

Submission in response to proposed amendments to the *Patents Act 1990* (the Patents Act) to introduce an Objects Clause and an exclusion from patentability for an invention the commercial exploitation of which would be wholly offensive to a reasonable and informed member of the public

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Summary

The endeavours of groups such as ACIP, the ALRC and IP Australia to ensure that Australia's patent system is working optimally are acknowledged and have clearly had significant impact on the effectiveness of that system. However, the benefit of including an objects clause in the Patents Act 1990 is debatable and the assumptions underpinning the precise wording of any clause that might be adopted require careful examination. The same is true of any attempt to craft a generalised exclusion to expand the class of alleged inventions that are considered unfit for patent protection in Australia.

The system of patent rights in Australia as elsewhere provides an anomaly to the concepts of competition and a free market which form a dominant economic paradigm in our society.¹ Nonetheless patent rights remain an accepted mechanism for encouraging innovation and knowledge sharing. These rights are limited in scope, function as a right to exclude rather than an affirmative right, and are constrained by the provisions of the Patents Act 1990 as judicially interpreted². To date the express limitations to patent protection have remained limited in scope with attempts to legislate for further restrictions being rejected and the Courts supporting the efficacy of existing provisions in the Act as a mechanism for determining what should be patentable³. Moreover identified weaknesses in Australia's patent system are being systematically addressed by specific amendments to particular provisions⁴. These amendments reflect more rigorous standards adopted by major trading partners and address specific needs around issues such as experimental and Crown use⁵. This targeted response is preferable to adopting novel generic clauses which may have unintended consequences.

Rights to health, adequate food, security, education and equality are recognised as important pillars of our society that need safeguarding⁶. However Australian society is culturally diverse giving rise to conflicting moral perspectives and beliefs regarding what might be acceptable and what might not⁷. Furthermore the sad truth is that even today different parts of our society have different access to health, adequate food, security, education and equality⁸. Proposed provisions that assume that all Australians enjoy a level playing field must be viewed with caution.

An alternative approach is suggested in answer to the specific questions posed in the consultation paper.

¹ R. Reynolds, N.P. Stoianoff, A. Adrian, A. Roy, *Intellectual Property Law: text and essential cases*, (4th ed, Federation Press, Sydney, February 2012)

² *ibid*

³ *ibid*

⁴ For example the amendments under *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*

⁵ Reynolds et al, above n. 1, and *Intellectual Property Amendments Bill 2013*

⁶ *The Universal Declaration of Human Rights 1948*

⁷ http://www.dfat.gov.au/facts/people_culture.html viewed 14 August 2013

⁸ Monitoring Inequality in Australia at < <http://www.publichealth.gov.au/inequality-graphs/monitoring-inequality-in-australia-introduction.html>> viewed 14 August 2013

1. Objects Clause

The purpose of an Objects Clause

Consultation paper

The consultation paper states that the purpose of an Objects Clause is to set out the underlying purpose of a piece of legislation⁹.

Response

The underlying purpose of the Patents Act 1990 is to regulate the granting of limited term monopolies for exploitation of subject matter that meets the conditions specified in the Act for the granting of such a monopoly, does not offend any of the exclusions or limitations specified with respect to the granting of such a monopoly, and is consistent with relevant international obligations to which Australia has acceded¹⁰. This purpose is self-evident and express statement of it in the Patents Act 1990 would be superfluous. Assertion that the purpose of the Patents Act 1990 is something more than or different from this purpose is to burden this Act with tasks beyond its scope.

However, some nations do make some stipulation in their patent laws as to the purpose of the legislation. For example, Article 1 of the Japanese Patent Act 1959 states:

Article 1 The purpose of this Act is, through promoting the protection and the utilization of inventions, to encourage inventions, and thereby to contribute to the development of industry.

Similarly, Article 1 of the *Patent Law of the People's Republic of China 2008* states:

Article 1 This Law is enacted for the purpose of protecting the lawful rights and interests of patentees, encouraging invention-creation, promoting the application of invention-creation, enhancing innovation capability, promoting the advancement of science and technology and the economic and social development.

There is no equivalent under US patent law. However, in the US Constitution, the intellectual property clause that confers the power to legislate in relation to intellectual property rights, more specifically copyright and patent rights, provides both a purpose and a limitation:

⁹ Commonwealth of Australia IP Australia, Patentable Subject Matter Consultation on an objects clause and an exclusion from patentability, July 2013 p 4

¹⁰ Reynolds et al, above n. 1,

*Congress shall have the Power to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.*¹¹

The UK patent law equally does not have an objects clause except in making the following introduction:

An Act to establish a new law of patents applicable to future patents and applications for patents; to amend the law of patents applicable to existing patents and applications for patents; to give effect to certain international conventions on patents; and for connected purposes.

What is evident from each of the above examples is that the purpose of patents is couched in positive terms. They each emphasise the intended benefit of granting patents and do not, with the exception of providing a time limit, engage with the issue of balancing competing rights between inventors and the rest of society.

Conversely, the new Patents Act 2013 of New Zealand provides a comprehensive purposes clause:

3 Purposes

The purposes of this Act are to—

- (a) provide an efficient and effective patent system that—
 - (i) promotes innovation and economic growth while providing an appropriate balance between the interests of inventors and patent owners and the interests of society as a whole; and*
 - (ii) complies with New Zealand's international obligations; and**
- (b) ensure that a patent is granted for an invention only in appropriate circumstances by—
 - (i) establishing appropriate criteria for the granting of a patent; and*
 - (ii) providing for procedures that allow the validity of a patent to be tested; and**
- (c) provide greater certainty for patent owners and the users of patented inventions that patents will be valid after they are granted; and*
- (d) address Māori concerns relating to the granting of patents for inventions derived from indigenous plants and animals or from Māori traditional knowledge; and*
- (e) ensure that New Zealand's patent legislation takes account of developments in the patent systems of other countries.*

¹¹ U.S. Const., art. I, §8, cl. 8.

It is not clear how such a set of purposes are to be interpreted. One would expect that paragraph (b) simply describes the content and operation of the Act and paragraph (c) provides an aspirational statement that the working of the system will produce greater certainty. Meanwhile paragraph (a) reflects the general objects clause of the TRIPS Agreement (Art. 7) and manages to do so without being adversarial in its language. Paragraph (e) does not make sense in that the legislation cannot 'take into account developments in ...other countries'. It would be the legislature that has that ability. Perhaps this is yet another aspirational purpose intending to place a burden on the legislature to amend the patent legislation in accordance with developments in other nations but at a very general level and without giving guidance as to how that is to proceed. More importantly, paragraph (d) provides a significant development, one that Australia could consider. This recognition of Maori concerns is reinforced by the establishment of a Maori advisory committee which has a role to play in the exclusions from patentability (see section 15(3) Patents Act 2013).

View of the Office of Parliamentary Counsel

Consultation paper

The consultation paper states that:

The Office of Parliamentary Counsel, which is responsible for drafting Australian Government legislation, states that:

Some objects provisions give a general understanding of the purpose of the legislation...Other objects provisions set out the general aim or principles that help the reader to interpret the detailed provisions of the legislation.^{12 13}

and that

*An Objects Clause may also be used by the Courts and others, such as patent examiners, in interpreting legislation where there is ambiguity or uncertainty*¹⁴.

Response

The consultation paper acknowledges that there is ambiguity as to the purpose the inclusion of an objects clause in an Act serves. It follows that the inclusion of an Objects Clause will not necessarily improve the Patents Act 1990 and in the worst case may lead to additional uncertainty regarding the purpose and function of the Act. This goes to the heart of statutory interpretation. For some time, it has been permitted to consider certain extrinsic material in the process of interpreting the meaning of a provision in legislation. This is also why there are Explanatory Memoranda – to provide an explanation for the legislative intention of the drafting of the statute. Further, there is the Commonwealth *Acts Interpretation Act 1901* which gives

¹² Office of Parliamentary Counsel, *Working with the Office of Parliamentary Counsel: A Guide for Clients* (3rd ed, 2008), [125]

¹³ Commonwealth of Australia, above n9 p4

¹⁴ Commonwealth of Australia, above n9 p4

guidance as to how the meaning of a provision is to be ascertained, noting at section 15AA that provisions in the legislation are to be interpreted in accordance with the purpose or objective of the legislation whether expressly stated or not.

ACIP Patentable Subject Matter report

Consultation paper

The consultation paper observes that ‘in their Patentable Subject Matter report, ACIP explained that an Objects Clause ‘would clarify the interaction between the patent system and competition policy’’.¹⁵

Response

Assuming an Objects Clause can meet this task presumes that it should do so and that it will be treated as doing so in interpretation of the Act. As noted above these presumptions are questionable.

Further, the construct “competition policy” is dynamic, addressed in and through diverse legislation and affected by changing global market practices as well as national policy and practice. Any attempt to craft a statement intended to define the place of patent law in this complex arena requires careful analysis.

TRIPS Objectives

Consultation paper

ACIP referred to the World Trade Organization *Agreement on Trade Related Aspects of Intellectual Property Rights 1994* (TRIPS) description of the objectives of the intellectual property system which states:

*The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.*¹⁶

Response

This statement deals with the protection and enforcement of IP rights not a Patents Act. The term “the intellectual property system” is reference to a diverse body of legislation and case law across multiple jurisdictions dealing with a range of property rights with different implementations and effects. It is a statement from an international treaty not national legislation. The purpose and effect of an international treaty is substantially different from the purpose and effect of a specific piece of national legislation.

¹⁵ Advisory Council on Intellectual Property (‘ACIP’), *Patentable Subject Matter* (2010), page 3, paragraph 2; Commonwealth of Australia, above n9 p4

¹⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 7, ‘Objectives’

Moreover this statement is extremely general. Thus its capacity to provide assistance in understanding the purpose and functioning of specific national patent legislation is debatable.

Rather, the TRIPS Objectives inform the design of patent legislation and establish the reasoning behind the key elements of a patent regime as described in Article 27ff of TRIPS. A balance of rights and obligations is demonstrated by having a limited term monopoly, the option to exclude certain subject matter from patentability, and the ability to compulsorily licence the technology protected under patent.

ACIP alternative to the TRIPS definition

Consultation paper

The consultation paper observes that ACIP provided a simplified alternative to the TRIPS definition, recommending that the Objects Clause

*....should describe the purpose of the legislation as being to provide an environment that promotes Australia's national interest and enhances the well-being of Australians by balancing the competing interests of patent rights holders, the users of technology, and Australian society as a whole.*¹⁷

Response

Australia comprises a diverse population of approximately 23 million. Australian Bureau of Statistics projections put the Aboriginal and Torres Strait Islander population at 575,552 at 30 June 2011. The rest of Australia's population are migrants or descendants of migrants who have arrived in Australia since 1788 from about 200 countries across Europe, the Asia–Pacific region, the Middle East and Africa. At 2009, about 25.6 per cent of the estimated resident population comprised those born overseas¹⁸.

More than 15 per cent of Australians speak languages other than English at home. The most commonly spoken languages after English are Italian, Greek, Cantonese, Arabic, Vietnamese and Mandarin. Australians speak more than 200 languages, including Indigenous Australian languages¹⁹.

Australia is a predominantly Christian country, with around 64 per cent of all Australians identifying as Christians. However, most other major religious faiths are also practiced.²⁰ What then is the Australian national interest? Ashton Calvert provides some guidance on this:

Australian national interest is something that is defined by the Australian Government and the Australian people. The national interest is not static, nor can it be defined in a mechanical way. It

¹⁷ Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter* (2010), page 5, 'Recommendation 2'

¹⁸ See Australian Government Department of Foreign Affairs and Trade, *about Australia, People, culture and lifestyle*, at <http://www.dfat.gov.au/facts/people_culture.html> viewed 14 August 2013

¹⁹ *ibid*

²⁰ *ibid*

*depends in part on prior strategic choices we have made, and is informed by the view we have of ourselves as a country, and by what we want to stand for. Finally, I believe we need to recognise that Australia's interests are global in scope and character, and that some of our interests are defined by geography and some are not.*²¹

There are substantial differences in the health and wellbeing of specific groups within our population. Although this is most evident for Aboriginal and Torres Strait Islander peoples, there are also many other disadvantaged groups in Australia. Inequalities arise based *inter alia* on age, sex, ethnicity and race, social and economic position, disability, geographical area and health status, access to education, material resources, safe working conditions, effective services, and living conditions in childhood.²²

As noted above Australian society is diverse so the concept of a collective interest on the one hand embraces either a vast range of potential exclusions to capture all potential interests or a diminishingly small range of potential exclusions that capture interests shared across diverse cultural groups.

The granting of patent rights is in itself based on balancing the interests of patent rights holders, the users of technology, and society. Thus an express statement to this effect is superfluous. Patent rights balance rewarding the investment in innovation made by patent holders with ensuring access to technology and knowledge. Moreover the interests of these groups are not necessarily in conflict and yet the proposed statement creates a conflict by referring to 'competing interests' of the various stakeholders.

Government acceptance of ACIP's recommendation

Consultation paper

The consultation paper observes that the Government accepted ACIP's recommendation that an object clause be included in its response to the Gene Patents Report²³ and that ACIP's recommended wording is proposed as **Option 1** for the wording of the Objects Clause.

The consultation paper goes on to observe that an important feature of both the ACIP and TRIPS descriptions is their technology neutrality reflecting the rationale that the same requirements should apply to all technologies and that the system should have sufficient flexibility to deal with current and future issues as they arise.

²¹From "The Evolving International Environment and Australia's National Interest" Address to the Lowy Institute by Ashton Calvert, Secretary Department of Foreign Affairs and Trade Canberra, 26 November 2003 viewed at <http://www.dfat.gov.au/media/speeches/department/031126_lowy_institute.html> on 16 August 2013.

²² Monitoring Inequality in Australia viewed at <<http://www.publichealth.gov.au/inequality-graphs/monitoring-inequality-in-australia-introduction.html>> on 16 August 2013.

²³ Australian Government Response to the Senate Committee Gene Patents Report (2011), page 13.

Response

While we question the need for an Objects Clause we agree that any Objects clause adopted in the Patents Act 1990 should be technology neutral. Moreover we observe that the issue of technology neutrality is also important with respect to any general proviso adopted with respect to patentable subject matter as technology neutrality is a requirement under the TRIPS Agreement.

Goals of the patent system

Consultation paper

The consultation paper observes that the patent system has both economic and social welfare goals reflected in the TRIPS Objectives and to a lesser extent in the proposed ACIP Objects Clause.

The economic goals of the patent system are to promote economic growth, trade and investment by encouraging innovation and the dissemination of knowledge and technology. The patent system encourages innovation by giving patentees a period of market exclusivity in which to recoup their development costs through commercialisation of their inventions. In exchange, patentees are required to disclose the details of their inventions to the public.

The patent system contributes to social welfare by providing Australians with access to new technologies and developments that otherwise would not have occurred and that improve our quality of life (for example new pharmaceuticals and medical technologies and improvements to safety and waste management technologies).

However, the patent system will only meet its economic goals if the positive effects of the patent system in stimulating investment in innovation and providing society with access to new technology are balanced against the potential negative effects of patents restricting access to follow-on innovation and increasing costs, and so restricting supply of new patented technologies.

Response

It is important to recognise that one of the tenets of the patent system and the existence of monopolies in general that normal free market cost controls are suspended. This is part of the trade off the system accepts for encouraging innovation.

An objects clause and a general exclusion from patentability are unlikely to impact abuses of monopolies where they may arise. Rather these issues are more effectively addressed through ensuring thresholds for patentability with respect to inventiveness are adequate, provision of research exemptions to promote follow-on research, providing clear and workable systems of Crown use and compulsory licensing and

reviewing the extent to which particular technologies such as pharmaceuticals should be entitled to privileged treatment with respect to the patent term.

Interests of patent applicants

Consultation paper

One concern with the specific wording proposed by ACIP is that it is silent with respect to the interests of patent applicants. Patent applicants are an important element of the system and it is important that the combined interests of both patent owners and applicants are accounted for and balanced with the interests of society and users of technology. ACIP's wording also does not focus on the way in which the patent system promotes the national interest, as stated in TRIPS and as widely acknowledged in Government policy, which is by promoting innovation and the dissemination of technology.

An alternate wording that addresses these two issues without moving away from ACIP's approach is provided below.

the purpose of the patent system is to provide an environment that enhances the well-being of Australians by promoting innovation and the dissemination of technology and by balancing the competing interests of patent applicants and patent owners, the users of technology, and Australian society as a whole.

*This wording is proposed as **Option 2** for the Objects clause.*

Response

The wording of the Option 2 Objects clause is superior to that of Option 1 in that it does identify key outcomes of the patent system and recognises patent applicants as stakeholders. Nonetheless it still disregards the cultural diversities and inequalities that exist in Australian society and presumes that a generic reference to the wellbeing of Australians is meaningful.

Moreover as discussed above a fundamental flaw lies in the assumption that matters are advanced by the adoption of an Objects Clause in the Patents Act 1990. As elaborated above the problems are essentially two fold. On the one hand the articulated rationale behind patent rights seeks to embrace more than it should and on the other hand the articulated rationale is compromised by generalised language that disregards the diversity and complexity of Australian culture and opportunity.

Perhaps one of the greatest challenges faced by the proposed clauses is that they endeavour to embrace moral concerns within a secular construct that is limited in its capacity to accommodate such concerns.

Option 2 does so in the context of Australians and Australian society, but such a group, despite its diversity, is still a privileged group compared to society at a global level and both options presuppose that Australia operates in isolation without responsibility for society at large. Noted the patent law is jurisdictional but it is situated, now more than ever, in a global context and Australia has an ever increasing role in global governance.

New Zealand's section 3(a) of the Patents Act 2013 recognises that the nation does not operate in isolation and also does not create an adversarial perspective between patent owners/inventors and society. The reference to 'competing interests' in both Options 1 and 2 presupposes that the interests of each stakeholder will compete with those of each other stakeholder ignoring the fact that the same person can be both a patent applicant/owner and user at the same time while remaining a member of [Australian] society as a whole.

2. Patentability Exclusion

Grant of patents to inventions the commercial exploitation of which society finds offensive

Consultation Paper

The consultation paper states that 'introducing an Objects Clause into the Patents Act will provide general guidance as to the intent and purpose of the patent system' but 'will not necessarily prevent the grant of patents to inventions the commercial exploitation of which society finds offensive'.

For this reason, both ACIP and the ALRC recommended the introduction of an explicit exclusion from patentability for inventions where society would have a moral objection to commercialisation of the invention.

Response

Patent rights are a negative right functioning as a right to exclude others from exploiting the invention whether that is in a commercial or non-commercial sense. The granting of a patent is not a licence to commercialise an invention. A prohibition to commercialise an invention ought to be achieved through other regulatory regimes.

TRIPS Obligations

Consultation Paper

As signatory to TRIPS, Australia is obliged to provide patent protection for inventions in all technologies where the invention satisfies relevant standards. However, TRIPS allows for some exclusions in certain circumstances. One such circumstance is to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.

*Members may exclude from patentability inventions....the commercial exploitation of which is necessary to protect ordre public or morality.*²⁴

Response

The paraphrasing of the relevant provision of the TRIPS Agreement in the Consultation paper is a little confusing so the full text is reproduced here for ease of reference:

Article 27(2) of TRIPS provides:

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

In understanding the option invoked by this provision it is necessary to examine the concept of *ordre public*. *Ordre public* concerns the body of principles that addresses fundamental societal values. However this concept is acknowledged as a contested notion that has a variety of broad connotations.²⁵ Thus if there is intent to reflect this option in Australian patent law it is important that scope and intent of the term is clear. Further under Article 27(2) the mere fact that exploitation of an invention is illegal is not sufficient for excluding it from protection.

Through the use of both terms TRIPS apparently sees *ordre public* as distinct from morality although it would readily be construed as an element of *ordre public*²⁶. The further language of the provision shows that TRIPS considers the rationale for excluding inventions from patent protection as including the protection of human, animal or plant life or health and avoiding serious prejudice to the environment but this is not intended as the full scope of the potential exclusion.

Moreover under Article 27(2) it is not the impact of the invention *per se* on *ordre public* or morality that must be evaluated but rather the impact of its commercial exploitation. If we accept morality as referring to questions of right and wrong behaviour²⁷ the notion that commercial exploitation triggers the harm requires consideration. The term commercial exploitation in a business sense refers simply to the development and use of a resource but in a pejorative sense it refers to unethical business practices aiming

²⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 27(2), 'Patentable Subject Matter'.

²⁵ De Lange R (2007) *The European Public Order, Constitutional Principles and Fundamental Rights* Erasmus Law Review 1, 3-24.

²⁶ Ibid.

²⁷ See <<http://www.merriam-webster.com/dictionary/moral>> viewed 16 August 2013.

to make a profit²⁸. The notion that development and use of a patented invention will cause harm where the invention itself does not, implies that the development and use of the invention is distinct from the invention in an ethical context. This leads to the ludicrous notion that for instance a cruel method of slaughtering animals would be patentable as long as it is not developed. On the other hand if the pejorative use of the term is intended then as long as such a practice was construed as an unethical business practice aiming to make a profit it would not be protectable but here again there is a dilemma. If the method were clearly unprofitable it would be protectable.

An arena in which such considerations make a little more sense is when one considers the idea that access to health care is a fundamental human right and that any exclusion of access on financial grounds is wrong. This is potentially a consequence of the patentability of pharmaceuticals and methods of medical treatment but the former is allowed in most jurisdictions and pharmaceutical companies make enormous profits from doing so. On the other hand the premium cost of pharmaceuticals under patent justified as recouping R&D costs means that access to treatment will be restricted unless there is government subsidy under a system such as the Pharmaceutical Benefits Scheme or health insurance schemes.

Thus it is readily apparent that while the intent of Article 27(2) may have been positive the actual wording of the provision is problematic and most likely fails to embody this positive intent.

Meanwhile, the proposed inclusion of a general *ordre public* or morality based exclusion ignores the fact that the *Statute of Monopolies 1623* is still part of Australian law and imports the concept of 'generally inconvenient', despite its difficulties as a concept, into the primary question of *manner of manufacture*. How will the two sets of concepts work together in the Patents Act 1990? If the Australian Patent Office and the Australian court system have been reluctant to invoke the concept of 'generally inconvenient' in determining whether an invention is appropriate subject matter for letters patent, then how will a general morality provision be invoked? To this end, we refer to the European Patent Office examiners manual on the issue of exceptions to patentability, Part G Chapter II, Section 4:

4.1

Matter contrary to "ordre public" or morality

Any invention the commercial exploitation of which would be contrary to "ordre public" or morality is specifically excluded from patentability. The purpose of this is to deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour (see also F-II, 7.2). Anti-personnel mines are an obvious example. This provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that

²⁸ See <<http://www.collinsdictionary.com/dictionary/english/commercial-exploitation>> viewed 16 August 2013.

the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable. If it is clear that this is the case, objection should be raised under Art. 53(a); otherwise not. The mere possibility of abuse of an invention is not sufficient to deny patent protection pursuant to Art. 53(a) EPC if the invention can also be exploited in a way which does not and would not infringe "ordre public" and morality (see T 866/01)...

The example given is not dissimilar to the inherent checks and balances provided by the Statute of Monopolies which raises the question, why not simply provide the Australian Patent Office examiners with additional guidance on how to utilise the concept of 'generally inconvenient'?

Similar patentability exclusions on non-economic grounds

Consultation Paper

The consultation paper observes that '[s]imilar patentability exclusions on non-economic grounds exist in the European [Patent Convention], Japan and New Zealand'²⁹ which exclude 'subject matter that is... contrary to public order or morality (EPC), contravene public order, morality or public health (Japan) or is contrary to morality (New Zealand)'.

Response

The ALRC has observed that consideration of the scope of these exclusions by courts and patent offices or in academic commentary has been very limited and that such provisions have rarely been invoked with any success.³⁰ Thus the fact that other countries have imported this type of provision into their domestic patent law is a questionable justification for Australia following suit.

Examples of the provisions used elsewhere are as follows.

European law provides an exclusion from patentability on the basis of 'ordre public or morality' in similar terms to the TRIPS Agreement. The exclusion is set out in art 53(a) of the European Patent Convention (EPC) and is replicated in article 6(1) of the European Parliament's Directive on the Legal Protection of Biological Inventions (EU Biotechnology Directive).

In addition, the EU Biotechnology Directive provides that certain inventions presumptively fall within the ambit of the exclusion from patentability on the grounds of ordre public or morality: processes for cloning

²⁹ Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter: Issues Paper* (2008), Section 10, 'Overseas Law and Practice', pages 57-61.

³⁰ ALRC, *Genes and Ingenuity: Gene patenting and human health* (ALRC Report 99)/7. Exclusions from Patentability Exclusions from patentability on social or ethical grounds, at < <http://www.alrc.gov.au/publications/7-exclusions-patentability/exclusions-patentability-social-or-ethical-grounds>> viewed on 16 August 2013.

human beings or for modifying the germ line identity of human beings; uses of embryos for industrial or commercial purposes; and processes for modifying the germ line identity of animals that are likely to cause them suffering without substantial medical benefit to humans or animals, and also the animals resulting from such processes.

Article 53(a) of the European Patent Convention 2000 provides that European patents *'shall not be granted in respect of inventions the commercial exploitation of which would be contrary to "ordre public" or morality'* and that *'such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting states'*.

Rule 28 Exceptions to patentability: Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

- a. *processes for cloning human beings;*
- b. *processes for modifying the germ line genetic identity of human beings;*
- c. *uses of human embryos for industrial or commercial purposes;*
- d. *processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.*

Under the Japanese Patent Act, an "Invention" is defined as a highly advanced creation of technical ideas utilizing the laws of nature (Article 2). *However* any invention that is liable to injure public order, morality or public health is not patentable (Article 32).³¹

Under US patent law, laws of nature, natural phenomena and abstract ideas are not eligible for patent protection [Diamond v. Diehr, 450 U.S. 175, 185 (1981)]. Further the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), § 33, prohibits issuance of a patent on a claim directed to or encompassing a human organism.³²

Article 5 of the Patent Law of China provides that patents shall not be granted for inventions or creations that violate the law or social ethics, or harm public interests; patent rights shall not be granted for

³¹ Standing Committee on the Law of Patents: WIPO program activities exceptions and limitations Electronic Forum viewed at <<http://www.wipo.int/scp/en/exceptions/replies/japan.html>> viewed 20 August 2013

³² Standing Committee on the Law of Patents: WIPO program activities exceptions and limitations Electronic Forum viewed at <<http://www.wipo.int/scp/en/exceptions/replies/us.html>> viewed 20 August 2013

inventions that are accomplished by relying on genetic resources which are obtained or used in violation of the provisions of laws and administrative regulations.

Article 25 of the Patent Law of China provides that patent rights shall not be granted for any of the following:

- (1) scientific discoveries;
 - (2) rules and methods for intellectual activities;
 - (3) methods for the diagnosis or treatment of diseases;
 - (4) animal or plant varieties;
 - (5) substances obtained by means of nuclear transformation; and
 - (6) designs that are mainly used for marking the pattern, color or the combination of the two of prints.
- (Note: three types of patent are granted under the Patent Law of China, i.e. inventions, utility models and designs)³³

The Indian Patents Act, 1970 provides a statutory provision regarding the public order or morality exclusion.

Section 3(b) excludes “*an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment*”.³⁴

Further, the New Zealand provision for exclusions to patentability is section 15 of the Patents Act 2013:

15 Inventions contrary to public order or morality not patentable inventions

(1) *An invention is not a patentable invention if the commercial exploitation of the invention, so far as claimed in a claim, is contrary to—*

- (a) *public order (which in this section has the same meaning as the term ordre public as used in Article 27.2 of the TRIPS agreement); or*
- (b) *morality.*

Examples

The commercial exploitation of the following inventions is contrary to public order or morality and, accordingly, those inventions are not patentable:

- *an invention that is a process for cloning human beings:*

³³ Standing Committee on the Law of Patents: WIPO program activities exceptions and limitations Electronic Forum viewed at <<http://www.wipo.int/scp/en/exceptions/replies/china.html>> viewed 20 August 2013.

³⁴ The Patents Act, 1970 (as last amended by Patents (Amendment) Act 2005) at <http://www.wipo.int/wipolex/en/text.jsp?file_id=295102> viewed 22 August 2013.

- *an invention that is a process for modifying the germ line genetic identity of human beings:*
- *an invention that involves the use of human embryos for industrial or commercial purposes:*
- *an invention that is a process for modifying the genetic identity of animals that is likely to cause them suffering without any substantial medical benefit to human beings or animals, or an invention that is an animal resulting from such a process.*

(2) For the purposes of subsection (1), commercial exploitation must not be regarded as contrary to public order or morality only because it is prohibited by any law in force in New Zealand.

(3) The Commissioner may, for the purpose of making a decision under this section, seek advice from the Māori advisory committee or any person that the Commissioner considers appropriate.

Diversity in how this concept is articulated in different countries is apparent.

Exclusions under s 18 (2)

Consultation Paper

The consultation paper observes that the Patents Act 1990 currently has two specific exclusions – ‘the first excludes the patenting of human beings and biological processes for their generation; and the second exclusion, only applicable to innovation patents, excludes the patenting of plants, animals and biological processes for their generation’.

Subsection 18(2) of the Patents Act states that:

*Human beings, and the biological processes for their generation, are not patentable inventions.*³⁵

This amendment was introduced into the Patents Act 1990 to address ethical concerns about the patenting of human life forms. It is consistent with the view that the Government should not be granting rights in respect of a technology that society as a whole considers offensive or inappropriate for commercialisation.

Response

The exclusion under s18(2) is a narrow one. The Australian Courts have resisted attempts to expand the range of excluded subject matter and a number of reviews have generated the same outcome³⁶.

³⁵ *Patents Act 1990, Section 18(2).*

Exclusions under s 18 (3)

Consultation Paper

Subsection 18(3) of the Patents Act states that:

For the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions.³⁷

This amendment was introduced at the time the Innovation Patent was introduced in 2001. Innovation patents were introduced to provide a shorter term of protection for lower level innovations that might not qualify for grant of a standard patent. The exclusion was to prevent the innovation patent interfering with Plant Breeder's Rights and in the absence of a clear need for protection for lower level animal inventions.

Response

This exclusion deals with the interaction of different types of right rather than express concerns regarding the suitability of the excluded subject matter for patent protection.

Exclusions under s 50

Consultation Paper

Paragraph 50(1)(a) of the Patents Act also allows the Commissioner to refuse to accept or grant a patent for an invention the use of which is contrary to law.

The paragraph states that:

(1) The Commissioner may refuse to accept a request and specification relating to a standard patent, or to grant a standard patent:

(a) for an invention the use of which would be contrary to law.³⁸

This provision only applies where there is no lawful use for the invention. It does not address circumstances where there may be a lawful use for the invention but where society objects to commercialisation of the invention.

³⁶ *Patents Amendment Bill 1996, Patents Amendment Bill in 2010, Advisory Council on Intellectual Property (ACIP) Patentable Subject Matter Final Report, December 2010; Genes and Ingenuity: Gene Patenting and Human Health (ALRC 99, 2004).*

³⁷ *Patents Act 1990, Section 18(3).*

³⁸ *Patents Act 1990, Section 50(1)(a).*

ACIP also noted that the exclusions in s 50, specifically the provisions relating to 'contrary to law', may not be compliant with TRIPS which states that a country cannot exclude an invention 'merely because the exploitation is prohibited by their law'.³⁹ Similar provisions in the New Zealand Patents Act have been removed as it was considered to be inconsistent with Article 27 of TRIPS.⁴⁰

Response

The exclusion under s50 does not appear to have been used in Australia since guidance indicates it should only be relied on in the clearest of cases where the invention cannot be put to a lawful use⁴¹. Further, the benefits of the provisions have been questioned to the extent that their removal has been recommended⁴². Thus s50 appears not to add materially to the scope of excluded subject matter. However, if the European Patent Office Examiner's Manual referred to above is any guidance, there is some similarity between the import of s.50 and the intended operation of the *order public* exception.

Replacing s 50

Consultation Paper

ACIP recommended retaining s 18(2) and s 18(3) but replacing s 50 with a patentability exclusion.

ACIP argued against specific exclusions, stating:

*This mechanism lacks flexibility, because changes to technology or to Australian society's values would require that the list of specific exclusions be updated.....This mechanism could also work against the objectives of the patents system, because wholly pre-empting an area of technology from being patented would remove an incentive for any future innovation in that area, whether or not it is undesirable.*⁴³ The ACIP report recommended the following exclusion:⁴⁴

... exclusion for an invention the commercial exploitation which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public.

In formulating the patentability exclusion, ACIP recommended that patent legislation should only address ethical issues associated with the commercialisation of the invention. ACIP believed that the ethical issues associated with the invention itself would be better addressed through other areas of law.

³⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 27, 'Patentable Subject Matter'.

⁴⁰ Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter* (2010), page 63, paragraph 5; and Section 4.1.4, 'Commissioner's discretion to refuse patents', pages 61-62.

⁴¹ See <http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm> viewed 4 June 2013

⁴² Advisory Council on Intellectual Property (ACIP) Patentable Subject Matter Final Report December 2010

⁴³ Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter* (2010), page 14, paragraph 2.

⁴⁴ Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter* (2010), page 17, paragraph 1.

As with their recommendation for the Objects Clause, ACIP chose to translate TRIPS language into contemporary language: replacing the term 'ordre public', which is not commonly used in Australia, with the more familiar term, 'wholly offensive'. It is important to ensure that any language that is adopted is applied in a manner consistent with Australia's international trade obligations, including with TRIPS.

To ensure the patentability exclusion test can be applied in a consistent, predictable and neutral manner, ACIP recommended the hypothetical addressee for the test should be an "ordinary reasonable and fully informed member of the Australian public".

Response

As discussed above the term 'ordre public' lacks clarity but none of the potential meanings are 'wholly offensive'. While the intent of using the term 'wholly offensive' is to clarify the scope and intent of the exclusion this term suffers the same problem, namely there is still room to argue what the term means because Australia is culturally diverse and what is morally abhorrent at what time in society may be deemed acceptable at another time.

The relevant assessment is said to be achieved via the hypothetical addressee in the form of an "ordinary reasonable and fully informed member of the Australian public". Existing experience with hypothetical addressees in Australian patent law arises in the context of inventive step. The law in this arena is informative as to the challenges associated with identifying such a hypothetical person. Moreover in the context of inventive step there is the opportunity to evaluate objective standards of knowledge and skill as opposed to subjective standards. Further as discussed above the diversity of Australian society further complicates assessment of what this hypothetical person should take into consideration.

3. Implementing the Patentability Exclusion

Consultation Paper

The consultation paper observes that '[p]atent examiners will be expected to apply the patentability exclusion during examination of patent applications'.

However, as noted in the ACIP report, the consideration of ethical issues is not a routine exercise for patent examiners. Patent examiners may also not be equipped to consider whether the commercialisation of an invention would be offensive to the Australian public. To address this problem ACIP recommended that the Patents Act be amended to provide the Commissioner with an explicit power to seek advice. This increases transparency and clarifies the Commissioner's powers to seek assistance when applying the patentability exclusion. ACIP recommended:

*that the Commissioner be given the power to seek non-binding advice, and have the discretion to decide the most appropriate way to do this.*⁴⁵

Response

As discussed above Australia comprises a diverse population reflecting significantly different cultural, religious and social backgrounds. Thus formulating a view regarding what would be considered offensive to the Australian public presents a significant challenge. The “typical Australian” is an artificial construct. What might be viewed as offensive may also vary over time.

An important consideration is the weight that should be given to the views of different groups within Australian society. So for instance there is an argument that considerable weight should be given to the views of the traditional custodians of the lands of Australia, Aboriginal and Torres Strait Islander peoples. However Indigenous Australians are a culturally diverse population which means that what might be considered offensive by a particular clan might not be viewed in the same way by other clans.

This issue also arises in relation to the numerous ethnic groups represented in the Australian population. Thus the Commissioner potentially faces an enormous challenge under the proposal with regard to accessing necessary advice in order to avoid challenge to rulings made with respect to particular technologies.

If the European model is to be invoked in this regard then the scope of discretion of a patent examiner in determining patentability seems not much different to what one would expect of them with respect to applying the concept of ‘generally inconvenient’. That means that a general exclusion provision would not advance the Australian Patent Office’s engagement with the question of morality much further than where it currently stands.

⁴⁵ Advisory Council on Intellectual Property (‘ACIP’), *Patentable Subject Matter* (2010), page 19, final paragraph.

4. Questions from the Consultation Paper

The following brief synopsis of our responses to the questions included in the consultation paper is provided. We also provide our suggestions regarding how the issues covered in the consultation paper might be effectively addressed.

1. Do you have a preference for either of the two options proposed for the Objects Clause? If so, please explain the reasons for your preference.

The wording of Option 2 is preferred over Option 1 but neither Option is considered desirable.

If you disagree with the wording of both of these options, please explain which elements you disagree with and why.

The rationale behind the proposal is flawed. The purpose of Object Clauses in general is ambiguous. The proposed wording in both Options provided in the consultation paper is so general as to lack clarity. The identified purpose of the Patents Act 1990 is overstated. The purpose of the Act is simply to:

regulate the granting of limited term monopolies for exploitation of subject matter that:

- **meets the conditions specified in the Act for the granting of such a monopoly;**
- **does not offend any of the exclusions or limitations specified in the Act with respect to the granting of such a monopoly; and**
- **is consistent with relevant international obligations to which Australia has acceded.**

The inclusion of such an object clause does not necessarily advance understanding or utilisation of the Act and therefore inclusion of it or any object clause in the Patents Act 1990 is of questionable merit.

2. Do you agree with the wording proposed by ACIP for the patentability exclusion? No

If you disagree with the wording, please explain which elements you disagree with and why.

The proposed patentability exclusion disregards the diversity of Australian society and relies on a standard and construct that is of indeterminate scope. The proposed exclusion is derived from an international treaty provision that itself is acknowledged as lacking in clarity. The existing provisions at least have the benefit of a body of case law to aid their interpretation a benefit that would be lost through the proposed

amendment. Maintaining the existing provisions but enhancing the procedure for their utilisation as outlined above would be preferable. – for example, more detailed guidance on invoking the generally inconvenient exclusion.

3. Do you agree with amending the Patents Act to explicitly provide the Commissioner of Patents with powers to seek advice on ethical matters? If you disagree please explain why.

While the ability of the Commissioner to consult on ethical matters may be desirable the ability to effectively and equitably engage in appropriate consultation remains an issue.

A preferable approach may be the provision of a set of criteria to be used in a process of determining whether the proposed patent is fit subject matter for patent protection. A set of specific criteria that a patent applicant and the public can expect to be applied in determining whether subject matter should be patentable would enhance transparency, predictability and potentially reduce the likelihood that decisions of the Commissioner would become engaged in protracted contest.

Such a list might include for example:

1. Does the alleged invention cause direct harm to human beings?
2. Does the alleged invention cause indirect harm to human beings where the risk of that harm arising would be a reasonably foreseeable consequence of exploiting the invention?
3. Does the alleged invention cause direct or indirect harm to non-human life forms where the benefit(s) of the invention are insufficient to justify the nature and/or degree of harm caused?
4. Does the alleged invention have potential to give rise to a breach of national security that cannot be prevented through provisions of the Act relating to Crown acquisition and secrecy?
5. Does the alleged invention cause harm to the environment?
6. Does the alleged invention offend the cultural or religious beliefs of an Australian community?
7. Does the alleged invention exploit traditional knowledge and or practices of one or more Aboriginal or Torres Strait Islander communities?

An answer in the affirmative to one or more of questions 1 to 5 would justify a rejection of the patent application on the grounds that the invention does not constitute patentable subject matter. An answer in the affirmative to question 6 or 7 would require close scrutiny to determine whether the granting of a patent could be justified. For example in relation to question 7 a patent could be rejected if the invention

has been created without authorisation of knowledge holders or no provision for benefit sharing with the community that holds the knowledge has been made.

By requiring the patent applicant to show how the invention satisfies the established criteria potential additional burden on the patent system would be reduced.

By advertising proceedings and allowing a period for comment by interested parties the Commissioner could benefit from diverse views on the merits of allowing particular subject matter to be patented. Such an approach could also potentially reduce the risk that third parties would subsequently challenge decisions of the Commissioner on this ground.