the first patents for their medicines. Further patents for such aspects as different dosage forms, the production process or for particular pharmaceutical formulations are referred to by the industry as 'secondary patents'. In general, blockbuster medicines' patent portfolios show a steady rise in patent applications throughout the life cycle of a product, also after product launch. Occasionally they show an even steeper increase at the end of the protection period conferred by the first patent. In patent litigation cases originator companies often rely on patents that were not yet filed when their product in question was launched.[87]

The European Commission also found that proprietary pharmaceutical companies have developed sophisticated "patent strategies" as a part of a "company's tool-box" used "to protect continuous revenue streams from pharmaceutical products by preventing or delaying generic entry".[88] These strategies are facilitated by different kinds of 'evergreening' patents which create "patent clusters" encircling the "base patent" thereby "creating several layers of defence" around the trade marked medicine.[89] The most extreme example of a patent cluster discovered by EC's investigators was a patent cluster containing 1,300 patents. The Commission explained the impact as follows:

> Thus where generic companies might manage to invalidate the base patent before its regular expiry they still cannot enter the market, if the originator company has succeeded in creating what some originator companies call "a multilayered defence" by other patents for such aspects as different dosage forms, the production process or for particular pharmaceutical formulations.[90]

That this evidence was only uncovered after the unprecedented action by the EC's Competition Division probably explains why the healthcare sector has not been

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[85] The International Herald Tribune, *Decline in generic drugs draws EU scrutiny and raids* (17 January 2011).

[86] *Pharmaceutical Sector Inquiry Final Report*, European Commission (8 July 2009).

[87] Ibid, 180.

[88] Ibid, 183.

[89] Ibid, 184.

[90] Ibid, 185.

scrutinised by Australian Competition and Consumer Commission (ACCC). To date the ACCC has not repeated the EC's action in Australia even though the "patent strategies" that the EC's investigators discovered are replicated around the world in other countries like Australia. It would be fair to conclude, however, that the kinds of abuses discussed in the EC's Final Report are very likely to exist in Australia. However, unless the ACCC acts as decisively as the EC acted, that evidence is unlikely to come out into the open.

The adverse impact[91] upon the Australian economy of this kind of inappropriate manipulation of the Australian patent system, has taken place without any adverse comment by IP Australia, the Advisory Council on Intellectual Property or the Department of Industry and Innovation, the organisations charged with overseeing the administration and performance of Australia's patent system. How each of these organisations has failed to detect and react to the kind of inappropriate activity of Australia's patent system by proprietary pharmaceutical companies is difficult to explain. Unfortunately, the view about the "powerful safeguard" against abuse provided by compulsory licensing, which the Department and IP Australia expressed in their joint submission to the Senate Inquiry into the Patent *Amendment (Human Genes and Biological Materials) Bill, 2010*, is unsupported in Alphapharm's experience.

In Alphapharm's opinion compulsory licensing in Australia is inefficient and ineffective. Consequentially, it is very unlikely that the threat of a compulsory licence is likely to encourage an Australian patentee to act reasonably.

The **fifth problem** is political and is exemplified by the *Agreement on Trade Related Aspects of Intellectual Property, 1995* (TRIPS) and the *Australia-U.S. Free Trade Agreement, 2004* (AUSFTA). While both Agreements are permissive of compulsory licences the approach to them is different when compared to the approach in the *Paris Convention, 1883*. The difference comes in the conditions that these Agreements impose on the ability of member countries to grant compulsory licences (although in neither of them is the term used).

The relevant provision in TRIPS is Art 31. This article restricts the member countries to the conditions stipulated in sub-articles (a) to (l) and while some of these are consistent with conditions in Art 5A of the Paris Convention, such as sub-articles (d)[92] and (e)[93], the majority are narrower in scope.

The relevant provision in AUSFTA is Art 17.9.7. This article is more restrictive than Art 31 TRIPS. It is useful to reproduce the entire clause:

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[91] "The impact such patent strategies can have on generic entry could also be observed in a case study based on the findings of the sector inquiry where an originator company had filed for more than 30 patent families translating into several hundreds patents in the Member States in relation to one product. More than a quarter of these patent applications were, in fact, filed after the launch of the product. These applications interfered with several generic companies' plans to develop and/or bring their generic versions of the original product to the market, led to several opposition procedures and subsequent legal disputes and in one case to abandoning the development of the generic product." Ibid, 197 (530).

[92] Non-exclusivity (Art 5A(4), Paris Convention).

[93] Non-assignable except with goodwill (Art 5A(4), Paris Convention).

A Party shall not permit the use 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; or

(b) in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency, provided that:

(i) the Party shall limit such use to use by the government or third persons authorised by the government;

(ii) the Party shall ensure that the patent owner is provided with reasonable compensation for such use; and

(iii) the Party may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorised for use in accordance with this paragraph.

It should be assumed that the current compulsory licensing provisions are TRIPS compliant. Whether they are AUSFTA compliant is a matter of conjecture.

Regardless, what TRIPS and AUSFTA suggest is the existence of an underlying trade-driven political agenda, which has ramifications that go well beyond Australia's patent system as Prof Peter Drahos's submission[94] to the Senate Inquiry into the *Patent Amendment (Human Genes and Biological Materials) Bill, 2010* indicates:

> Relying on crown use/compulsory licensing provisions is not a politically feasible strategy. The U.S. has been a great critic of the use of these provisions and has brought trade pressure to bear on countries that have gone down this path (e.g. Thailand). It is true that China and Brazil have been prepared to confront the U.S. in the WTO over trade disputes concerning intellectual property, but one wonders whether Australian political leaders would be prepared to tread this same confrontational path.

This trade-driven political agenda makes it more difficult for individual countries to carve out of agreed global or bilateral intellectual property legal standards the kinds of checks and balances that were envisioned by the British governments in 1875 and 1883, and indeed, by the original signatories of the *Paris Convention, 1883*. As a result since 1883, but particularly since 1995 when the WTO was formed, there has been a systemic incremental erosion of these checks and balances.

The prescriptive language of Art 17.9.7 AUSFTA limits the use of compulsory licences to "anti-competitive conduct" or to "cases of public non-commercial use, or national emergency, or other circumstances of extreme urgency". And while it is possible, in some circumstances, that the manipulation of Australia's patent system may amount to anti-competitive conduct, whether it does so will depend on the scope of anti-competition laws. The question that Alphapharm poses is whether Australia's anti-

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[94] Submission 25: Senate Legal and Constitutional Affairs Committee: Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill, 2010.

competition laws are capable of remedying the kinds of patent abuses that are occurring within the Australian patent system?

The Office of the Intellectual Property Regulator.

Today, intellectual property is universally acknowledged to make an important contribution to economic growth. For this reason the patent systems which operate around the globe, though not truly harmonised, are today, more than at any time since the Vienna Convention, linked by minimum agreed standards through TRIPS and other relevant international agreements. Intellectual property rights are formally recognised to be legitimate aspects of international trade and commerce, and have been since the establishment of the World Trade Organisation.

On the other hand, it has also been long recognised that intellectual property can be the subject of abuse and that such abuse may in certain circumstances impede, rather, than promote, economic growth. There is a real tension between policies concerning the creation and maintenance of intellectual property rights and those concerning competition. That tension is inherent because intellectual property rights are an exception to the normal rule against monopolies.

In the context of the Australian patent system, being a derivative of the British patent system, mechanisms, such as compulsory licensing and Crown use, are there to provide some capacity for third parties who are adversely impacted by patent rights and the manner in that they are being, or not being, exploited, and for governments, to interfere with those rights. The objective is to provide remedies for the abuse of the patent system by patentees. These kinds of remedies have been available to countries since the formation of the Paris Union in 1883 and have, over time, been refined. However, since TRIPS and, particularly, in the proliferation of bilateral and plurilateral free trade agreements that has occurred since then, such as AUSFTA, the circumstances in which patent rights can be made the subject of unauthorised use, have been significantly narrowed.

With this in mind, and reminded of the speech made by Lord Cairns in the House of Lords in 1875, without appropriate checks and balances there is a real potential for patent systems to be the subject of abuse. In the context of AUSFTA, this is confined to mean "anti-competitive conduct".

The problem is, that what amounts to anti-competitive conduct in this specific context has not been defined in the *Patents Act, 1990 (Cth)*. Moreover, there is no objects clause in the Act to provide any assistance to judicial or administrative organs as to how to interpret its provisions in the context of this kind of abuse. Consequently, the apparent focus of the Act is to facilitate the grant of patents, once they have been assessed to meet the relevant statutory requisites. And while IP Australia is empowered to examine patent applications and administer the patent system, it does not intervene in regard to disputes over patent rights even though it has the power to do so. More to the point, the ACCC does not investigate abuses of the Australian patent system in the context of what might be anti-competitive conduct. This much is readily apparent by contrasting the approach taken by the European Commission's Competition Division in regard to its investigation of the abuse of the European patent system designed to

improperly delay the market entry of generic medicines. A possible explanation may be the scope of the current *Competition and Consumer Act, 2010 (Cth),* in so far as it applies to the exploitation of patent rights. Another may be, as already mentioned, the absence of any relevant provisions in the *Patents Act, 1990 (Cth),* empowering the ACCC to intervene. Whatever the cause, given the ineffectiveness and inefficiency of the compulsory licensing provisions, there is presently no practical mechanism with in Australia's patent system to deal with the kinds of abuses that are presently being perpetrated on the Australian patent system e.g., evergreening.

It is also important that the *Patents Act, 1990 (Cth)* be amended so that it dovetails into the operation of the modern Australian economy rather than, as it does at present, contain antiquated provisions that are practically irrelevant to the economy. The present compulsory licensing provisions are historically linked to British economic policy encapsulated in patent legislation going back to 1883.

Consequently, rather than amending the compulsory licensing provisions a more nuanced response is for a government regulator to be established and empowered to, among other things, oversee the operation of the intellectual property system in Australia and provide appropriate intervention and relief in cases of abuse on such terms as it deems fit taking into account the nature of the intellectual property right in issue, its importance to, and its impact on, the Australian economy or any sector within the economy.

Recommendations:

1. That the compulsory licensing provisions in the *Patents Act, 1990 (Cth),* be repealed;
2. That the *Office of the Intellectual Property Regulator* be established and be empowered to, among other things, oversee the operation of the intellectual property system in Australia and provide appropriate intervention and relief in cases of patent abuse on such terms as it deems fit taking into account the nature of the intellectual property right in issue and its importance to and impact on the Australian economy or any sector within the economy; and,
3. That the *Patents Act, 1990 (Cth),* be amended to insert:
   a) an objects clause which sets out, with sufficient particularity, the role and function of the Australian patent system within the Australian economy and its economic objectives;
   b) a provision defining abuses of the Australian patent system;
   c) a provision providing civil and criminal remedies for abuses of the Australian patent system; and,
   d) a provision providing market based incentives to encourage third parties to challenge granted patents.