

SUBMISSION
TO THE PRODUCTIVITY COMMISSION
ISSUES PAPER
COMPULSORY LICENSING OF PATENTS
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The authors are members of the Centre for Law and Genetics in the Law Faculty at the University of Tasmania. The Centre developed out of a project funded by the Australian Research Council (ARC) from 1994 to 1997. The primary focus of the project was the ethical and legal implications of advances in genetic technology. Since then, the Centre has had ongoing funding from the ARC discovery grants program and has expanded its areas of research to include broader issues associated with commercialisation of genetic technology, and access to healthcare. Professor Dianne Nicol leads the intellectual property component of the Centre's research program. Her research interests focus on the interface between innovation, research and access to healthcare in biomedicine. Dr Jane Nielsen's research focus is on the interface between patent law and competition law, which means that she has particular expertise in responding to the Productivity Commission's Issues Paper. John Liddicoat is a research fellow at the centre and has been working with the team for the past two years on the role of patents in biotechnology commercialisation.

The authors of this submission are currently in receipt of funding from the ARC for a project examining the relationship between patenting and innovation in the Australian biotechnology industry, with particular focus on the potential role of collaborative strategies, including patent pooling, on innovation within the industry. The project is being undertaken in collaboration with colleagues from Swinburne University, Japan and Norway.

Licensing

Q *What incentives does a patent holder have to license its invention? Are these sufficient to ensure an efficient licensing system? Do the incentives to license vary according to firm size and across industries?*

A patent is an asset. In the case of many small to medium sized entities, the firm's patent portfolio constitutes its greatest opportunity to attract investment and raise revenue. Firm size is likely to be a strong determinant of propensity to license. For example, in a recent European study Gambardella et al found that: 'the size of the firm is by far the most important determinant of both the propensity to license and the actual licensing. Small firms are orders of magnitude more likely to license than large firms'.¹

Aside from firm size, technology sector is perhaps the greatest determinant of propensity to license. In high technology industries such as biotechnology and information technology, innovation is cumulative in the sense that a number of steps on the research continuum are required before a 'consumer' product is available.² Upstream inventions become inputs for downstream inventions. It is clearly in the interests of upstream patent holders to license their inventions when they are tools for translational and downstream research, and the upstream inventors lack the capacity to develop the technology. Smaller firms are unlikely to have the capacity to bring products to market, nor are public sector organisations. In this sense, patents allow valuable research to be progressed, by providing a tool for the facilitation of strategic alliances.

It is very likely that incentives to license do vary across industries. Licensing is likely to be more prevalent in cumulative industries. Our research to date has focused on licensing in the biotechnology industry, and our comments in the licensing context are limited to this industry. Our research results have indicated that licensing in this industry in Australia is prolific, although many companies and public sector organisations find it difficult to find a party interested in licensing their technology despite being willing to licence.³

Our most recent research illustrates this point well. We used data from an Australian Inventor Survey undertaken in 2007 by the Intellectual Property Research Institute of Australia to compare strategies for utilising patents in the development of products and processes between biotechnology, pharmaceutical, information and communication technology and other inventors. The responses to the question 'Has there been any attempt to license or sell this patent to a third party?' are summarised by industry sector in Table 1. Statistical analysis of the data confirmed that biotechnology inventors were significantly more likely to attempt to license, and to do so more successfully than the other groups except pharmaceuticals.

¹ Alfonso Gambardella, Paola Giuri and Alessandra Luzzi, 'The Market for Patents in Europe (2007) 36 *Research Policy* 1163.

² See, eg, Suzanne Scotchmer, 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law' (1991) 5 *Journal of Economic Perspectives* 29.

³ Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* Centre for Law and Genetics Occasional Paper No. 6 (2003) 100-102. See also Australian Law Reform Commission (ALRC) Report 96, *Genes and Ingenuity* (2004) 417.

Table 1: Attempts to license across industry groups

	Biotech		Pharma		ICT		Other	
	n	%	n	%	n	%	n	%
Yes, Not Successfully	22	22.7	21	24.7	65	20.3	542	24.8
Yes, Successfully	39	40.2	38	44.7	68	21.3	371	17.0
Total Yes	61	62.9	59	69.4	133	41.6	913	41.7
No	30	30.9	25	29.4	160	50.0	1164	53.2
Unsure	6	6.2	1	1.2	27	8.4	110	5.0

Note. 'Total Yes' is the sum of 'Yes, Not Successfully' and 'Yes, Successfully'

Q What reasons would a patent holder have for refusing to license its invention?

Patent licensing must be seen within the broader context of patent ownership. Barring exceptional circumstances, the grant of a patent awards patentees the exclusive right to exploit the patent;⁴ in many circumstances this includes the option not to exploit it. In our view, therefore, 'refusals to license' should not ordinarily be viewed as problems, as most refusals to license will be entirely legitimate and justified on efficiency grounds.⁵

There are a number of legitimate reasons why a patentee might refuse to license its invention. The most obvious circumstances in which a patentee might be reluctant to license include: licensing to a competitor; where the patentee has the ability to further develop a patented invention and wishes to do so exclusively; or where it has already issued an exclusive licence to another party. It is also likely that a patentee might wish to retain exclusivity until it decides which of a number of development options it might exercise. Alternatively, there may be no market for the invention in Australia or concerns that it would not be economically viable.

Of more concern is a situation where a patent has been sought for the purpose of blocking competing or follow-on research;⁶ although this can only ever be for research that is not exempt under the new experimental use provision.⁷ While a patentee has an obligation under the patent privilege to fully disclose its patent and the best methods of performing it,⁸ the patent monopoly can be used in such a way to block any further development of a patented invention by another party before the patent expires. There will be various circumstances where a patentee might apply for a patent but not exploit it if it is more lucrative to hold onto the patent. This might arise, for example, if the patentee chooses to shut down new technological innovations that would damage its current business.

⁴ *Patents Act 1990* (Cth) s 13(1).

⁵ See Jane Nielsen, 'Biomedical Innovation: How Compulsory is Competition?' (2010) 38 *Australian Business Law Review* 100, 118-123.

⁶ See the discussion in *ibid*, 120.

⁷ *Patents Act 1990* (Cth) s 119C. See below.

⁸ See Hon Simon Crean, Minister for Science and Technology, Second Reading Speech, *Patents Bill 1990*; *Patents Act 1990* (Cth) s 40(2)-(4).

In most instances where an invention is valuable for further research (and thus highly sought after by potential licensees) refusals to license are unlikely, because it is more profitable to collect licence fees and facilitate further development of the patented technology than to retain exclusivity. In fact, decisions about whether to license or not are often far more complicated than a simple yes or no. Research on biotechnology patent licensing by public research organisations in the USA shows that a highly nuanced approach is taken to licensing, with exclusive licenses in some fields of use and non-exclusive licensing in others.⁹

Perhaps the greatest current concern about the capacity of the patent system to restrict follow-on innovation from the US perspective is the so-called patent troll or non-practising entity. The true nature of patent trolls has been aptly described by Donald Chisum, one of the leading intellectual property scholars in the USA as follows:

individuals, small companies, or investment groups who obtain, by issue or by purchase, patents but who do not actually produce anything under the patent or even enter into prospective, cooperative licensing arrangements. Instead, a troll hides under bridges, metaphorically speaking, waiting for companies to produce and market products, that is, to approach and cross the bridge. The ugly, evil troll then leaps up and demands a huge toll, that is, a licensing fee settling actual or threatened patent litigation, litigation that could result in an injunction halting the product line.¹⁰

To date, there is little evidence that Australian businesses have been exposed to the 'troll' problem. However, this should not make us complacent that this will remain the case.

In any patent system, decisions must be made as to whether it is more desirable to strongly encourage upstream research (through the grant of broad patents) or downstream research (through, for example, the enactment of permissive compulsory licensing provisions).¹¹ These decisions invariably involve complex economic considerations,¹² and strengthening a compulsory licensing regime should not be undertaken lightly. Nevertheless, it is unlikely that the public interest will be adequately served by an absolute patent monopoly, and in cumulative innovation systems, unfettered privileges at the upstream stage may be detrimental to innovation, particularly where patent holders refuse to licence.

Q *Are the results of the OECD survey of European and Japanese patent licensing representative of the Australian experience? If not, how does Australia differ?*

We have conducted extensive research in the healthcare sector of the medical biotechnology industry in Australia, and our research suggests that licensing in this particular sector broadly aligns with Europe and Japan. One interesting feature of licensing in this sector in Australia is that more firms seek to license offshore. This is

⁹ L Pressman, R Burgess, RM Cook-Deegan, SJ McCormack, I Nami-Wolk, M Soucy 'The Licensing of DNA Patents by US Academic Institutions: an Empirical Survey (2006) 24 *Nature Biotechnology* 31.

¹⁰ Donald S. Chisum, 'Reforming Patent Law Reform' (2005) 4 *John Marshall Review of Intellectual Property Law* 336 at 339-340

¹¹ See, eg, J H Barton, 'Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation' (1997) 65 *Antitrust LJ* 449.

¹² *Ibid.*

due primarily to the lack of funds available within the Australian pharmaceutical and venture capital industries.¹³

Australian biotechnology firms out-license for a number of reasons, but it is certainly the case that in the drug discovery and development sector out-licensing is primarily undertaken to facilitate product development. With rare exceptions, the high cost involved in taking a drug through phase 3 clinical trials and on to product launch necessitates the involvement of large pharmaceutical companies. Consequently, the business plans of almost all firms in this sector are directed towards licensing-out core patented technology, either in the form of a bare licence or tied to an ongoing collaboration or strategic alliance aimed at taking lead products through phase 2 clinical trials and beyond.¹⁴

Equally, our research indicates that there might be a number of reasons why firms in this sector fail to out-license, including the issue of an exclusive licence to another party, or the fact that the party requesting the licence is a competitor.¹⁵ Another simple reason for failing to out-license is the difficulty faced by small firms in finding suitable licensing partners. Concern over the reputation or financial situation of a potential licensee were also given as reasons for refusing to out-license.¹⁶ Both survey data and interview data indicated that refusals to license patents are not a pervasive issue for participants in this industry (in both contexts of out-licensing and in-licensing).¹⁷ Nonetheless, some respondents to our surveys have suggested that while they had not encountered outright refusals to license, they had been offered in-licences on terms that were restrictive enough to make a licence deal impossible.¹⁸ We do not have more precise figures on the number of times these 'constructive' refusals to license occur. But concerns about such dealings are alleviated by the finding that virtually no respondents in our studies reported a cessation of research activities due to an express or constructive refusal to license, because they had a rich diversity of research opportunities open to them, thus rendering refusals to license fairly innocuous.

Not unexpectedly, the situation differs somewhat in the diagnostics sector of the Australian biotechnology industry. While patent royalties are likely to be included in the purchase price of some commercial diagnostic test kits, many service providers predominantly use their own diagnostic tests in-house. Our interviews and surveys with industry participants in this sector suggest that they are actually faced with very few, if any,¹⁹ demands for licences from patentees claiming rights to gene sequences, methods of diagnosis and related subject matter.²⁰ Yet, in common with many other

¹³ Dianne Nicol, John Liddicoat and Jane Nielsen, 'Relationships Between Products, Patents and Collaboration in Drug Discovery in Australia' (forthcoming). See also the discussion in Dianne Nicol and Jane Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347.

¹⁴ *Ibid.*

¹⁵ Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* Centre for Law and Genetics Occasional Paper No. 6 (2003), 145-148.

¹⁶ *Ibid* 148.

¹⁷ *Ibid* 145-147.

¹⁸ *Ibid* 146.

¹⁹ Interviews held with 4 leading diagnostics providers in Australia indicated that since the 'GTG/Myriad issue', no gene patent holders have sought licences.

²⁰ Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* Centre for Law and Genetics Occasional Paper No. 6 (2003), 201; Dianne Nicol

countries, providers of genetic testing services in Australia are concerned that they could face licensing demands, and even refusals to license in the future.²¹ The most notorious example of a refusal to license in this context relates to Myriad Genetics, Inc's refusal to allow diagnostics laboratories in the USA to undertake genetic tests for the presence of mutations in two genes associated with hereditary forms of breast cancer. While there have been concerns in Australia that Genetic Technologies Ltd (GTG), the exclusive licensee of the relevant Myriad patents in Australia and New Zealand, might take the same approach in here, this has not happened to date.²²

Q *How do parties typically reach a patent licensing agreement in Australia? What are the usual features of such an agreement?*

We are not in a position to make a detailed submission in respect of this question, because it has become increasingly evident to us during the course of conducting our research that agreements are reached on a commercial in confidence basis. It is very difficult to glean evidence of how parties might 'typically' reach a patent agreement. Compounding this is the fact that patent licences are tacitly agreed on a frequent basis, so that there is no written agreement as such on the terms comprising the agreement.

We would, however, comment that in the medical biotechnology industry, there is no typical agreement. Our survey and interview evidence indicates that there are many different types of agreements, tailored to meet the requirements of the parties transacting and the technology involved. Thus a patent licence agreement (in this industry at least) may contain a myriad of terms, although it is recognised that there are some 'industry standards'.²³ While there have been attempts to draft standard licensing agreements for the licensing of genetic inventions,²⁴ their success has been limited, probably due to the fact that so many different licence terms are used within the industry, and because the technology being licensed is in a constant state of development and modification.

Q *Are there any problems with the current system of patent licensing in Australia and how might they be solved? Are compulsory licensing provisions part of the problem? Can the broader system of patent licensing be improved through reform of compulsory licensing provisions?*

'Balancing Innovation and Access to Healthcare through the Patent System - An Australian Perspective' (2005) 8 *Community Genetics* 228.

²¹ Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* Centre for Law and Genetics Occasional Paper No. 6 (2003) 201; Dianne Nicol 'Balancing Innovation and Access to Healthcare through the Patent System - An Australian Perspective' (2005) 8 *Community Genetics* 228.

²² However, it should be noted that such action has been threatened. See, Australian Senate Legal and Constitutional Affairs Legislation Committee, *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (2011) 8.

²³ See, eg, Jeffrey P Somers, 'Biotech Patent Licensing': Key Considerations in Deal Negotiations' at www.mbbp.com/resources/iptech/biotech_patent_licensing.html visited 26 August 2012.

²⁴ See, eg, Organisation for Economic Cooperation and Development, 'Guidelines for the Licensing of Genetic Inventions' at www.oecd.org/health/biotechnology/policies/guidelinesforthelicensingofgeneticinventions.htm visited 26 August 2012.

As we have outlined above, there is no ‘system’ of patent licensing in Australia. Patent licensing is based on freedom of contract, so that many potential licensees and licensors are required to negotiate licences on a case-by-case basis. In medical biotechnology, most industry participants in Australia are would-be licensors. There are problems for Australian companies and research institutions falling into this category due mainly to their naivety and lack of bargaining power. This inequality in bargaining power will generally be reflected in an imbalance in the terms contained within any agreement reached. As pointed out in the Issues Paper, patent agreements are not required to be registered, and this might be perceived to be a problem. It is difficult, however, to see how a system of registration could be implemented, particularly given the limited resources of IP Australia, the sheer quantity of patent licence agreements negotiated that would require registration and the fact that many agreements are tacit rather than written.

It is difficult to say whether the compulsory licensing provisions are part of the ‘problem’ given the fact they have been used so infrequently. It is arguable that the very existence of compulsory licensing provisions is in fact a solution because it has the effect of bringing parties to the bargaining table and forcing negotiation. Parties may be likely to be more willing to license if the threat of a compulsory licence exists. Indeed, frequently this is the rhetoric that is used to support the compulsory licensing system in its current form. However, we are unaware of the existence of concrete evidence that supports the rhetoric. Equally, the compulsory licensing provisions might be argued to be ineffectual due to their cumbersome nature, and to have little effect in compelling voluntary licensing.

Diagnostic genetic testing is one area of technology that is often seen as being amenable to compulsory licensing. The argument is that if a patentee refuses to license patent rights relating to gene sequences or methods of diagnosis, or only agrees to license on restrictive terms, an application could be made for a compulsory licence to ‘satisfy the reasonable requirements of the public’. However, in a round of interviews that we undertook with providers of diagnostic genetic services this year, it was universally reported that applications to the Federal Court for compulsory licences were out of reach. Cost and uncertainty were the major deciding factors.

Australia’s System of Patents and Compulsory Licensing

Q *To what extent do the research and regulatory use exemptions solve the problem of access to patents for the purposes of obtaining regulatory approval or undertaking research? Is there any need to invoke compulsory licensing in these cases? If further reform is required, what should be done?*

In many respects our research has demonstrated there has long been a ‘practice based’ research exemption, meaning that there is an unwritten rule that patentees do not enforce their patent rights against research users.²⁵ The recent amendment to the legislation as discussed in the Issues Paper merely gives legitimacy to that practice. In

²⁵ See particularly Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* Centre for Law and Genetics Occasional Paper No. 6 (2003) 219-222.

the case of the regulatory use exemption, it made sense to extend the reach of this exemption beyond pharmaceuticals.

The difficulty remains with patented research tools, which are not protected by either exemption; technologies falling into these categories might be candidates for compulsory licensing. There have been some isolated instances where foundational research tools have not been widely disseminated because of enforcement of patent rights,²⁶ although for the most part Australian have been spared the threat of enforcement, either because the relevant technologies were not patented here, or because patentees have decided not to pursue Australian users. Hence, there have not been significant issues in this respect for Australian researchers.

One set of fundamental gene patents in respect of which there have been problems in Australia is the so called 'junk DNA' patents held by GTG.²⁷ While GTG has not refused to licence these patents, the licence terms insisted on by them are seen to be prohibitive from the perspective of some parties in receipt of cease and desist letters. This neatly demonstrates that even where refusals to license are not a significant problem, licensing on terms that are seen as unreasonable to users may well be. Terms might be considered to be unreasonable if, for example, they demand excessively high royalties or rights to future inventions that have the effect of diminishing incentives to innovate, or include field of use restrictions. A licence deal that cannot be concluded on the grounds that the terms sought are considered to be unreasonable might be considered to be a tacit refusal to license.

Non-Voluntary Access to Patents

Q *In what situations have the Crown use provisions been invoked by the Commonwealth, State and Territory Governments?*

There is limited guidance from the case law as to the circumstances in which the Crown use provisions might be invoked. We are familiar with two cases that suggest this provision is intended to cover such things as the use by a state rail authority of an invention for the construction of rail carriages (*General Steel Industries Inc v Commissioner of Railways (NSW)* (1964) 112 CLR 125) and the use by a local government authority of a meter relating to measurement of water supply (*Stack v Brisbane City Council* (1995) 32 IPR 69).

Q *What, if any, further clarification is required on the circumstances where governments could use the Crown use provisions as an alternative to compulsory licensing, and what is the appropriate form of such clarification?*

In our view, the full extent of the Crown use provisions remain uncertain. We have previously made the argument that Crown use rather than compulsory licensing could

²⁶ See generally *ibid* 40-49.

²⁷ The patents comprise methods of using non-coding DNA polymorphisms, and GTG implemented different licensing practices to research and commercial institutions. See Dianne Nicol 'Balancing Innovation and Access to Healthcare through the Patent System - An Australian Perspective' (2005) 8 *Community Genetics* 228.

have been utilised for the purpose of implementing the TRIPS Protocol (dealing with the provision of medicines to other countries in certain situations).²⁸ However, now that a draft bill has been released proposing to include additional grounds for the grant of compulsory licences as a means of implementing the TRIPS Protocol,²⁹ the argument that Crown use may be a better alternative now appears redundant.

However, we submit that the Crown use provisions may still have a legitimate role to play with regard to domestic issues relating to access to healthcare. The provisions were considered during the ALRC's gene patenting inquiry. The ALRC considered that the Crown use provisions have the potential to be particularly useful when access to a patented genetic invention is required in the provision of public healthcare and, potentially, where access is required for public research purposes.³⁰ These considerations led the ALRC to recommend that amendments should be made to s 167 (1) of the *Patents Act 1990* (Cth) (the *Patents Act*) to clarify that 'for the services of the Commonwealth or of a State' includes the provision of healthcare services or products to members of the public.³¹ We are generally supportive of this recommendation as it relates to the provision of healthcare services, but we are uncertain whether Crown use could extend so far to encompass research as well.

Q *In areas where governments are responsible for service provision, such as healthcare, do the Crown use provisions in the Patents Act provide a means of overcoming concerns about the effectiveness and efficiency of compulsory licensing? How could the Crown use provisions be amended to address any identified limitations?*

See our submission above.

Q *Do the three forms of non-voluntary access under the Patents Act — compulsory licensing, Crown use and acquisition by the Commonwealth — constitute an acquisition of property under s. 51(xxxi) of the Constitution and does the Patents Act provide for just terms compensation? If not, why not?*

We do not have sufficient expertise in the field of constitutional law to address this question with certainty.

How Efficient and Effective is Compulsory Licensing?

Q *What is the likely financial cost and time involved in applying to the Federal Court for a compulsory licence order? What are the key determinants of the cost and time involved? To what extent could the cost and time vary depending on the nature of the application?*

Although answering this question is outside our area of expertise, our empirical evidence indicates those who would consider applying for a compulsory licence

²⁸ Jane Nielsen and Dianne Nicol, 'Whither Patent Use Without Authorisation in Australia' (2008) 36 *Federal Law Review* 333, 362-363.

²⁹ Exposure Draft, Intellectual Property Laws Amendment Bill 2012 (Cth).

³⁰ Australian Law Reform Commission (ALRC) Report 96, *Genes and Ingenuity* (2004) 601-602.

³¹ *Ibid*, Recommendation 26-2, 606-608.

perceive that the financial cost is prohibitively high. We have already mentioned that in a recent round of interviews with providers of diagnostic genetic services the general view was that practically it would be impossible for them to attempt to obtain compulsory licences. From experience, they have found that the court of public opinion (the media) is far more useful in diffusing the threat of patent enforcement.

Q *To what degree have applications for a compulsory licence order been discouraged by the likely time and cost? What evidence is there to support your answer?*

We submit the fact that there have been so few applications for compulsory licences indicates that there is very likely some issue associated with the time and cost involved in making applications. Even if the argument that the existence of a compulsory licensing scheme encourages voluntary licensing negotiations is accepted, we would still expect to see at least a few more applications than we have seen since the enactment of s 133. The very fact that there have been so few applications would suggest that applications are perceived to be too costly. Comments made to us during the course of our interviews support this contention.

Q *What proportion of patents do you think would be sufficiently profitable to justify the cost of applying for a compulsory licence order?*

We submit that it is impossible to provide an accurate answer to this question. In the case of medical biotechnology, the barrier to applying for a compulsory licence is perhaps not so much the financial cost, but the value it would provide.

Q *Could the financial cost and time involved in applying for a compulsory licence order be reduced significantly? If so, how and to what extent? What would be the advantages and disadvantages of reducing the time and cost?*

The costs involved in applying for a compulsory licence could be reduced in a number of ways. We submit that the key to reducing the obstacles to applying for a compulsory licence lie in making the application procedure administrative rather than judicial. We would argue for compulsory licensing applications to be heard by the Commissioner for Patents or other administrative body, with a right of appeal to the Administrative Appeals Tribunal, rather than the Federal Court.

Effectiveness of the Australian Provisions

Q *What are the objectives of the current provisions for compulsory licensing? Are they sufficiently clear, so as not to discourage use of those provisions? Are they appropriate?*

The objectives of the reasonable requirements of the public test in current compulsory licensing provisions have never been entirely clear, but in our submission the most likely purpose was succinctly recognised by the Intellectual Property and Competition Review Committee in its 2000 report as ‘hark[ing] back to a period where the primary concern was the promotion of domestic industry, rather than securing the best use of

resources and achieving high levels of productivity'.³² The idea of requiring local manufacture of patented products, or products made by patented processes has some attraction from the perspective of promoting indigenous innovation (which, incidentally, is also the long stated justification for the patent system itself). However, a local working requirement may be contrary to Australia's broad international trade obligations under the WTO Agreements, and specific obligations under the AUSFTA.³³

Since the enactment of s 133, amendments to the section have added anti-competitive conduct as a ground for application for a compulsory licence. The objectives behind this amendment are clear, as demonstrated by explanatory memoranda accompanying the legislation.

Q *Do the existing tests for invoking compulsory licensing provisions operate effectively? Should either of the tests be removed from the Act?*

It is very difficult to say whether the provisions operate effectively, as they have been invoked so infrequently. This in itself might be an argument that they do not operate effectively. We do, however, submit that there would be difficulties in establishing a patent holder has engaged in anti-competitive conduct. The provisions of the Competition and Consumer Act are notoriously difficult to make out in any circumstance, more so where intellectual property is concerned. While this ground probably 'operates effectively', it is unlikely to be useful in most circumstances where access is sought to a patent or group of patents. Section 46 is the provision most likely to be invoked where a compulsory licence is sought, and establishing the elements of this section is onerous. We have previously written on this issue, and given detailed consideration to the circumstances in which a patent holder is likely to have breached s 46.³⁴ These circumstances would be very rare. We do not seek to submit that the anti-competitive ground should not have been included in s 133; indeed, we previously argued for its inclusion in our submissions to the ALRC. Our contention is that the anti-competitive grounds are unlikely to assist those seeking a compulsory licence to any great extent, and the efficacy of the other compulsory licensing grounds is doubtful. While s 46 remains in its current form, compulsory licences are extremely unlikely to be granted under s 133(2)(b). The key to rectifying this situation no doubt lies more broadly in reform of s 46, consideration of which is outside the scope of this inquiry.

³² Intellectual Property and Competition Review Committee (IPCRC) Final Report, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000) 62; e.g. Commonwealth, *Parliamentary Debates*, House of Representatives, 30 September 1903, 5620 (King O'Malley).

³³ See Jane Nielsen and Dianne Nicol, 'Whither Patent Use Without Authorisation in Australia' (2008) 36 *Federal Law Review* 333, 357-359.

³⁴ Jane Nielsen, 'Biomedical Innovation: How Compulsory is Competition?' (2010) 38 *Australian Business Law Review* 100. See also Jane Nielsen and Dianne Nicol, 'Whither Patent Use Without Authorisation in Australia' (2008) 36 *Federal Law Review* 333, 350-352.

Q *What, if any, changes should be made to the public interest test to make it more efficient and effective? Does the definition of the reasonable requirements of the public in s. 135 of the Patents Act place undue emphasis on the development of domestic industries, compared to the broader wellbeing of the Australian community as a whole?*

We submit that the problem with the ‘reasonable requirements of the public’ test is that the label given to the test is misleading. The focus of this ground for application has always been domestic manufacture and industry, therefore it is wrong to call it a public interest test because it is not. As pointed out in previous reviews of s 133, careful consideration of the extrinsic material connected with s 133 reveals that the core of the reasonable requirements of the public test is the development of domestic industries. This has nothing to do with ‘public interest’ as such. If there is a perceived need for a public interest test in s 133, the necessary step is to amend the section to include such a test. In any case, there is some doubt as to whether such an amendment would be permitted under the AUSTFA. Grounds for compulsory licensing other than the anti-competitive conduct ground would appear to be restricted to situations of national emergency, other circumstances of extreme urgency and public non-commercial use by Art 17.9.7(b)(i) of the AUSFTA.

Q *What types of conduct in connection with a patent are likely to contravene Part IV of the Competition and Consumer Act 2010 (CCA)?*

As we commented above, the provision most likely to be contravened in the CCA is s 46, the misuse of market power provision. This provision will be breached where a corporation unilaterally misuses its market power by taking advantage of market power for a purpose proscribed by the provision. If a refusal to license is alleged to be illegal, s 46 is the provision that will be brought into play. Similarly, tacit refusals to license (through the imposition of unreasonable licence terms or conditions) may be captured by s 46.

Other provisions that may be contravened by conduct involving the use of a patent include s 45 (prohibiting contracts, arrangements and understandings that substantially lessen competition) and s 47 (prohibiting exclusive dealing). These provisions might be contravened through the operation of particular terms and conditions contained in a patent licence agreement.³⁵ The terms that may potentially breach Part IV provisions are many and varied, and we have mentioned several of them above. As we have noted in articles we have previously written, although these terms may disadvantage licensees, in most circumstances this will not render the terms anti-competitive.³⁶ This is because licensing is generally pro-competitive in that it encourages the wide dissemination of technologies protected by intellectual property rights.³⁷ The circumstances in which licensing may be problematic is where the patent monopoly is

³⁵ The Trade Practices Commission (the predecessor to the Australian Competition and Consumer Commission) released a Background Paper detailing when intellectual property licensing practices would be likely to contravene these provisions. See Trade Practices Commission, *Background Paper: Application of the Trade Practices Act to Intellectual Property* (1991).

³⁶ See, in particular, Jane Nielsen, ‘Biomedical Innovation: How Compulsory is Competition?’ (2010) 38 *Australian Business Law Review* 100; Jane Nielsen, ‘Reach-Through Rights in Biomedical Patent Licensing: A Comparative Analysis of their Anti-Competitive Reach’ (2004) 32 *Federal Law Review* 169.

³⁷ Intellectual Property and Competition Review Committee (IPCRC) Final Report, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000) 24.

effectively extended through these contractual arrangements because it extends the scope of the granted patent and where the patent holder restricts the ability of the licensee to practise the invention as fully as the patent holder was entitled to practise it.

Q *Does the framework provided by the Patents Act and Part IV of the CCA prevent patent holders from charging higher prices than would be achieved in a competitive market? If not, is such behaviour likely to lead to significant efficiency losses?*

We submit that this is unlikely given the cumbersome nature of the provisions in both statutes. However, there are other factors that limit the prices that may be charged by patent holders for their technology, for example, demand for the technology, the ability of others to invent around and effective substitutes available. As to whether this leads to significant efficiency losses, this is a complex question that is really impossible to answer. In each transaction, there may be some efficiency cost associated with the price charged in a licence, but in granting a patent monopoly society acknowledges that innovation must be best served by the grant of exclusivity. This may involve some corresponding increase in the price charged for a technology, but in most cases the market will determine its value. It will only be in very rare cases that licensees will be forced to pay significantly more than protected technology is supposedly worth, but this may occur where the technology is foundational and required by in order for research in a particular area to proceed. The example of GTG given above is one such instance. In these cases our research findings indicate that there may be other avenues open to licensees to drive the price down, for example approaching the media.

Q *Should the link between the Patents Act and CCA be reformed?*

We submit that there is some argument that all competition related provisions should be contained within the CCA for consistency, although this may necessitate removing the reasonable requirements of the public ground for application for compulsory licence. Since there is some doubt as to whether this ground complies with the AUSTFA in any case, this may not be a major concern. It does seem illogical that a compulsory licence can be sought under the *Patents Act* or the CCA as the legislation currently stands. Sections 87(1) and 80(5) of the CCA would appear to allow a compulsory licensing order as a remedy for a breach of Part IV. It is now beyond dispute that this power provides an alternative access regime to that provided by s 133 of the *Patents Act*,³⁸ that is, the procedure contained in s 133 of the *Patents Act* is not a code. Arguably this could give rise to difficulties, because the safeguards contained within s 133 of the *Patents Act* are not contained in the CCA remedy provisions referred to above.

We have discussed the implications of this in some detail in an article dealing with the 2006 amendments to s 133.³⁹ We concluded that an order under the remedy provisions of the CCA would most likely take into account the safeguards contained within s 133, and impose similar conditions upon the grant of a licence. This cannot, however, be guaranteed, and as such it is possible that the 'alternative' access regime contained within the CCA may weaken the regime contained in s 133. This could be remedied by

³⁸ Explanatory Memorandum, Intellectual Property Laws Amendment Bill 2006 (Cth) 45.

³⁹ Jane Nielsen and Dianne Nicol, 'Whither Patent Use Without Authorisation in Australia' (2008) 36 *Federal Law Review* 333, 350-352.

'moving' the provisions contained within s 133 to the *Patents Act*, but we would submit that this is not a desirable option because it limits the inclusion of future grounds for application for a compulsory licence. Instead, the safeguards contained within s 133 should be built into the remedy provisions of the CCA.

Consideration may also need to be given to the appropriateness of retaining the void condition provisions in their current location in ss144-146 of the *Patents Act*.

Q *Are competition issues better addressed directly through the CCA? Are the exemptions in section 51(3) of CCA appropriate?*

In relation to the exemptions contained within s 51(3) of the CCA, this provision has attracted as much criticism and been reviewed as frequently as s 133 of the *Patents Act*. We have written extensively on the problems associated with s 51(3), and made numerous submissions for its reform.⁴⁰ Despite the recommendations of various review bodies,⁴¹ s 51(3) remains in virtually its original form, which is problematic in a number of aspects. Without providing a detailed exposition on previous arguments we have made in relation to s 51(3), we submit that an exemption in the CCA for intellectual property licensing terms and conditions is entirely appropriate, because it has the effect of encouraging the dissemination of technology through licensing. However, the exemption is poorly drafted and thus ambiguous, and does not apply to all the Part IV provisions so that any certainty it might have provided to intellectual property owners wishing to include certain terms in an agreements, is lacking. It would appear to us that wholesale consideration of the provision is outside the scope of this inquiry, and thus our submission is simply that the exemption is entirely appropriate, but ineffectual given its current composition. We refer the Commission to arguments we have previously made in published papers.

Q *How effective are the compulsory licensing provisions as a safeguard to deal with cases where the reasonable requirements of the public are not being met or a patentee engages in anti-competitive conduct? What aspects of the provisions, if any, cause them to be less effective than they could be?*

We have previously addressed this issue. We reiterate that the threat of application for a compulsory licensing order may be useful, although there must be some doubt as to whether this threat has teeth at the current time due to the problems with the compulsory licensing provisions discussed above.

⁴⁰ See, for example, Jane Nielsen, 'Biomedical Innovation: How Compulsory is Competition?' (2010) 38 *Australian Business Law Review* 100, Jane Nielsen, 'Reach-Through Rights in Biomedical Patent Licensing: A Comparative Analysis of their Anti-Competitive Reach' (2004) 32 *Federal Law Review* 169; Jane Nielsen, 'Innovation in Medical Biotechnology: Mapping the Intersection of Intellectual Property and Competition Law' (2007) 35 *Australian Business Law Review* 407; Jane Nielsen, 'Competition Law and Intellectual Property: Establishing a Coherent Approach', in *Emerging Challenges in Intellectual Property*, Oxford University Press, K Bowrey, M Handler, D Nicol (eds), Melbourne, pp. 183-201. (2011)

⁴¹ These include: National Competition Council, Review of Sections 51(2) And 51(3) of the Trade Practices Act 1974 Final Report (1999); Intellectual Property and Competition Review Report, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000); and Australian Law Reform Commission (ALRC) Report 96, *Genes and Ingenuity* (2004).

Q *Why have there been so few applications for a compulsory licence order?*

Again, the fact that a compulsory licensing scheme exists within the *Patents Act* may be enough to deter unlawful refusals to license. Alternatively, the cumbersome nature of the provision may discourage applications under s 133.

Q *What evidence is there that, despite the limited number of applications for a compulsory licence order, the provisions have been an effective deterrent to patentees who seek to deny access to inventions on reasonable terms and conditions?*

Any evidence we have garnered in response to this question is purely anecdotal.

Q *How prevalent is the behaviour that the compulsory licensing provisions target? In what circumstances would a patent holder deny a licence?*

This is a very difficult question to answer due to the fact that there has been no systematic study seeking to ascertain how ubiquitous refusals to license are. Further, because patent licence agreements are not required to be registered (nor should they be), unearthing restrictive terms that might result in a tacit refusal to license is virtually impossible.

Our research indicates that in medical biotechnology, refusals to licence are probably rare because most companies would not ask competitors for licences. There is unlikely to be a problem generally because licences over upstream patents will either be granted, or revealed by due diligence to be unnecessary.⁴²

Where a refusal to license is encountered, various methods of counteracting the refusal are employed by industry participants, including challenging patents, inventing around, or ignoring the patents and continuing to conduct research.⁴³ The reality is that there are few circumstances in which a patent holder would deny a licence, and in most cases the refusal will be entirely justifiable.

We have commented above on the circumstances in which a licence might be refused.

Impact of International Agreements on Australia

Q *Are the current compulsory licensing provisions in the Patents Act consistent with Australia's international obligations? What are the implications of the potential inconsistency between these provisions and AUSFTA?*

Australia is not limited to a great degree by its multilateral international treaty obligations, in fact, the TRIPS Agreement does not limit the grounds on the range of permissible types of uses without authorisation. TRIPS contains a very broad provision in Article 31 that encompasses both compulsory licensing and Crown use, but which does set stringent requirements on the conditions that must be imposed on such uses. However, there is some debate in the academic literature as to whether the local

⁴² See generally, Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* Centre for Law and Genetics Occasional Paper No. 6 (2003) 145-148, 182-184.

⁴³ *Ibid* 211-224.

working requirement ostensibly included in the reasonable requirements of the public test is contrary to TRIPS.⁴⁴ This follows a dispute brought to the WTO brought to the WTO by the USA challenging the legitimacy of local working requirements in Brazilian patent law. Although the dispute was later discontinued. It raised questions about the extent to which TRIPS proscribes compulsory licensing based on failure to locally work and invention.

As mentioned earlier in this submission, the AUSTFA does place significant limitations on the grounds for use without authorisation. We query whether the reasonable requirements of the public ground is legitimate, taking into account the restrictions imposed by the AUSFTA.

Q *What constraints do Australia's international treaty obligations impose on potential reforms to its compulsory licensing provisions and alternatives such as Crown use? How could the constraints be addressed while still complying with the treaties?*

Art 17.9.7(b)(i) of the AUSFTA clearly imposes significant limitations. It has been suggested elsewhere that because the AUSFTA is bilateral, its scope is limited and the reasonable requirements of the public ground would not be available against patentees from the USA. However, we have argued that the Most Favoured Nation provision in Article 4 of TRIPS would seem to preclude this.⁴⁵

In addition, it should be noted that Article 17.9.7(b)(i) of the AUSFTA imposes a further restriction that limits the ground of public non-commercial use, national emergency, or other circumstances of extreme urgency, to use the Government or third parties authorised by the Government, suggesting that this is a matter for Crown use rather than compulsory licensing.⁴⁶

Q *What contentious treaty interpretation issues have the potential to increase the time and cost of an application for a compulsory licence order?*

If a compulsory licence is ordered, the *Patents Act* specifies that the order must not be 'inconsistent with a treaty between the Commonwealth and a foreign country'.⁴⁷ As outlined above, this is quite a contentious area and would potentially make any compulsory licence application more costly. We envisage that these treaty interpretation issues are matters that should be resolved by law reform and policy debate. They should not unduly burden applicants for compulsory licences.

Compulsory Licensing in Other Countries

Q *What are the key differences between compulsory licensing arrangements in Australia and other developed economies?*

⁴⁴ For example, Paul Champ and Amir Attaran, 'Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute' (2002) 27 *The Yale Journal of International Law* 365.

⁴⁵ Jane Nielsen and Dianne Nicol, 'Whither Patent Use Without Authorisation in Australia' (2008) 36 *Federal Law Review* 333, 358-359.

⁴⁶ *Ibid* 358.

⁴⁷ *Patents Act 1990* (Cth) s 136.

TRIPS provides a considerable number of grounds on which compulsory licences may be issued, so the compulsory licensing arrangements in other developed economies are very different to those contained within s 133. The US position is very limited in that compulsory licences may only be granted where a patent holder has engaged in anti-competitive conduct. Other developed countries have far broader compulsory licensing provisions. For developing and least developed countries, the primary focus to date has been on implementation of the TRIPS Protocol.

We are not aware of any published research that has concisely illustrated the key differences between compulsory licensing regimes in developed countries. We do note that Professor Reto Hilty and Dr Matthias Lamping at the Max Planck Institution for Intellectual Property and Competition Law are currently undertaking research to explore user rights, including compulsory licensing, in 100 countries through questionnaires. Their report will probably not be published for another few years yet, but a presentation of the preliminary results will be discussed at a conference in Taipei in December this year.⁴⁸

Q *What is the frequency, and impact, of compulsory licences in other developed economies?*

We are unable to make a submission in respect of this question.

Q *Aside from compulsory licensing provisions embodied in patents legislation, what other arrangements do developed economies have for the non-voluntary licensing of patented inventions? How frequently are these arrangements used and what are their impacts?*

Some different forms of non-voluntary licensing are emerging in Europe. We direct the Commission to the work of our Belgian colleague Professor Geertrui Van Overwalle and her team.⁴⁹

Specific Concerns Raised in the Terms of Reference

Q *How might compulsory licensing be utilised to address the specific concerns related to genes, food security, climate change mitigation and alternative energy technologies, and standard essential patents? Is compulsory licensing the most effective means to address these concerns?*

We question the effectiveness of compulsory licensing both in general and in particular, in relation to these specific concerns. There are wide ranging strategies that may be

⁴⁸ John Liddicoat is a co-author on the Australian response. This response is overseen by Professor Andrew Christie at the University of Melbourne.

⁴⁹ Geertrui Van Overwalle, *The Implementation of the Biotechnology Directive in Belgium and its Aftereffects: The Introduction of a New Research Exemption and a Compulsory License for Public Health* (2006) 37 *International Review of Intellectual Property and Competition Law (IIC)* 889; Esther van Zimmeren and Requena, G., 'Ex-officio Licensing in the Medical Sector: The French Model', in: Geertrui Van Overwalle (ed.), *Gene Patents and Public Health*, Brussels, Bruylant (2007), 123-147; Esther Van Zimmeren, and Geertrui Van Overwalle, 'A Paper Tiger? Compulsory License Regimes for Public Health in Europe' (2011) *International Review of Intellectual Property and Competition Law (IIC)* 4.

useful in addressing some of the concerns related to these matters. We submit that it is vital to take a holistic approach to intellectual property law reform in dealing with these concerns. Recent changes to Australian patent law resulting from Raising the Bar amendments are an important first step. As well as compulsory licensing, Crown use, licensing guidelines, competition law as well as other initiatives such as patent pooling and clearinghouse mechanisms were canvassed by the ALRC in its inquiry into gene patents and human Health.⁵⁰ These should remain active areas of law reform and policy development. We have argued elsewhere that it is equally important to recognize that ex-ante policy decisions must to be made by governments, funding agencies, universities and other research institutions and industry as to whether or not patenting is the optimal strategy for innovation and dissemination of knowledge in particular fields of technology.⁵¹

Q Should the compulsory licensing provisions be altered to specifically address issues related to genes, food security, climate change mitigation and alternative energy technologies, and standard essential patents? What are the advantages/disadvantages of altering the provisions in such a way? Would maintaining a more general (technology neutral) approach be preferable?

As with all generalist legislation, technological neutrality should be preferred. The rate of change is so rapid in the areas listed above that it would be near impossible for technology-specific laws to remain relevant. In respect of patent law, it is also mandated by Article 27 of the TRIPS Agreement. However, this would not prevent the issuance of technology-specific guidelines.

Q To what extent are compulsory licences useful in cases where 'fair, reasonable and non-discriminatory' terms already apply?

This question is beyond our expertise.

Q Are there other areas that could benefit from utilising compulsory licensing or other forms of non-voluntary access to patented inventions?

In the US, a report published in 2010 by the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) on gene patents and licensing practices, looked specifically at DNA patents in the genetic diagnostic testing context. SACGHS suggested that there was a 'near perfect storm' developing at the 'confluence of clinical practice and patent law' and that there was evidence that patents have already limited the potential of some genetic tests.⁵² Relevant evidence included a series of eight case studies of genetic testing for 10 clinical conditions focusing on test development, access,

⁵⁰ Australian Law Reform Commission (ALRC) Report 96, *Genes and Ingenuity* (2004).

⁵¹ Dianne Nicol and John Liddicoat, 'Legislating to Exclude Gene Patents: Difficult and Unhelpful or Useful and Feasible' *Journal of Law, Information and Science* in press.

⁵² Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) *Gene Patents and Licensing Practices and their Impact on Patient Access to Genetic Tests* (2010) 89.
<http://oba.od.nih.gov/SACGHS/sacghs_documents.html#GHSDOC_011>.

and quality.⁵³ These case studies were conducted by the Center for Genome Ethics, Law and Policy, at Duke University's Institute for Genome Sciences and Policy. The SACGHS also heard presentations for experts during the course of its study and gathered further information and perspectives on its draft report through the solicitation of public comments.⁵⁴ The Committee concluded that there was evidence of denial of access to tests not covered by insurance, difficulties in obtaining second opinions and one instance where a patent dispute restricted access for an 18-month period.⁵⁵ Although SACGHS found that patents or exclusive licences could stimulate development of a genetic test, it found no cases in which possession of exclusive rights was a necessary prerequisite.⁵⁶ Ultimately, SACGHS recommended the creation of exemptions from patent infringement for use of genetic tests for patient care purposes and for use of patent-protected genes for research purposes.⁵⁷

In response to this recommendation recent literature has suggested that increasing regulatory burdens mean that if such an exemption was implemented, many genetic tests and emerging 'companion tests' may not be developed; a companion test is a test that evaluates genetic, proteomic or gene expression markets to predict whether a drug will work in someone or not – one of the bases for personalised medicine.⁵⁸ However, these arguments are primarily made from a US perspective, and it may be worth considering variations of this exemption from an Australian perspective.⁵⁹

It is also worth noting that we are in the preparatory stages of surveying the Australian human genetic diagnostics industry. The purpose of this survey is to create empirical data on the impediments caused by patents in the provision of genetic diagnostic tests. We are working towards making results from this survey available by the end of 2012.

Measures to Improve Compulsory Licensing

Q *Should the Patents Act be amended to include a statement of objectives? What are the main objectives that should be included in this statement?*

We submit that the inclusion of a statement of objectives is desirable because it would assist in interpretation of the Act. The Australian Council on Intellectual Property has outlined considerations that should be embodied in a statement of objectives,⁶⁰ and we generally echo general their sentiments. However, we suggest that in drafting this statement, considerations should be given to the regulatory effects of the *Patents Act*,⁶¹

⁵³ Appendix A; the findings of these case studies were reported in a special supplement to Volume 12 of *Genetics in Medicine*, *Patently Complicated: Case Studies on the Impact of Patenting and Licensing on Clinical Access to Genetic Testing in the United States* (April 2010) S1-S211.

⁵⁴ Secretary's Advisory Committee on Genetics, Health and Society (SACGHS), *Gene Patents and Licensing Practices and their Impact on Patient Access to Genetic Tests* (2010) 10.

⁵⁵ *Ibid* 42.

⁵⁶ *Ibid* 9.

⁵⁷ *Ibid* 94-95.

⁵⁸ Jeanene Swanson, *Companion Diagnostics Take Off* (October 2009) Genomeweb <<http://www.genomeweb.com/dxpgx/companion-diagnostics-take>>.

⁵⁹ Michael M Hopkins & Stuart Hogarth, 'Biomarker patents for diagnostics: problem or solution?' (2012) 30(6) *Nature Biotechnology* 498.

⁶⁰ Advisory Council on Intellectual Property, *Review of Patentable Subject Matter* (December 2010) 22-30.

⁶¹ See Chris Dent's forthcoming article, 'The Possibilities of a Regulatory Approach to Answer the Question: Should Genetic Inventions be Patentable' (2012) *Journal of Law Information and Science* (in-press), he outlines various issues that should be contemplated when drafting a statement of objectives.

it is quite clear that the *Patents Act* directly influences the behaviour of innovators and investors.

Q *Should a separate objects clause be attached to the compulsory licensing provisions of the Act? What should be the main objectives in that clause?*

In our submission, a separate objects clause attached to the compulsory licensing provisions would be inappropriate. The objects and principles governing the compulsory licensing provisions are (and should be) embraced by the requirement to broadly balance the competing interests at stake in matters relating to patents, which should be contained in the general objects clause. Attributing a specific object to the compulsory licensing provisions would invariably present difficulties in interpretation of the compulsory licensing provisions, as there may be conflict between the general objects clause and the specific clause. If the Commission were to recommend the inclusion of a clause in relation to s 133 and related provisions, we submit that it should mirror the guiding principles contained in the general objects clause.

Q *Should better guidance be provided by the Australian Government or a specific agency on the criteria for granting a compulsory licence and, if so, what form should it take?*

We have previously argued in earlier submissions to the ALRC that the ACCC should provide better guidance as to what is likely to constitute anti-competitive conduct in relation to the use of intellectual property. The IPCRC and the ACCC have both made similar recommendations.⁶² The Government requested that the ACCC issue such guidelines in 2003,⁶³ and the ACCC indicated that it would do so upon s 51(3) being amended. As yet, s 51(3) has not been amended, and no guidelines have been forthcoming.

As we discussed above, a Background Paper on the Application of the Trade Practices Act to Intellectual Property was released by the TPC in 1991. This background paper provides some guidance as to when certain terms and conditions in licensing agreements might be exempted from the CCA (previously the *Trade Practices Act 1974* (Cth)), and when they might breach Part IV provisions. It also provides some very limited guidance as to the conduct that might constitute a misuse of market power. Unfortunately the assistance given by the background paper is very limited, and to some extent redundant given amendments to the CCA over the past ten years. While we agree that guidelines could be more usefully produced after amendment to s 51(3) (and indeed that amendment to s 51(3) is desirable), delay in the inclusion of such an amendment should not preclude the issue of guidelines generally. The lack of certainty currently provided to intellectual property holders may be detrimental to licensing transactions generally. There is no reason why some guidance as to when conduct involving intellectual property might breach s 46, could not be provided now.

⁶² Intellectual Property and Competition Review Committee (IPCRC) Final Report, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000) 215; Australian Law Reform Commission (ALRC) Report 96, *Genes and Ingenuity* (2004) Recommendation 24-2.

⁶³ Trade Practices Act Review, *Review of the Competition Provisions of the Trade Practices Act* (2003) 87.

We do not argue the background paper provides no useful material. In fact, it does provide some advice that could be built on in drafting more detailed guidelines. There is precedence in other jurisdictions, such as that provided by antitrust authorities in the US and the EU. These jurisdictions take quite different approaches to governing the interface between intellectual property and competition law. Determining which approach to take in drafting guidelines involves complex considerations on how best to balance the competing interests of parties to intellectual property licences. We have touched on this above. It also depends to some degree on the views of the ACCC in relation to intellectual property licensing. To address this point briefly, we submit that the US approach provides a useful starting point for licensing guidelines, as it provides some certainty to holders of intellectual property, while still leaving scope for examination by the antitrust authorities in the event that the effect of a condition in a licence is uncertain.

Q *Should better guidance be provided on the criteria used by the Federal Court to determine the terms of compulsory licences, including their price? What form should such guidance take and how specific should it be?*

While we agree that transparency is a desirable aim, we submit that it would be difficult to be prescriptive in laying down the criteria that the courts would use in determining compulsory licensing terms. Indeed, to do so would be virtually impossible given the diversity of patents and licences being negotiated. For example, what constitutes a reasonable attempt to negotiate access in one case, may not in another. Factors such as the nature and value of the invention, the relationship between the parties, and the level of licensing activity in the particular market will all be relevant.

There may be some scope within the context of these factors to include a non-exhaustive list of the matters that will guide the Federal Court in determining compulsory licensing applications. For example, the manner in which the nature and value of the invention will impact on the Court's reasoning could be fleshed out. Matters such as the inventiveness of the invention, the importance of the invention to future research and the purpose for which the licence is sought are some of the matters that might be considered. All of these issues involve a great degree of subjectivity, however, and prescribing relevant factors in anything but the broadest terms, would be very difficult.

Q *Is there a case for retaining some uncertainty in the criteria used by the Federal Court to determine pricing and other licence terms, to encourage out-of-court settlements?*

Again, we submit that there should be some flexibility, but not necessarily uncertainty. Legislation and the Federal Court Rules now require there must have been genuine attempts to settle out of court, and this should assist in encouraging settlement.⁶⁴ The compulsory licensing provisions require a reasonable, unsuccessful attempt at negotiation in any event.⁶⁵ Hence, any guidance provided should be for the purpose of assisting parties in deciding whether to go ahead with an application, and not just to encourage out-of-court settlement.

⁶⁴ *Civil Dispute Resolution Act 2011* (Cth) pt 2; *Federal Court Rules 2011* (Cth) rr 5.02, 8.02.

⁶⁵ *Patents Act 1990* (Cth) s 133(2)(a)(i).

We submit that the question of whether the Federal Court should retain jurisdiction is an open one. We have noted above that an administrative body may be a more appropriate forum to hear applications for compulsory licensing. In the alternative, jurisdiction could be given to an expanded Copyright Tribunal in the form of an Intellectual Property Tribunal.

Q *Do the compulsory licensing, Crown use and acquisition provisions in the Patents Act share a common purpose? What is the case for improving the consistency of the relevant provisions?*

There is certainly some commonality to the compulsory licensing and Crown use provisions, because they both amount to use without authorisation, as specified in Article 31 of the TRIPS Agreement. However, we submit that the acquisition provisions tend to have a slightly different focus, not only do they give the Crown a right to use, but they also take away the right to use (and to authorise others to use) from the patentee.

Q *Would there be benefits in consolidating the compulsory licensing, Crown use and acquisition provisions in a single part of the Patents Act with a common objects clause?*

This proposal seems to make good sense. It does seem strange that the compulsory licensing provisions are included in a section with the revocation provisions. This is, no doubt, due to a historical anomaly. It might be worth considering combining the use without authorisation provisions at this time, when reform of the provisions is being contemplated. On the other hand, it is doubtful that this restructure would make a significant difference to the practical utility of any of these provisions.

Q *Should the criteria adopted by the Federal Court in determining the terms on which access to a patent is granted be consistent for all types of non-voluntary access to patents, including compulsory licensing, Crown use and acquisitions?*

We submit that caution should be exercised in standardising the terms on which access will be granted, because the different types of use without authorisation are intended to serve different purposes and apply in diverse circumstances. This will invariably mean that the terms of access are likely to differ depending on various factors, and the criteria adopted in determining these terms must take into account the type of non-voluntary access sought.

Q *What is the case for giving an alternative dispute resolution body powers to consider applications for compulsory licences? Which body could be given such powers and how would this arrangement work in practice?*

An expanded Copyright Tribunal may be the most suitable option. This body already has experience with setting royalties and taking a variety of issues into consideration when arbitrating agreements.

Q *In addition to the areas mentioned in this section, are there any other ways to improve the operation of the compulsory licensing provisions?*

See below.

Q *Is lack of awareness of compulsory licensing provisions a significant problem?*

It would appear that parties involved in patent licensing transactions are aware of the compulsory licensing provisions, at least in the biomedical/biotechnology industry in which we have conducted empirical research. The problem is not so much awareness of the provisions, as their cumbersome and expensive nature. There are perceived to be more effective means of working around problem patents than applying for a compulsory licence. However, as noted above, respondents have stated it would be convenient if compulsory licencing were more accessible.

It is well known that many solicitors and barristers conduct pro bono cases. Many parties who could benefit from compulsory licences are not aware of this. Perhaps what should be considered is ensuring intellectual property lawyers are on pro bono networks, and ensuring that organisations, particularly not-for-profit institutions such as hospitals, know that such networks exist and how to access them. This could probably be achieved quite easily via piggybacking on pro bono networks that already exist, and then advertising the availability of the resource.

We expect that such networks would be seldom used, but knowing they exist may enable some companies to access compulsory licencing provisions or at least assist compulsory licencing to have the *in terrorem* effects it is designed to achieve.

Q *What are the specific challenges in raising awareness of the compulsory licensing provisions among small businesses and the healthcare sector?*

If raising awareness is considered by the Commission to be necessary, IP Australia could perhaps be involved in disseminating information about the compulsory licensing provisions, given that IP Australia currently devotes resources to public dissemination of its work.

Q *What measures are currently utilised to raise awareness of the compulsory licensing provisions and which bodies are responsible?*

We are not in a position to respond to this question.

Q *What awareness raising measures should be implemented, particularly for small businesses and the healthcare sector? Who should administer the measures?*

Whilst raising awareness might be helpful, small businesses unlikely to be able to afford to make use of compulsory licensing the provisions in their current form anyway.

Alternative Mechanisms

Q *What would be the advantages and disadvantages of having non-voluntary licensing of patents by a collecting society?*

In our submission to the ALRC's inquiry into gene patents and human health, we expressed support for the creation of a statutory licensing scheme for some types of patents, particularly in the field of genetic technology. For example, such a scheme might be applicable for licensing gene patents for use in diagnostic testing, or for licensing of research tools. However, while the ALRC received in principle support for statutory licensing in some of its consultations, it was ultimately decided that in 2004 there was no pressing need to consider this option. There is no clear evidence at the present time that the need for such a mechanism has increased in the area of genetic technology. However, it may be the case that there is a growing need to explore this option further, given increasing concerns about the capacity of patents to deter innovation in emerging technologies associated with genetic technology, food security, climate change mitigation and alternative energy technologies.

A voluntary scheme may be more appropriate, on the basis that it would be least likely to offend against the provisions of the TRIPS Agreement. In effect, a voluntary scheme would operate in much the same way as the voluntary licensing schemes apply under the *Copyright Act 1968* (Cth). However, there may be scope for introducing non-voluntary statutory schemes along the lines of the statutory schemes in the *Copyright Act 1968* (Cth).

Q *In what specific areas would collecting societies play a useful role for patent licensing? Would there be sufficient demand to justify establishing a collecting society to undertake collective rights management in the areas you have nominated?*

As noted above, we suggest that collecting societies would be most appropriate in areas of newly emerging technologies, or, indeed, wherever patent thickets have the capacity to interfere with incremental innovation. Non-voluntary schemes may need to be restricted to particular sectors, in the same way that the statutory schemes under the *Copyright Act 1968* (Cth) are restricted to educational institutions and the like. For example, in the area of genetic technology, a non-voluntary scheme may be applicable for the public research sector and/or the public health sector.

Q *Should existing patents be subject to non-voluntary licensing by a collecting society? If so, how should this be handled? Would existing patent holders need to be compensated and, if so, how?*

As we see it, one of the key purposes of a licensing scheme, whether voluntary or not, is that reasonable remuneration is paid to the licensor. On this basis, it would be double dipping to give the patentee further compensation.

Q *What alternatives to compulsory licensing should be considered as part of this inquiry? What are the advantages and disadvantages of your suggested alternative mechanisms compared to compulsory licensing?*

We argue that governments should consider supporting industry-led initiatives like patent clearinghouses or patent pools if they arise. Other initiatives might include: competition law guidelines; tax incentives; support for companies that aggregate patents to enable research; priority for patent examination of certain technology; and a range of other factors.