



**Australian Government**

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**Advisory Council on Intellectual Property**

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**Patentable subject matter**

**OPTIONS PAPER**

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**September 2009**

The **Advisory Council on Intellectual Property (ACIP)** is an independent body appointed by the Australian Government to provide advice to the Minister for Innovation, Industry, Science and Research and to IP Australia on matters of intellectual property policy and administration. The Minister has requested ACIP to take a broad, strategic view of the role of intellectual property and its contribution to the development of Australian industry. Members of ACIP are drawn from business and manufacturing sectors, the patent attorney and legal professions, government, the tertiary and research sectors, and technology and commercialisation groups.

IP Australia is the federal agency responsible for administering the patent, trade marks, design and plant breeder's rights systems.

### **Sending your submission**

ACIP invites written comments on this options paper, specifically submissions directed to the options set out in the chapter entitled *retain, clarify, replace, delete or enhance?*. Submissions should state in as much detail as possible reasons for the positions taken and provide specific suggestions for reform. Submissions may be made in electronic form or in hard copy. Where possible, comments sent by email are preferred. Comments may be sent to the ACIP Secretariat by:

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This paper is available at [www.acip.gov.au](http://www.acip.gov.au).

Please note: As this is a public inquiry, written comments submitted to ACIP will be made publicly available and placed on the ACIP website unless specifically requested otherwise.

**Comments should be provided no later than  
Friday 13 November 2009**

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## Introduction

The Minister for Innovation, Industry, Science and Research has asked the Advisory Council on Intellectual Property to inquire and report on patentable subject matter. This document is the second consultation paper published as part of that inquiry and provides a number of options for reforming the law. The options and discussion are set out in this paper in three chapters.

In “**promoting innovation to benefit society**”, we provide an overview of the key issues relating to patentable subject matter and set a framework for possible reform. We first discuss the controversies and perceived problems with patentable subject matter. We then briefly identify the objectives of the patent system and the way in which the legislation currently defines patentable subject matter. Finally, we set out a framework for options to address any gap between the law and its objectives.

In “**retain, clarify, replace, delete or enhance?**”, we look at the main options for reform. The options follow a framework having three parts. The first part, *economic tests*, looks at the key concept of manner of manufacture. It identifies options that retain, clarify, replace or delete that test. The second part, *social filters*, provides options for social exclusions from patentable subject matter. The options focus on the generally inconvenient proviso and on alternative ways of excluding undesirable inventions from the patent system. The third part, *enhancements*, provides further options for enhancing the law and its administration. We then invite public comments on the options.

In “**patentable subject matter – the issues in detail**”, we provide a more in depth analysis of the main issues concerning the tests for patentable subject matter. This includes consideration of the submissions received and the public consultations held following publication of our Issues Paper.<sup>1</sup>

The **appendices** set out the details of the review process, including the terms of reference for the review.

## Promoting innovation to benefit society

*Patents provide incentives to individuals by offering them recognition for their creativity and material reward for their marketable inventions. These incentives encourage innovation, which assures that the quality of human life is continuously enhanced.<sup>2</sup>*

In 1959, Australia's highest court held that an invention must have two essential qualities to be patentable. First, it must consist of an artificially created state of affairs. Second, the significance of the invention must be economic.<sup>3</sup> This precedent has shaped a flexible and permissive approach to patenting new technologies in Australia.

In the intervening 50 years, patent protection has extended to methods of medical treatment, living organisms, biological and genetic materials, and computer software. Patenting in each of these fields has been controversial. Fuelling the debate in Australia is the ownership profile of patents. Up to 90% of patents in Australia are foreign-owned.<sup>4</sup> People have queried the wisdom of a broad approach to patenting when the benefits flow mainly to foreign firms.

Critics have questioned the law itself and the way it has developed. The Australian Law Reform Commission (ALRC) called the law 'ambiguous and obscure'. It is unclear whether inventions can be excluded from patenting on public policy grounds, such as for being 'generally inconvenient'. Moreover, the lack of clear distinction between patentable innovations and non-patentable discoveries has created concern, particularly in the field of genetics.

In addition, there are concerns that decision makers have extended the reach of patents on legal rather than economic grounds. The boundaries of patentable subject matter have expanded through administrative and judicial decisions. Some believe this has left little opportunity for public debate. *Venturous Australia* (the Review of the National Innovation System) found the ease with which patents are granted in areas such as software and business methods may be hampering innovation.<sup>5</sup>

The counter argument to this criticism is that the permissive approach to patenting has produced significant benefits to society. Many innovators may not have developed beneficial technologies without the incentives provided by patents. An example given is Australia's record of innovation in healthcare and medical devices. Restricting patentable subject matter would undermine investor confidence and result in less investment in innovation, and would promote secrecy over disclosure.

The Intellectual Property and Competition Review Committee (IPCRC) said the number of patents owned by foreign firms illustrated how important technological imports are to Australia. Without patents, this technology may be unavailable to Australia or only available at a higher cost.<sup>6</sup> The Government's recent statement on innovation recognised that the bulk of the knowledge we rely on is generated abroad.<sup>7</sup> Patents facilitate transfer of that knowledge.

Contrary to views that the law is too permissive, some believe the law is too restrictive. Service sector industries have come to dominate productivity growth in Australia with a higher share of output than in some other advanced economies. Innovation in those industries occurs largely outside the narrow industrial coverage of the patent system. Some argue that extended patent protection would spur further innovation in this sector.

We note here that the Advisory Council on Intellectual Property (ACIP) has previously looked at patents for a new area of innovation: business systems.<sup>8</sup> That 2003 report found that business system patents do not appear to be of major economic consequence in Australia. It also found a lack of evidence that patenting of business methods was stifling competition, contrary to the concerns expressed in *Venturous Australia*.

A specific controversy is the patenting of genetic material. The Australian Senate is currently inquiring into gene patents.<sup>9</sup> Many of the issues raised in submissions to the Senate reflect concerns cited generally across the patent system. Stakeholders expressed concerns over the width of patents, access to technology, use of patented inventions in research, and the ability of the system to distinguish between patentable and unpatentable subject matter. The context of the gene patent inquiry is important. It concerns the health and wellbeing of Australians. Patents in that field present some unique challenges. However, many of these issues apply to the patenting of other technologies as well.

The Senate inquiry into gene patents provides a specific example of the types of issues that ACIP is tackling more generally. We have not set out to answer directly the specific question on whether isolated genes should be patentable. The ALRC dealt with that issue in detail and the Senate Committee will give it further consideration. Our approach is to identify the principles involved in determining what subject matter is patentable, and to ensure that the law on it is sufficiently clear. This will ensure that questions of patentability can be dealt with clearly and transparently as they arise, both now and in the future.

### **Objectives of the patent system**

The terms of reference to this review require ACIP to inquire, report and make recommendations to the Australian Government on patentable subject matter. As such, it is not a review of the patent system as a whole. However, any test for patentable subject matter must support the objectives of the system. It is useful to consider what these objectives are.

The Patents Act does not contain a statement of objectives.<sup>10</sup> Nevertheless, the patent system is widely acknowledged as having an economic objective. The system aims to benefit society through optimising innovation and public access to new technologies. The World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) captures the modern objectives of the patent system:

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.<sup>11</sup>

The way the patent system operates reflects these objectives. Commentators sometimes refer to patents as representing a social contract or *quid pro quo*. The Government awards creators exclusive rights to exploit their invention. The exclusive rights are limited both in time and in nature<sup>12</sup>, but provide an opportunity for the creator to generate profits. This provides an incentive for investment into research and development of new products and processes. In return for this exclusive right, the creator makes the details of their invention available to the public. This allows the public to build on the knowledge of the invention, or to innovate around the invention to avoid infringement during the patent term. At the end of the patent term, the public has unrestricted access to the invention. To put this crudely, as a result of a patent society incurs short-term pain for long-term gain.

It follows from the social contract theory that patents are not appropriate for inventions that are detrimental, either socially or economically. That is, granting patents for inventions that the public finds unacceptable does not satisfy the *quid pro quo* basis of the system.

### **Conducive to social and economic welfare**

The IPCRC considered the objective of intellectual property law in Australia to be utilitarian, and more specifically economic rather than moral in character. However, it is clear that the patent system has both economic and non-economic (social) aspects. The patents legislation reflects this view, as it clearly excludes some subject matter from patenting on social policy grounds.

In Australia, only an invention is patentable. The patents legislation defines invention with reference to old English law, the *Statute of Monopolies* of 1623:

*“invention” means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention.*<sup>13</sup>

This definition of invention gives little guidance by itself as to what is or is not patentable. However, a body of case law underpins the definition. As already noted, the High Court has interpreted the requirement for invention as meaning that there must be something that has been artificially created and that it must have value in the field of economic endeavour. There must be some material advantage in the sense that the invention belongs to the useful arts as distinct from the fine arts. These are the so-called *NRDC*<sup>14</sup> principles.

The legislation states that not all inventions according to this definition are patentable. Only those inventions that meet a number of legislative tests are patentable. Under current law, an invention is patentable only if the invention:

- is a manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*<sup>15</sup>;
- is novel and involves an inventive step<sup>16</sup>;
- is useful; and
- was not previously secretly used in Australia by the patent applicant or their predecessor in title.

As the IPCRC noted:

The threshold tests are used as a rough proxy for the benefits of the claimed invention to society, since it is usually not possible to do a detailed cost-benefit analysis for each patent, partly because the value of new inventions is generally difficult and expensive to predict.<sup>17</sup>

In addition, the legislation specifically excludes some subject matter from patentability. Human beings, and the biological processes for their generation, are not patentable inventions. For the purposes of an innovation patent, plants and animals are not patentable inventions.

The Commissioner of Patents also has the discretion to refuse a patent where:

- the use of the invention would be contrary to law;
- a substance is capable of being used as a food or medicine and it is a mere mixture of known ingredients; or
- the name of a person is used as the name of the invention in a claim.

There is an open question as to whether patents can also be excluded on the basis that the patent would be ‘generally inconvenient’.

The legislation thus sets out a number of tests to define patentable subject matter. These tests advance the economic goals of the system. The legislation also filters out some subject matters where patents may be undesirable, taking social concerns into account. This distinction between economic and social welfare is not straightforward and may appear somewhat simplistic. Nevertheless, the threshold tests can be viewed as chiefly economic in nature, while the filters or exclusions for undesirable subject matter are predominantly social in nature. Figure 1 illustrates this point.

There are question marks concerning the manner of manufacture test in Figure 1, highlighting fundamental questions regarding the test: Is the current ‘manner of manufacture’ test appropriate? What are the objectives of the test for patentable subject matter over and above the other legislative tests? What are its justifications? Does it provide an economic test only or does it also filter out socially undesirable subject matter? These are questions for this review.

**Figure 1: Justification of current requirements for patentability**

<b>Requirement</b>	<b>Section</b>	<b>Test</b>	<b>Objective</b>	<b>Justification</b>
Novel	18(1)(b)(i)	Invention is not disclosed in the 'prior art' (all that was previously known or used)	To preclude the grant of exclusive rights to things that already exist or are already known	Economic
Inventive	18(1)(b)(ii)	Invention is not obvious to a person skilled in the art	To preclude the grant of exclusive rights to things that would develop as a matter of course	Economic
Useful	18(1)(c)	Invention achieves the promised results	To ensure the claims are limited to things that achieve the promise of the invention	Economic
No secret use	18(1)(d)	Invention has not been secretly used	To prevent the period of exclusivity to a thing protected by a patent being longer than the duration of the patent. (An inventor may choose to rely on either secrecy protection or patent protection, but not on both.)	Economic
Not a human being or a process for its generation	18(2)	Invention is not a human, or a human fertilized ovum up to time of birth	To preclude the grant of exclusive rights to human beings	Social
Not contrary to law	50(1)(a)	Sole or main use of an invention would not be unlawful, and a lawful use has been described	To preclude the grant of exclusive rights to unlawful activities	Social
Not mere food or medicine of known ingredients or process to produce such	50(1)(b)	In respect of an invention that is capable of being used as a food or medicine, the invention is not a mere mixture of known ingredients with no synergistic effect	To preclude the grant of exclusive rights to mere recipes or prescriptions for a food or medicine	Social
Not claim a person's name	50(2)	In respect of a claim to an invention that contains a name, the name is not a person's name	To preclude the grant of exclusive rights to a person's name. (This may arise, for example, in a claim to a plant or flower where a person's name is used for the plant variety name)	Social
An invention or alleged invention: manner of manufacture within Statute of Monopolies	18(1) (a) and definition of invention in schedule 1	?	?	?

## **The Advisory Council's approach**

After considering the issues, including the submissions and public consultations in response to our Issues Paper, our view is that the legislation must be able to regulate what can and cannot be patented, as determined both economically and socially. In addition, the legislation must be logical, compliant and practical. It must be logical in that it is internally consistent. It must be compliant in that it is not inconsistent with Australia's international obligations. And, it must be practical in that administration of the law is effective and transparent.

We believe the best way forward is to explore a number of specific options. As discussed above, the patents legislation adopts a structure that provides a flexible threshold test for patentable subject matter together with filters to exclude undesirable subject matter. Submissions largely supported this legislative framework, though opinions diverged sharply on specific issues. The options we have devised follow a similar approach, of economic tests and social filters, to define the field of patentable subject matter. In addition, there are a number of changes that could enhance the operation and administration of the law.

### **Economic test**

The threshold economic test is the test for invention. There are four basic options for reform of this test:

- A. Retain the manner of manufacture test;
- B. Clarify the language of the definition of invention;
- C. Replace the manner of manufacture test with an alternative test; or
- D. Delete the test.

### **Social filters**

The legislation currently excludes undesirable subject matter by a mixture of explicit exceptions (such as human beings) and general filters (such as inventions that are contrary to law and arguably inventions that are generally inconvenient). We have identified three options for reform:

- E. Retain the current exceptions and filters;
- F. Add specific exclusions, such as a list of specific subject matters that are not patentable; and
- G. Add general social filters, such as excluding inventions that are 'generally inconvenient' and/or 'contrary to *ordre public* or morality'.

These options for social filtering are not mutually exclusive. For example, the legislation could provide a combination of specific exclusions and general filters.

## **Enhancements**

We have identified a number of additional enhancements that could simplify the legislation and provide greater transparency and certainty to decision making:

- H. Reform the requirements for inventiveness on the face of the specification;
- I. Reform the requirements relating to the usefulness of an invention; and
- J. Provide for an advisory panel to advise the Commissioner of Patents on matters of social policy or morality relating to patentable subject matter.

The following chapter explores each of these options in detail.

## Retain, clarify, replace, delete, or enhance?

*... it is indeed odd that the key concept of ‘manner of manufacture’ depends on a provision in a 380 year old English statute that has long since been repealed in the jurisdiction in which it was enacted; and that the relevant section of the statute is not reproduced in Australian patent legislation.<sup>18</sup>*

We set out in this chapter our options for reforming the law on patentable subject matter. As noted in the preceding chapter, our options follow a framework of economic tests, social filters, and enhancements to the system. We give detailed consideration of the issues, submissions and consultations that informed our views in the following chapter.

In Australia, an ‘invention’ must be a ‘manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*’. A major issue for this review is whether the key concept of manner of manufacture remains relevant. This chapter consists of three parts.

Part 1 looks at the ‘manner of manufacture’ test and provides four options for reforming the law: retain, clarify, replace, or delete the manner of manufacture test.

Part 2 focuses on the social aspects of the patent system. While the requirement for invention supports the primary goal of the patent system of promoting innovation, the ultimate purpose of the system is to benefit society. Some inventions may be technological advances, but are morally repugnant.

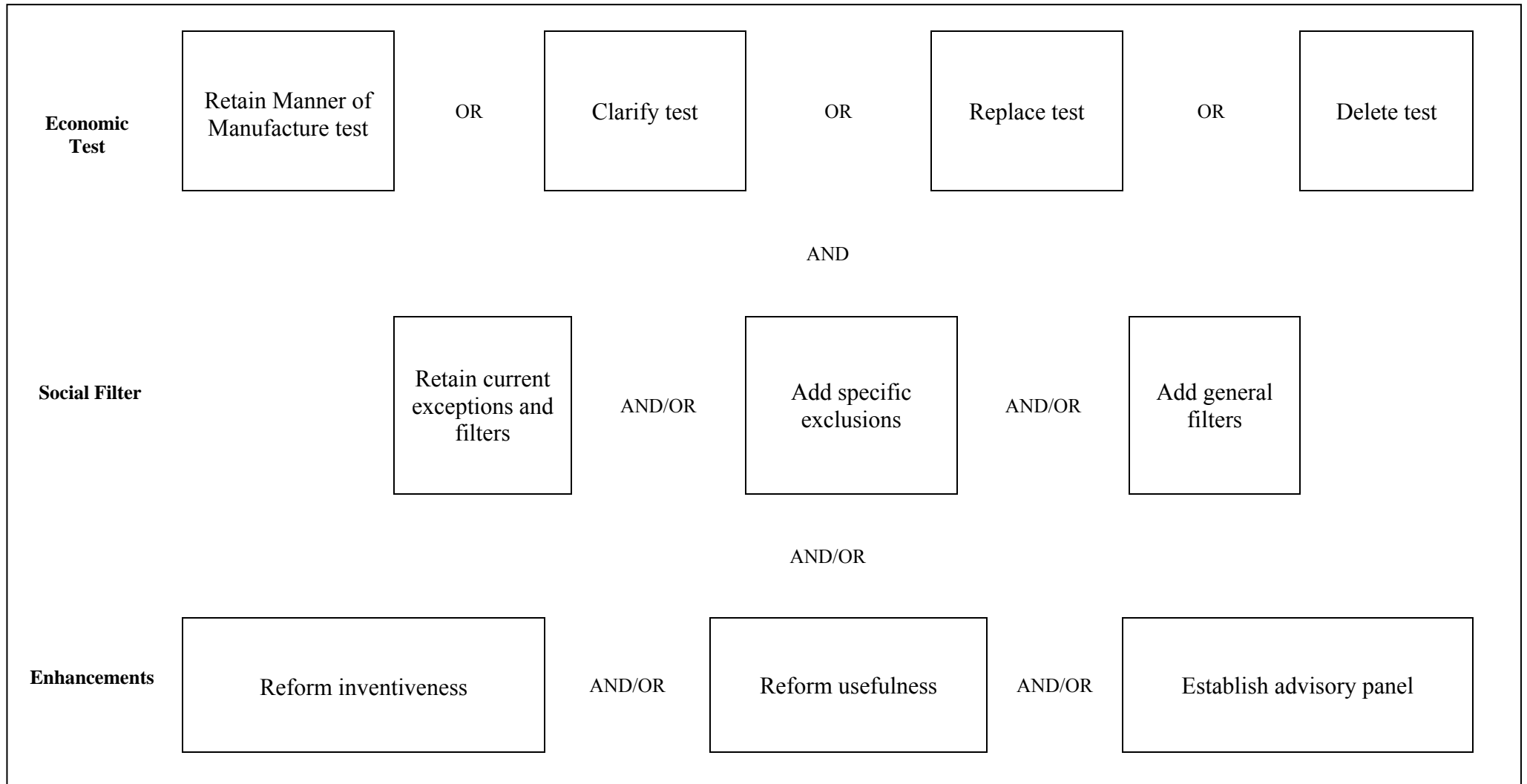
One possible way of excluding patents on public policy grounds is the historical requirement that patents not be ‘generally inconvenient’. However, the circumstances when this proviso applies are uncertain. The options in part 2 focus on the generally inconvenient proviso and on alternative ways of excluding undesirable inventions from the patent system.

Part 3 provides options for enhancing the patent system. The definition of invention incorporates aspects of newness and utility. This is despite the law separately codifying these provisions. We have considered these issues in devising options for a subject matter test. We have also provided options for addressing these issues directly.

Part 3 also sets out an option for an advisory panel to assist the Commissioner of Patents in making decisions on the public policy or morality aspects of patentable subject matter.

Figure 2 sets out the relationship between all these options.

**Figure 2: Relationship between options**



## Part 1. Economic Test

The Australian Law Reform Commission (ALRC) believed the manner of manufacture test needed review. The ALRC considered the test ambiguous and obscure. The ALRC also believed that the case law that has evolved around the meaning of this provision offers no clarity.<sup>19</sup>

The Intellectual Property and Competition Review Committee (IPCRC) previously considered the manner of manufacture test in 2000.<sup>20</sup> The IPCRC reported that Australia had on the whole benefited from the adaptiveness and flexibility that has characterised the manner of manufacture test. The IPCRC recommended that the test be retained. Of note is that almost all submissions to the IPCRC argued for retention of the manner of manufacture test.<sup>21</sup>

In contrast, over half of the written submissions to the current review argued that the test did not adequately meet the objectives of the system. Various stakeholders said the test failed to properly address economic and/or social issues or was so vague that non-specialists could not understand the law. Of those who considered that the current test was inadequate, most believed that more restrictive requirements on patentability were necessary or that greater clarity on patentability was required. However, a small number of respondents considered that a more permissive approach to patentability would provide greater incentive for innovation in service sector industries.

In the following pages, we set out four mutually exclusive options for reforming the manner of manufacture test. Our options are:

- A. Retain the manner of manufacture test. This option retains the requirement that an invention must be a ‘manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*’.
- B. Clarify the language of the definition of an invention, for example by using the *NRDC* requirements that an invention must be an artificially created state of affairs in a field of economic endeavour.
- C. Replace the manner of manufacture test with an alternative test, such as the TRIPS Agreement language that patents are available for any inventions in a field of technology.
- D. Delete the requirement for an invention. Under this option, the objective tests of novelty, inventive step and usefulness would do the economic work of limiting patentable subject matter.

## A. Retain

Retain the current definition of invention.

This option retains the requirement that an invention must be ‘a manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*’.

### Effect

This option maintains the status quo. The body of precedential case law interpreting the manner of manufacture test would remain undisturbed.

While the current definition of invention would be undisturbed, there would still be opportunity to provide additional clarity to the law as discussed in parts 2 and 3 of this chapter.

### Strengths

- Flexible and adaptable
  - The current test has the flexibility to cope with a variety of concepts and to adapt to new technologies.
  - A long line of precedent has refined the scope of the current test. It has been tested in a range of scenarios and a number of principles have been developed for its application.
  - Some of the problematic areas of patent law such as business methods have been dealt with by applying the principles developed from *NRDC* (albeit in the Full Court of the Federal Court and not the High Court).
- Avoids cost of change
  - Changing to a new test would introduce some level of uncertainty until the test had been interpreted by the High Court.

### Weaknesses

- Ambiguous and obscure
  - The ‘manner of manufacture’ language is archaic and its meaning is not discernable from the legislation.
  - A significant number of people outside the patent attorney and legal professions do not understand the test.
  - The interaction between manner of manufacture and other requirements for patentable inventions is not always clear.
- Uncertainty
  - The flexibility of the test also involves a certain amount of unpredictability. The reach of patents into non-traditional areas is a concern for some people.
  - There is uncertainty over the ongoing applicability of a ‘generally inconvenient’ exclusion.
  - It may not adequately deal with the social concerns of patenting held by a significant number of people, particularly in light of views expressed by the courts on the difficulty or inappropriateness of applying social policy considerations.

## B. Clarify

Clarify the language used to define an invention by replacing the reference to the language of the *Statute of Monopolies* with a modern interpretation.

For example, provide that an invention is ‘an artificially created state of affairs in a field of economic endeavour’.

### Effect

This option modernises the language used to define invention but does not substantially change the boundaries of patentable subject matter. It provides two limbs to the test for invention. The first part of the test sets out that an invention must have steps or properties that create an artificial effect in the physical world. A physical effect in the sense of a concrete effect or phenomenon or manifestation or transformation is required. Mere schemes, abstract ideas and mere ‘intellectual information’ are not patentable. The second part requires that such an effect apply to the useful arts rather than the fine arts, reflecting the economic purpose behind the patent system. An invention must have an industrial or commercial or trading character.

This option removes any residual aspects of public policy contained in the manner of manufacture test, such as excluding inventions that are contrary to law or generally inconvenient. The options set out in part 2 of this chapter would deal with these matters. This approach may provide additional clarity to the law.

### Strengths

- Greater clarity
  - The key features of ‘invention’ are set out directly in the legislation, providing greater transparency of the law.
  - Although the *NRDC* decision dates from 1959, the language used does not suffer the problems of ‘archaic language’ levelled at the manner of manufacture test.
  - More clearly defines the threshold test as separate from the other legislative tests such as inventive step.
- Maintains key principles of law
  - This option is largely a restatement of the current law as applied by the courts. It expresses the legislation in the words of the test that courts apply now.

### Weaknesses

- On its own, it does not exclude socially unacceptable inventions
  - Any safety net provided by a general inconvenience exception is removed.
- Uncertainty
  - Like the manner of manufacture test, its adaptability is both a strength and source of uncertainty.
- By focussing on a particular phrase within the *NRDC* decision, there is a risk that other important principles of patentability may be lost.

## C. Replace

Replace ‘manner of manufacture’ with an alternative test.

For example, provide that patents are available for ‘any invention in a field of technology’.

### Effect

This option would restrict patents to inventions in a field of technology. It provides a minimalist approach to defining invention, while continuing to restrict patents to those areas where an economic incentive to invent is required. The ‘field of technology’ test requires patentable subject matter to have some element of physicality or some technical effect. The requirement that an invention be in a field of technology may be similar to the *NRDC* principle that inventions belong to the useful rather than fine arts.

A ‘field of technology’ test may broaden the scope of what may be patented compared to the current manner of manufacture test. The drafters of the European Patent Convention (EPC) felt the need to supplement the requirement for an invention to be in a field of technology with a list of specific excluded subject matters, being subject matters considered not to be in a field of technology.<sup>22</sup> Submissions to this review generally saw the European exclusions to be problematic. There was little support for adopting a similar list in Australia.

### Strengths

- Adaptable
  - Has the potential to be adaptable. The words ‘field of technology’ could be interpreted according to the technologies of the day.
  - ‘Field of technology’ may have less of the industrial overtures attached to ‘manufacture’.
- Modern language
  - Provides modern language for concepts similar to manner of manufacture and the *NRDC* principles.
  - Removes overlap between current tests, such as any additional requirement of inventiveness or usefulness.
- Internationally recognised
  - Consistent with language used in the TRIPS Agreement and in the legislation of a major patent jurisdiction (the EPC).

### Weaknesses

- Uncertainty
  - Transfers problem to defining what is in a field of technology. Although there are definitions of ‘technology’ that seem on their face to be clear, the European experience has demonstrated considerable uncertainty around the definition.
  - Replacing manner of manufacture with a technology requirement may therefore simply substitute one uncertainty for another.

## D. Delete

Delete the requirement for an invention.

Remove all references to ‘manner of manufacture’ and section 6 of the Statute of Monopolies from the *Patents Act 1990*, by deleting section 18(1)(a) and the Schedule 1 definition of ‘invention’.

### Effect

There would be no separate threshold test for patentable subject matter. The objective criteria of novelty, inventive step and usefulness would handle the economic testing of the subject matter for which a patent should be granted. The options set out in part 2 of this chapter would deal with matters of social policy.

This approach may be insufficient to exclude all inappropriate subject matter, particularly in view of the constrained way in which the tests of novelty, inventive step and usefulness have been applied in the past. A view commonly put in public consultations was that the threshold requirement of subject matter being an invention was necessary to contain patents to the useful arts.

### Strengths

- Objectiveness
  - Allows patentability to be determined by reference to objective tests of novelty, inventive step and usefulness.
- Clarity
  - Greater clarity would result, as any subject matter that is new, inventive and useful would be patentable.

### Weaknesses

- Social
  - Need to ensure that any social filters put in place are comprehensive of all matters that need to be addressed.
  - Any safety net provided by a general inconvenience exception is removed.
- Economic
  - The prime economic test for identifying the subject matters for which patents should be available is removed. It is not clear, for example, that mere discoveries, schemes or innovations in the realm of the fine arts would be excluded from patentability under this option.
  - The economic criteria of novelty, inventive step and usefulness may not be sufficient to exclude all subject matter that was inappropriate to patent. This may force these requirements to do work that they are not designed to do.

## Part 2. Social Filters

The patents legislation excludes certain subject matter from patenting for social policy reasons, even though the subject matter may otherwise be an invention. Parliament has specifically excluded from patenting human beings and the biological processes for their generation. The Commissioner of Patents also has the discretion to refuse patents for inventions the use of which would be contrary to law.

Arguably, patents may also be refused on public policy grounds where the grant of a patent would be ‘generally inconvenient’. This arises from the reference to section 6 of the *Statute of Monopolies* in the definition of invention. Unlike the other exclusions, general inconvenience forms part of the definition of invention rather than a category of inventions to be excluded from patentability. However, its meaning and its ongoing application is unclear.

A number of submissions to this review argued that patent law was a blunt instrument for dealing with social issues and that direct regulation of the targeted behaviour was vastly superior. The argument is that ethical issues do not arise merely because a patent is granted; they arise as a result of the manner in which the invention is used. It is therefore more appropriate to regulate use of inventions rather than exclude inventions from patentability.

While these arguments have credence, the purpose of a patent is to provide an incentive for firms to invest in research and development and to encourage public disclosure of new knowledge. It seems anomalous for the government to encourage research and knowledge dissemination in areas that the public abhors. Providing patents for inventions that are repugnant or illegal may also bring the patent system into disrepute. It is important that the patent system is able to exclude undesirable inventions from patenting, so that the system maintains integrity and continues to be socially beneficial.

We have devised a number of options to ensure that patents continue to promote innovation and knowledge dissemination in a manner conducive to social wellbeing. The first of these options is to maintain the current exceptions and filters (Option E). We have assumed here that the law currently regards manners of manufacture that are ‘generally inconvenient’ to be unpatentable, while noting there is uncertainty about this. Other options provide for specifically excluding certain inventions from being patentable (Option F) and for adding general social filters to exclude undesirable subject matter (Option G). The TRIPS Agreement optional exclusion of inventions the use of which is contrary to *ordre public* or morality is an example of a general social filter. It is of course an option to have a combination of specific exclusions and general filters.

## E. Retain current exceptions and filters

Retain the current exceptions:

- Patents are not available for inventions that are generally inconvenient.
- Human beings, and the biological processes for their generation, are not patentable inventions.
- 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.

In addition, retain the current discretion for the Commissioner of Patents to refuse patents for:

- an invention the use of which would be contrary to law;
- a substance that is capable of being used as a food or medicine (for humans or animals) and that is a mere admixture of known ingredients;
- a process for producing such a substance by mere admixture;
- a person's name as the name of the invention in a claim.

### Effect

This option maintains the status quo. While there is some doubt, we have assumed that the 'generally inconvenient' exclusion is part of current Australian law.

Each of the options to clarify, replace or delete the manner of manufacture test in part 1 of this chapter would omit the 'contrary to law, mischievous to the state, or general inconvenience' provisions from the threshold test. In these cases, the legislation would need to explicitly provide for such exclusions to retain the current filters under this option.

### Strengths

- Last resort measure to exclude undesirable inventions
  - General inconvenience may provide a safety net to exclude certain subject matter.
- Avoids cost of change
  - Changing to a new test would introduce some level of uncertainty until the High Court has interpreted the test. This advantage may depend on whether the manner of manufacture test is also retained.

### Weaknesses

- Uncertainty
  - There is uncertainty about whether the 'generally inconvenient' exclusion still applies and, if it does, what subject matter it excludes from patenting.
  - There may also be doubt over whether patents that are contrary to law can be revoked as part of the manner of manufacture test or are subject only to the Commissioner's discretion to refuse a patent.
  - There is a lack of jurisprudence in Australia over each of these exceptions.

## F. Specific exclusions

Provide a list of specific subject matters that are not patentable.

Under this option, the legislation would list specific subject matters that are not considered to be patentable. One such possible exclusion is ‘a mere discovery’.

### Effect

This option allows the parliament to exclude specific subject matter. This option does not provide a list of things that are not regarded as inventions, such as that contained in the European Patent Convention. It provides a list of things that are not patentable because they do not benefit society, regardless of whether they are inventions. Any exceptions would need to comply with Australia’s international obligations.

### Strengths

- Certainty
  - Specific exclusion could promote greater certainty, particularly if interpretation issues can be properly managed.
  - Greater transparency, as exclusions to patentability are set out in the legislation rather than in common law.

### Weaknesses

- Reactive
  - Legislation would usually be enacted after a problem has surfaced. Unless the legislation was retrospective in operation, society would have to put up with the problem of any patents granted before the legislation was enacted.
- Not adaptive
  - Changes to technology or to social or ethical values would require legislative change. There can be substantial delays in effecting legislative change.
- Inclusive or exclusive?
  - Unless carefully implemented, there may be questions over whether a list of specific exclusions is inclusive or exclusive.

## G. General filters

Provide a general social filter in the legislation to exclude patents for inventions that would be contrary to public policy or morality.

For example, the legislation would exclude inventions from being patentable where the use of the invention would be ‘contrary to *ordre public* or morality or generally inconvenient’.

### Effect

The legislation would exclude patents for inventions that are contrary to public policy or morality. Refusing patents removes an incentive to innovate in areas deemed undesirable. The practical effect would be to prevent patents being granted for inventions that the public would find abhorrent.

The social filter would be applied during the patent application process. Thus, IP Australia would assess an invention against the social filter prior to grant of a patent. This could be done during examination, during any opposition to grant, or during both such procedures.

Examiners could be supported by an advisory panel as discussed in Option J of this document. Alternatively or additionally, an objective set of guidelines or regulations could be provided to assist patent examiners assess patent applications against this criteria.

In addition to being a ground of examination and/or opposition, the social filter could be a ground of revocation. Courts could assess the invention and revoke a patent where the use of the invention was contrary to *ordre public* or morality or was generally inconvenient. We note that the Australia-US Free Trade Agreement provides that a patent may only be revoked on grounds that would have justified a refusal to grant the patent. Thus, it is not an option to have the social filter applied by a court only.

### Strengths

- Proactive
  - Problematic areas can be dealt with according to the social mores of the time.
- Recognises social concerns
  - The incentive to innovate in areas that are not socially acceptable is removed.
  - Refusing clearly immoral inventions protects the integrity of the patent system.

## Weaknesses

- Inherent uncertainty
  - Any conceptual test such as ‘general inconvenience’ or ‘*ordre public* or morality’ has some inherent uncertainty.
  - There is potential for inconsistent and subjective application of a social filter.
- Potential for over-exclusiveness
  - Imposing exclusions may have economic consequences in removing incentives for innovation, whereas the social consequence of not imposing exclusions may be limited as patents do not provide a positive right to use an invention.
  - There are concerns that such a provision may include inventions that are later found to be beneficial due to changing social values.
- Potential for breach of international obligations
  - Expressly incorporating the ‘generally inconvenient’ exclusion may make the legislation non-compliant with the TRIPS Agreement.

### Part 3. Enhancements

In addition to the options discussed above, we believe there are further opportunities to improve the law on patentable subject matter and to improve the administration of the law.

The law on patentable subject matter has developed from the broad statement set out in section 6 of the *Statute of Monopolies* in 1623 to the current requirements set out in section 18 of the *Patents Act 1990*. The historical development of the *Patents Act* has left the legislation dealing with some requirements partly by explicit provisions and partly within the general bounds of the manner of manufacture test. This has created uncertainty in the application of the law. In particular, it has not always been clear how the courts have imposed the requirements of inventiveness and usefulness.

We have considered these issues when formulating the options in part 1 of this chapter. However, we have also included further options to address these issues directly. The High Court of Australia has said that the Commissioner of Patents may refuse an application for patent protection where a specification "on its face" shows the invention claimed is not a manner of new manufacture. This may arise, for example, from admissions concerning novelty. This partly clarified an earlier decision of the High Court that referred to a threshold of inventiveness. Option H provides a means of addressing the uncertainty around the lack of inventiveness on the face of a patent specification.

The ALRC in its report on *Genes and Ingenuity* considered a need for reform of the way in which the requirements for patentability address the usefulness of an invention. A number of submissions to this review supported the ALRC recommendations on usefulness. There is an implicit requirement within the manner of manufacture test that an invention be useful, as well as a specific requirement that an invention be useful. We consider that adopting the ALRC recommendation that there be a separate requirement that an invention must have specific, substantial and credible utility (option I) will provide additional clarity to the law.

We note that IP Australia is proposing to amend the patent legislation to ensure that 'the requirement of usefulness is only satisfied if the patent specification discloses a specific, substantial and credible use of the invention' in accordance with the ALRC proposal. IP Australia is also considering changes to the test for inventive step.<sup>23</sup>

Several submissions raised concerns that there was a lack of opportunity for public representation into decisions on patentable subject matter. Many also felt that patent examiners were not equipped to deal with issues of social policy or morality. We have proposed an advisory panel to assist the Commissioner of Patents and patent examiners to decide on matters of social policy (option J).

## H. Inventiveness

Ensure that the legislation explicitly deals with inventiveness under the requirement that a patentable invention involves an inventive step.

For example, remove the reference to the *Statute of Monopolies* in the definition of ‘invention’ in schedule 1. Alternatively, adopt a different subject matter test to the manner of manufacture test as discussed in Options B to D of this paper.

### Effect

Currently, the legislation deals with some aspects of inventiveness through the definition of invention (‘a manner of *new* manufacture’). The legislation also separately requires the invention to be a manner of manufacture and states that an invention must involve an inventive step. The dual reference to the *Statute of Monopolies* in section 18 and in schedule 1 of the *Patents Act 1990* has led to much confusion. As noted by the High Court, the Commissioner of Patents may refuse an application for patent protection where a specification "on its face" shows the invention claimed is not a manner of new manufacture. This may arise, for example, from admissions concerning novelty.

This option would ensure that patent examiners and courts deal with such considerations under the specific provision that an invention involves inventive step rather than as a separate threshold requirement for inventiveness.

### Strengths

- Clearer and simpler legislation
  - Removes the overlap between the requirement for an invention to be a manner of new manufacture and the requirement that an invention has an inventive step.

### Weaknesses

- Possibly increased transaction cost
  - May increase the evidentiary burden for a party seeking to have a patent revoked where the invention lacks inventiveness on the face of the specification.
- May lower inventive threshold
  - The test for an inventive step may be too constrained to deal with some aspects of inventiveness currently dealt with by the manner of manufacture test.

## I. Usefulness

Implement the ALRC recommendations on usefulness.

The ALRC recommended that IP Australia examine and report on the usefulness of an invention as a separate requirement, and that such use must be specific, substantial and credible.

### Effect

The current patent legislation requires an invention to be useful, both as an express requirement that an invention be useful and as an implicit requirement that an invention be a manner of manufacture. An explicit provision that inventions have a specific, substantial and credible utility would rationalise these requirements. The use of an invention would need to be:

- (a) specific – the use is specific to the subject matter of the invention and not a generic use;
- (b) substantial – no further research is required to identify a real or specific use;
- (c) credible – the use is logical and consistent with the state of the art.

Both the ALRC and IPCRC considered that the requirement for usefulness has taken on greater importance in some new technologies, where the dividing line between mere discovery and invention has become difficult to define. This option would also require patent examiners to assess, and report on, the usefulness of an invention as a separate requirement.

### Strengths

- Greater clarity
  - It would remove confusion about the application of the ‘usefulness’ requirement.
- Internationally recognised
  - The specific, substantial and credible utility test is applied in some other major comparable jurisdictions, such as the United States.
- Higher presumed validity of granted patents
  - Examination of the usefulness of an invention would preclude a patent for an invention when further research is required to understand its practical application.

### Weaknesses

- Lack of jurisprudence
  - Although US courts have considered ‘specific, substantial and credible utility’, the test has not been subject of a ruling by an Australian court.
- Lack of evidence
  - Evidence that an invention does not have a specific, substantial and credible use may not be available to patent examiners.

## J. Advisory Panel

Establish an advisory panel to advise the Commissioner of Patents on the application of social filters (such as a contrary to *ordre public* or morality filter, or a ‘generally inconvenient’ exclusion) to the patentability of inventions.

### Effect

The panel would provide non-binding advice to the Commissioner of Patents on specific problematic cases where issues of public policy or morality arise. The Commissioner could refer contentious patent applications to the panel for advice. The advisory panel would assist in a more proactive approach to managing the law.

Implementation details would need to be carefully considered. These details include: how decisions are made by the Commissioner to refer applications to the panel; whether the panel’s advice is confidential or part of the public record; and the extent of involvement of the patent applicant or third parties in the process (including review mechanisms).

### Strengths

- Proactive
  - Provides a mechanism for a proactive approach to managing the law and deciding on what should be patentable.
- Transparent
  - Provides greater community input.
  - Addresses issues about patent examiners not being in a position to address questions of social policy or ethics.

### Weaknesses

- Consistency
  - The exact approach taken to any issue may be dependant upon the makeup of an advisory panel and differently constituted panels may take inconsistent positions.
  - Increased uncertainty may result in situations where the Commissioner decides to not follow the panel’s advice.
- Efficiency
  - There are additional administrative costs in establishing and supporting a panel.
  - Referring patent applications to an advisory panel may delay the prosecution of patent applications, so that the grant of a patent or refusal of the application is delayed.
- Technological diversity
  - May be difficult to put together a sufficiently diverse yet workable panel given the range of technologies and probable low ongoing workload after initial establishment.

## Your comments

We have set out above a number of options for reforming patentable subject matter. We now seek public input on these options. We invite you to provide comments on any or all of the above options including any evidence you may have to support your views.

In developing the above options, we have considered Australia's international obligations, including the TRIPS agreement. We would also welcome any additional comments on the international compliance of the options.

The ACIP prefers that comments are publicly available. Unless your submission is specifically marked as confidential, we will place it on the ACIP website and may quote from it in publications. However, you may also ask us to treat your submission as confidential where it contains sensitive material. Any request for access to a confidential submission is determined in accordance with the *Freedom of Information Act 1982*.

Comments should be provided to the following address by the close of business on Friday, 13 November 2009.

email: [mail.acip@ipaaustralia.gov.au](mailto:mail.acip@ipaaustralia.gov.au)  
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## Patentable subject matter – the issues in detail

*Provided also, and be it declared and enacted that any declaration beforementioned shall not extend to any Letters Patent, and grants of privilege for the term of 14 years or under hereafter to be made of the sole working or making of any manner of new manufactures within this realm to the true and first inventor and inventors of such manufactures which others at the time of making such Letters Patent and grants shall not use so as also they be not contrary to the law nor mischievous to the state by raising prices of commodities at home or hurt of trade or generally inconvenient, the said 14 years to be accounted from the date of first Letters Patent or grant of such privileges hereof to be made, but that the same shall be of such force as they should if this Act had never been made, and of none other.<sup>24</sup>*

The submissions we received in response to our issues paper and the discussions at our public forums revealed divergent and often polarised views on several of the key issues relating to patentable subject matter. In this chapter, we look in more detail at these issues and the submissions that helped us frame our options for reform. We start out by looking at the international framework for the patent system, Australia's need to comply with certain international norms and the relationship with other national patent systems. We then consider the Australian system, the current law and the perceived issues with the current tests for patentable subject matter. Finally, we consider how the tests for patentable subject matter address economic and social objectives and weigh up other possible improvements.

### **The international framework**

#### **Treaties**

Australia is a signatory to a number of international treaties relating to intellectual property (IP) rights. The most prominent of these is the TRIPS Agreement.

The TRIPS Agreement sets out the minimum standards of patent protection that countries must apply. It says that patents shall be available for inventions in all fields of technology, provided they are new, inventive and capable of industrial application.<sup>25</sup> Patents shall be available and patents rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. The agreement also gives member countries the option to exclude certain inventions from patentability.

The TRIPS Agreement thus provides a general principle that inventions in a field of technology are eligible for patent protection. Excluding an invention from patentability is an exception to that rule and must fall into one of the exceptions allowed for by the TRIPS Agreement.

Australia also has several bilateral agreements that include provisions on patentable subject matter. The Australia-United States Free Trade Agreement (AUSFTA) contains provisions similar to the TRIPS Agreement on patentable subject matter, with some exceptions. Unlike the TRIPS Agreement, the AUSFTA does not allow Australia or the US to exclude plants and animals from patent protection.<sup>26</sup>

Australia has also recently signed two further Free Trade Agreements. The ASEAN-Australia-New Zealand Free Trade Agreement and the Australia-Chile Free Trade Agreement both reinforce Australia's existing rights and obligations under the TRIPS Agreement.

Submissions in response to our issues paper generally supported the view that Australia's laws were compliant with our international obligations. The Law Council of Australia was representative of many submissions when it stated:

Although there are possible interpretations of articles of TRIPS and AUSFTA that might support arguments of non-compliance with Australia's international obligations, we consider the better view is that Australia is compliant.

Some submissions expressed a contrary view:

- There were concerns about excluding inventions that are mischievous to the state, or hurt of trade or generally inconvenient.<sup>27</sup> In Australia, a patent may be refused if *granting a patent* would be generally inconvenient. In contrast, the TRIPS Agreement exclusion applies only if *the commercial exploitation of an invention* would be contrary to *ordre public*<sup>28</sup> or morality. It was felt by some that there might be some examples where the exclusions are equivalent, and others where they are not.
- One submission felt the 'contrary to law' exclusion in Australian law might not be compliant. The TRIPS Agreement states that a country cannot exclude an invention from patentability 'merely because the exploitation is prohibited by their law'. The use must be contrary to *ordre public* or morality. The fact that the use of an invention is contrary to law is, at best, one of the arguments necessary to meet the conditions prescribed by the TRIPS Agreement.<sup>29</sup>
- Several submissions expressed the view that the exclusions of mere admixtures and persons names may offend the TRIPS Agreement if they are new and inventive. If not inventive, the view was that the provisions are redundant.<sup>30</sup>
- One submission doubted that Australia had properly implemented the industrial applicability/utility provisions specified in the TRIPS Agreement and the AUSFTA, but conceded that patent examination practice seems to be in compliance.<sup>31</sup>

The Australian Government amended the patent legislation in 1994 'to bring it into line with the standards and principles prescribed for patents in the Agreement Establishing the World Trade Organization'<sup>32</sup>. The Government also amended the legislation in 2004 to 'fulfil Australia's obligations under the Free Trade Agreement between Australia and the United States'<sup>33</sup>. It is clear that the Australian Government believes that our law complies with these agreements.

New Zealand, on the other hand, repealed its provisions equivalent to those in section 50 of the *Patents Act 1990* when it amended its legislation to comply with the TRIPS Agreement. The New Zealand *Patents Act 1953* originally included a provision allowing the Commissioner of Patents to refuse certain patent applications. The New Zealand *Patents Amendment Act 1994* (No 122 of 1994) repealed this provision and replaced it with a discretion to refuse applications that were contrary to morality.

New Zealand considered the ‘contrary to law’ provision to be inconsistent with article 27 of the TRIPS Agreement.<sup>34</sup>

In Australia, international treaties do not, of themselves, impose obligations on individuals or create rights. Such obligations or rights only arise when the treaty is implemented in domestic law. Nevertheless, treaties may influence the development of the common law and may assist in the interpretation of statutes. We note that the exclusions in section 50 of the Patents Act are discretionary and are rarely used. A breach of obligations would occur only if the discretion was exercised in a manner contrary to the agreements.

One suggestion was to amend the legislation to state that an application may only be refused on a ground permitted under the TRIPS Agreement or the AUSFTA. We believe such an approach may introduce an element of uncertainty and force decision makers to interpret international law rather than resolving the issues of Australian law at hand. We are also concerned that this approach may lead to interpretations that do not promote Australia’s national interests, particularly if the only jurisprudence comes from other countries. The preferred method of giving effect to treaties is to translate the relevant provisions of the treaty into traditional legislative language.<sup>35</sup>

## National systems

The TRIPS Agreement sets a general principle in favour of patentability for inventions with separate provisions for public policy exclusions. However, it provides no guidance as to what constitutes an invention. Countries have adopted two general methods of defining the field of patentable subject matter. The first method is to define ‘invention’ – either positively by way of a statement of what is an invention, or negatively by way of a list of subject matters that are not inventions – and then specify inventions that cannot be patented for public policy reasons. The second method is to list all subject matter that cannot be patented, regardless of whether it is an invention. In this case, the scope of patentable subject matter is extracted from a list of exclusions.<sup>36</sup>

The main patenting jurisdictions define ‘invention’ as follows:

### *creation of technical idea*

- The Patent Law of Japan defines ‘invention’ as meaning ‘a highly advanced creation of technical ideas by which a law of nature is utilized’.
- Korea similarly defines ‘invention’ as meaning ‘the highly advanced creation of a technical idea using the rules of nature’.

### *process, machine, manufacture or composition of matter*

- The US allows patents for ‘any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof’. US courts have interpreted this to include ‘anything under the sun made by man’.
- Canada defines ‘invention’ as meaning ‘any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter’. Canada also explicitly excludes patents for ‘any mere scientific

principle or abstract theorem’. Canadian courts have required an essentially economic result in relation to trade, commerce or industry.

### ***manner of manufacture***

- Australian and New Zealand patent laws include definitions of invention that refer to a manner of new manufacture, maintaining a direct link to section 6 of the *Statute of Monopolies*.

### ***define by exclusion***

- The European Patent Convention (EPC) allows patents for any inventions, in all fields of technology. The EPC does not define invention but contains a list of subject matters that are not inventions. The national laws of European countries follow the EPC model.
- The Eurasian Patent Convention<sup>37</sup> allows patents for any invention that is new, involves an inventive step, and is industrially applicable. The regulations under the convention provide a list of subject matters that are not recognised as inventions. The regulations also state that an invention shall be considered to be industrially applicable if it can be used in industry, agriculture, public health or other fields of human activity.
- India defines ‘invention’ as meaning ‘a new product or process involving an inventive step and capable of industrial application’. India defines a list of subject matters that are not patentable, whether inventions or otherwise.
- China does not define invention but provides a list of subject matters that are not patentable, whether inventions or otherwise.

Internationally, similarly worded tests for patentable subject matter can provide different results. For example, Australia and New Zealand both require an invention to be a manner of new manufacture. New Zealand courts adopting this test have held that methods for the medical treatment of the humans are not patentable, as these patents would be generally inconvenient.<sup>38</sup> In Australia, the Federal Court has held such methods to be patentable.<sup>39</sup>

The US and Canada also have similarly worded tests, but the list of subject matter prohibited from patentability in Canada differs significantly from the US. For example, a method of surgery or therapy on living humans and animals is not considered to be within the scope of ‘invention’ in Canada. Canada also excludes higher life forms from patentability.<sup>40</sup>

Despite European countries sharing a common legal framework, courts have produced diverging decisions on the patentability of software. The President of the European Patent Office (EPO) has referred concerns on the application of the exclusion of computer programs to the EPO Enlarged Board of Appeals. The Enlarged Board of Appeals has received public comments and is currently considering the issue.<sup>41</sup>

These outcomes suggest that courts account for national interests when interpreting ‘invention’, beyond the literal wording of any test. The varying definitions of invention, together with explicitly legislated exclusions create considerable variation in patentable subject matter in different countries.<sup>42</sup>

## Harmonisation

In our issues paper we asked for comments on whether it was more important to achieve best practice or to harmonise Australian law with the law in a major jurisdiction. While there was some support for harmonisation of laws, several submissions stressed that this should not be at the expense of Australia's national interests. Overall, most submissions believed that Australia should strive for best practice taking into account our national interest.

Some submissions pointed out that harmonisation is not an appropriate policy rationale, but it is a relevant consideration when deciding how to express policy. The need for inventors to tailor patent applications to different jurisdictions adds additional costs to innovators. Accordingly, it is desirable that changes to Australian law increase rather than reduce international harmonisation. One submission said it is important that Australia has access to the most effective and efficient technologies, the majority of which are invented outside Australia. To the extent that harmonisation facilitates such access, it is important.<sup>43</sup>

A number of recent court decisions in the US on patent-eligibility and inventiveness have curtailed the scope of patentable subject matter to some extent in that country.<sup>44</sup> Many other countries place restrictions on subject matters such as software, business methods, and methods of medical treatment or diagnosis. Australia is arguably more permissive of patenting in these fields than most other jurisdictions. However, as a number of submissions pointed out, patent applicants often get around exclusions by creative drafting of patent specifications. It is often difficult to ascertain what, in practice, are the real differences between countries on patentable subject matter.

## The Australian patent system

Australia is obliged to provide patent protection for inventions as a member of the World Trade Organization (WTO). However, patent protection has been available in Australia since well before the WTO's TRIPS Agreement came into force. In fact, patents were available in Australia prior to Federation under legislation administered separately by the colonies.<sup>45</sup>

Since Federation, section 51(xviii) of the Australian Constitution has given the Federal Parliament the power to make laws with respect to "copyrights, patents of inventions and designs, and trade marks". The *Patents Act 1990* sets out the current legislative scheme for patents with the requirements for patentable subject matter residing primarily in section 18.

The roles of the patent system are threefold: to provide incentives to innovate; to encourage dissemination of knowledge; and to facilitate technology transfer, commercialisation and diffusion of knowledge.<sup>46</sup> Although a number of submissions expressed the objectives of the system in different ways, most were variations or subsets of the objectives set out in Article 7 of the TRIPS Agreement:

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.

Some have suggested that it would be desirable for the Australian patent legislation to contain an express statement of objectives. If such a statement were to be included, it might well be modelled on the language of Article 7. As the Centre for Law and Genetics said, it is “difficult to challenge this dominant paradigm, given that it is so clearly enunciated in TRIPS”<sup>47</sup>. They added that “TRIPS does not just provide an economic rationale for the patent system; social considerations also need to be taken into account”.

In 1623, the ‘balance of rights and obligations’ was achieved by limiting patents to any manners of manufacture that were new to the realm and that were ‘not contrary to the law nor mischievous to the state by raising prices of commodities at home or hurt of trade or generally inconvenient’. It is important to note that, in the modern legal system, this balancing is not all done by the tests for patentable subject matter. The patents legislation sets out a number of exceptions and limitations to patent rights.<sup>48</sup> Competition policy, implemented through the *Trade Practices Act 1974*, also plays a role in regulating the use of patents.

### Economic effects

A criticism that has been made of some previous reports discussing patentable subject matter is that they accept the value of the patent system in promoting innovation.<sup>49</sup> A small number of submissions to this review argued that there is little or no evidence that patents promote innovation and that most innovation would occur anyway. This was said to be particularly true for Australia, where foreigners filed up to 90% of patent applications. In this case, some submissions argued that the grant of an Australian patent would play little part in the innovative process.<sup>50</sup>

Some of these criticisms point to economic analysis performed in the early 1980’s. The Industrial Property Advisory Committee (IPAC) conducted a review into the Australian patent system and published its report in 1984.<sup>51</sup> As part of that review, IPAC commissioned a report into the economic effects of the Australian patent system (Mandeville *et al*<sup>52</sup>). The report argued that the benefit/cost ratio of the patent system in Australia was negative, or at the very best, in balance. It concluded that there was no economic justification for widening the grounds of patentability in Australia.

The Bureau of Industry Economics (BIE) conducted a literature review of the economic impact of the patent system in 1994.<sup>53</sup> The BIE considered that, apart from a greater recognition of the need for international competition, the policy implications of their findings were not substantially different from Mandeville *et al*. The BIE believed that it was not in the national interest to alter the system in a way that curtails technology transfers from abroad. Nor was it in Australia’s interests to protect patent rights beyond accepted international norms.

The Intellectual Property Competition Review Committee<sup>54</sup> (IPCRC) disputed arguments that direct incentives to invention and innovation would provide greater efficiency than the grant of exclusive rights:

These arguments, compelling though they may be, rest on the assumption that governments ... will make fewer or less costly errors in allocating resources to creative effort than are caused by the market-oriented mechanism of intellectual property rights. ... Finally, it wrongly assumes that intellectual property rights serve only to fund investment in creative effort. In practice, they also act to promote the disclosure of new ideas (particularly where secrecy is a viable alternative), and by allowing well-defined rights to be traded, they facilitate the allocation of the ownership of creative works to those who can put them to their most highly valued use. Since no 'direct method' of stimulation has yet been found that comes close to matching these effects, calls for a wholesale retreat from patents are poorly based.

The IPCRC also considered:

... that the goals underpinning the National Competition Policy are well served by a patent policy that rigorously distinguishes between discoveries that advance our understanding of the nature, structure and properties of matter, and inventions that apply this understanding to useful products and processes. Within such a policy, only the latter should qualify for patent protection.

And:

On business schemes, the Committee is not convinced that this area requires incentives for innovation. ... However, we believe that no additional specific recommendations for business schemes are needed since most will not pass the general test for patent grant ...”

A report by ACIP on the patenting of business systems in 2003 found that the issue was not one of great concern in the general Australian business community at that time. There was a lack of evidence that business method patents were hampering innovation. While there was some evidence that patents were stimulating greater investment in the research, development and commercialisation of business systems, the evidence was inconclusive. The report recommended that no changes be made to Australian legislation.<sup>55</sup>

Since the ACIP report on business systems, the Federal Court has confirmed that schemes without physical effect are not patentable under current law. It is necessary that there be some useful product, some physical phenomenon or effect resulting from the working of a method.<sup>56</sup>

The Review of the National Innovation System, *Venturous Australia*, believed the ease with which patents are being granted in areas such as software and business methods is very likely hampering innovation.<sup>57</sup> This finding was informed partly by research from the United States. Bessen and Meurer, two US economists, argued that the cost of obtaining and protecting patents outweighs the financial benefits.<sup>58</sup> It is not clear how well the methodology used by these authors transfers to the Australian system. As the authors note, some of the problems they identify with the American system are unique. Nevertheless, their finding that uncertainty is a key inefficiency in the patent system is worth noting.

US Courts have since held that a process must be tied to a particular machine or apparatus, or to transform a particular article into a different state or thing (*In re Bilski*<sup>59</sup>). As a result, the patenting of business methods, and possibly other types of processes such as diagnostic methods, has been restricted in the US. Some commentators have suggested that the *Bilski* decision moved US law closer to international norms, while Australian law is arguably similar to or broader than the new US position.<sup>60</sup>

The Intellectual Property Research Institute of Australia (IPRIA) has recently published two papers on the effect of patents on different aspects of the innovation system. The research shows that patents provide a small but positive effect in the successful commercialisation of inventions in Australia. The effect was greatest in the pharmaceutical technologies. There was also a small effect for public research organisations, SMEs and individuals. The second paper showed that patents provide a premium to Australian innovators, but failed to find evidence that the effect was different across technologies. The authors considered this surprising, given that other empirical studies showed patents are more valuable in pharmaceuticals and chemicals than other technology areas.<sup>61</sup>

The UK Strategic Advisory Board for Intellectual Property Policy (SABIP) hosted a forum on the economic value of IP in June 2009. In a paper written for that forum, Professor Bronwyn Hall analysed the international economic literature on patents. Hall said that the empirical evidence provided four conclusions:

- Strengthening the patent system (for example by lengthening term or broadening subject matter coverage) results in increased use of the system.
- It is less clear that these changes also result in an increase in innovative activity, although they may redirect such activity towards things that are patentable and away from things protected by trade secret. Hall notes that software is an area where there has been a shift away from secrecy to patenting, resulting from a combination of software patenting and the growth of the internet.
- Any increase in innovation is likely to centre on the pharmaceutical and biotechnology areas, specialty chemicals, and possibly medical and scientific instruments as well as small-scale machinery.
- The existence and strength of the patent system affects the organisation of industry by allowing trade in knowledge.

Hall concluded that it is clear that patents encourage innovation in many areas and they have beneficial effects for industry structure, knowledge markets, and the financing of new innovative firms. The challenge is to design a system with these benefits without also hampering innovation in other areas. Hall stated:

A clear implication of the forgoing for policy is that optimal design is likely to differ across technologies and sectors. Many firms in the ICT sector view the current system as a tax on their innovative activity, whereas firms in pharmaceuticals and biotechnology are strong supporters of the existing system. ... But most analysts have recognised that tailoring the system to technologies now available would inevitably leave it unable to adapt to new technologies as they arrived, and would lead to substantial strategic behaviour on the part of patent applicants to place their technology in such a way as to secure the best possible protection for their particular

invention. The difficulty is that technological change moves much faster than legislative change, which means that fine-tuning of the patent system is inevitable out-of-date by the time it is in place.<sup>62</sup>

According to the submission by IPRIA, the main factor determining whether intellectual property, grants or prizes are the most appropriate incentive depends on the size and duration of dead-weight losses.<sup>63</sup> IPRIA contends that:

The type of technology, whether the knowledge or idea is embodied in a physical product, whether the creation involves treating humans or involves living organisms, whether the creation is technical in nature, are not relevant *per se*.

The Centre for Law and Genetics submitted that in biotechnology, relaxation of patent thresholds occurred in parallel with a surge in the industry. While the causative effect is difficult to assess, their own research revealed that industry participants support the notion that patenting is vital to their success.<sup>64</sup> Industry submissions to this review also confirmed they view patents as an important driver in undertaking research.

Some participants at our public forums suggested that much of the innovative research occurring in Australia was in early-stage research. This was often then taken up by foreign entities. It was in Australia's interests to support this upstream research with patent protection.

## Current law

The Patents Act adopts a technology-neutral approach to patents. The Act sets out the field of patentable subject matter by defining 'invention', then limits the inventions that can be patented to a defined class of 'patentable inventions'.

The definition of 'invention' in Australia is complex and relies largely on the common law. It incorporates aspects of newness, utility and public policy. Invention is defined as 'any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the *Statute of Monopolies*'. Section 6 of the *Statute of Monopolies* provides that patents are only available for manners of new manufacture that are 'not contrary to law nor mischievous to the state by raising prices of commodities at home or hurt of trade or generally inconvenient'. This results in a definition of invention that goes beyond technological development and includes social and economic factors.

The definition of 'patentable invention' also separately codifies some of the principles from the *Statute of Monopolies*. It requires a patentable invention to be a manner of manufacture, to be novel, have an inventive step, and be useful.

The dual reference to manner of manufacture and the overlapping requirements for newness and utility in the definitions of 'invention' and 'patentable invention' add further complexity to the legislative scheme.

The legislation also explicitly excludes certain inventions for social reasons, and provides the Commissioner of Patents with a mechanism to prevent publishing patent specifications that contain scandalous matter.<sup>65</sup>

## Issues with current law

### Archaic language

The Australian Law Reform Commission considered that the terms of section 6 of the *Statute of Monopolies* are ambiguous and obscure. In our Issues Paper, we suggested that this language might impede users of the system from properly understanding and correctly applying the manner of manufacture test.

A number of submissions contested the ALRC view that the use of archaic language was a problem. They considered that the language used in the legislation had not hindered the application of the test and that the courts had developed a body of principles in modern language. The references to section 6 of the *Statute of Monopolies* merely invoked these principles. The test had shown sufficient flexibility to deal with the kinds of inventions that were beyond comprehension in 1623. Any change in language would create uncertainty until it had been judicially interpreted.<sup>66</sup>

On the other hand, a significant number of responses considered the language needed updating to promote further innovation. It was widely felt that the manner of manufacture test was barely understood outside the legal and patent attorney professions. The Australian National University reflected the views put in a number of submissions when it said:

Whatever merits the system of precedents and common law may have, one of them is not clarity and ready accessibility of law. If the central content of patent law must be sifted from lengthy (and often mutually inconsistent) judicial pronouncements, one may conclude that the codification of these principles is called for.

Some submissions contended that the manner of manufacture language did not capture the economic rationale for patenting. It carried a history of interpretation that was not always consistent, either legally or with the economic objective of the patent system. The open-endedness of the definition had led to categories of patentable subject matter that are not patentable in other jurisdictions.<sup>67</sup>

### Invention v discovery

A number of submissions raised concerns about the lack of clear distinction between inventions and discoveries. Submissions discussing the patenting of genetic material typically raised this concern.<sup>68</sup> Not all of these submissions saw a need for different treatment of genes. Some believed greater scrutiny was required during examination and that the current test should exclude isolated genes as discoveries.

The patenting of genetic materials has been controversial for some time. It has been debated vigorously in Australia and overseas. Several previous reviews have discussed the invention - discovery dichotomy, often raised as part of that debate.

The IPCRC<sup>69</sup> asserted that mere discovery, without demonstration of utility in a field of economic endeavour, did not meet the core requirement of the patent system. The IPCRC considered that the goals underpinning the National Competition Policy are served by a patent policy that rigorously distinguishes between discoveries and inventions.

In practice, the distinction in patent law between invention and discovery has not always been easy to make. The High Court has noted<sup>70</sup>:

The truth is that the distinction between discovery and invention is not precise enough to be other than misleading in this area of discussion. There may indeed be a discovery without invention - either because the discovery is of some piece of abstract information without any suggestion of a practical application of it to a useful end, or because its application lies outside the realm of "manufacture". But where a person finds out that a useful result may be produced by doing something which has not been done by that procedure before, his claim for a patent is not validly answered by telling him that although there was ingenuity in his discovery that the materials used in the process would produce the useful result no ingenuity was involved in showing how the discovery, once it had been made, might be applied.

The IPCRC recommended that the distinction between discovery and invention be implemented by requiring that patentable inventions have a specific, substantial and credible utility. The IPCRC believed this would exclude the mere identification of a gene sequence from patentability.

The ALRC also discussed discoveries in its report *Genes and Ingenuity*. The ALRC made recommendations similar to those made by the IPCRC on usefulness. However, the ALRC felt that a new approach to the patentability of genetic material was not warranted:

It would represent a significant and undesirable departure from accepted international practice with respect to genetic inventions, and may adversely affect investment in the Australian biotechnology industry.<sup>71</sup>

It is clear from the submissions we have received and from public consultations that implementing the ALRC recommendations on usefulness would help address some of the concerns in this area. If nothing else, it would bring greater clarity to the law and greater transparency to the process involved in patent examination. Previous recommendations by the ALRC and ACIP to introduce an exception to infringement for experimental use would also help.<sup>72</sup> However, several submissions to this review believed isolated gene sequences were not inventions, regardless of whether the patent applicant has identified a specific use.

Many stakeholders in the public health sector believe that gene patents adversely affect access to technology and the cost of healthcare. Discoveries are excluded from patenting because they have unlimited potential for follow-on research and can potentially benefit a great number of people. It was argued that this applied to genetic sequences. It was claimed that the contribution of the patent applicant does not match the benefits provided by owning the patent and the associated costs to society.

Other stakeholders argued that excluding these technologies from patents would remove the incentive to research in this area. Isolated genetic sequences with utility are considered patentable as inventions because they do not exist in a purified, isolated form in nature. The rationale is that isolating the gene sequence results in an artificially created state of affairs. Other measures such as exempting experimental use from infringement, Crown use or compulsory licensing of patents, competition

law, patent pooling, or increased health funding were seen as better solutions for solving any problems associated with accessing patented technology.

One submission felt that there are strong grounds for limiting patents to use-bound claims.<sup>73</sup> The current practice of IP Australia is to allow a patent for a newly discovered substance as long as the substance is isolated or synthesized and the patent applicant has identified a practical use for the substance.<sup>74</sup> The exclusive right may be granted to the substance without being limited to that use. The patent applicant needs only to describe the use in the descriptive part of their patent specification.

The Senate Community Affairs Committee is currently investigating the specific issue of gene patents and has received similar submissions on discoveries.<sup>75</sup> The issue is also receiving some attention in the United States. The Secretary's Advisory Committee on Genetics, Health and Society has produced a draft report on gene patents and licensing practices.<sup>76</sup> Also in the US, the American Civil Liberties Union and others have filed a lawsuit against the USPTO and Myriad Genetics over patents relating to two cancer-related genes. One of the arguments raised is that the patents are invalid because genes are a product of nature.<sup>77</sup>

### **Threshold inventiveness**

As discussed above, the Patents Act defines invention as 'any manner of new manufacture ... within section 6 of the *Statute of Monopolies*, and includes an alleged invention'. The High Court has stated that the threshold requirement of 'an alleged invention' is not satisfied if it is apparent on the face of the specification that the subject matter lacks the necessary quality of inventiveness. If it were clear on the face of the specification that the subject matter is merely a new use of an old product,<sup>78</sup> the specification would itself admit the absence of an 'alleged invention'. The subject matter would not be patentable without need to consider the specific legislative tests for newness, such as novelty and inventive step.<sup>79</sup>

Courts in the United States may also require some level of inventiveness on the face of the specification as part of the threshold requirement for patentability. As noted by Stern:

Claimed processes typically implement some underlying scientific principle, phenomenon of nature, or abstract idea ("underlying principle") by using a device. The implementing device may be a machine, article of manufacture, or other product. Although the principle, of itself, is not patent eligible, the process or implementing device may be patent eligible. The clue to patent-eligibility is whether the device differs from the prior art i.e. what was already known – in a way that is not concededly, or on its face, trivial.<sup>80</sup>

In the United Kingdom, Lord Hoffman cautioned against this approach in the House of Lords:

One can of course imagine cases in which the alleged subject-matter is so obviously not an invention that it is tempting to take an axe to the problem by dismissing the claim without inquiring too closely into which of the conditions has not been satisfied. So in *Genentech Inc's Patent* [1989] R.P.C. 147, 264 Mustill L.J. said, by reference to the ordinary speech meaning of "invention":

"You cannot invent water, although you certainly can invent ways in which it may be distilled or synthesised."

This is obviously right and in such a case it may seem pedantic to say that water fails the condition in paragraph (a) of section 1(1) because it is not new. Unfortunately, most cases which come before the courts are more difficult. Judges would therefore be well advised to put on one side their intuitive sense of what constitutes an invention until they have considered the questions of novelty, inventiveness and so forth.<sup>81</sup>

In our Issues Paper, we questioned whether the threshold of inventiveness discussed in *Philips v Mirabella* still stands and whether it meets the objectives of the system. Submissions from the patent attorney professional organisations<sup>82</sup> considered that the High Court had clarified the matter in *Lockwood v Doric*<sup>83</sup>. In that case, the High Court affirmed the proposition that the Commissioner of Patents may refuse a patent application where a specification 'on its face' shows the invention claimed is not a manner of new manufacture.

On the other hand, a number of submissions argued that the concept of a threshold of inventiveness was an anomaly, that it did not reflect the intent of the legislation, and that matters of 'newness' were better dealt with under the heads of novelty and inventive step. It may also impose additional financial and red tape costs by creating uncertainty in the thresholds necessary for patentability.<sup>84</sup>

The Federal Court has referred to *Philips v Mirabella* at least twice since we received public comments to this review.<sup>85</sup> On each occasion, the court reaffirmed the threshold requirement for an invention will not be met if, on the face of the specification, the subject matter lacks the necessary quality of inventiveness under the *Statute of Monopolies*.

Submissions proposed various measures to address the perceived problem. One common suggestion was to remove the definition of invention from schedule 1 of the Patents Act. Others suggested removing the concept of manner of manufacture altogether.

Deleting the definition of 'invention' in Schedule 1 may not be sufficient to remove the overlap on inventiveness. The majority of the High Court in *Philips v Mirabella* decided that a claim to a mere new use of a known product would not be a manner of manufacture within section 18(1) (a) of the Patents Act, as well as falling outside the definition of 'invention'.

Some commentators have suggested that the relatively low standards of novelty and inventive step in Australia provide the rationale for the threshold test for inventiveness.<sup>86</sup> The Patents Act places constraints on the documents that can be considered when assessing the novelty or inventive step of an invention. It also limits common general knowledge<sup>87</sup> to that existing in Australia. The majority of the High Court in *Philips v Mirabella* expressed difficulty with the proposition that an invention might satisfy the requirements of inventive step, notwithstanding that it lacked any quality of inventiveness according to traditional principles. However, the Court thought it unnecessary to decide that issue.

We note here that the reference to ‘a new use of an old product’ by the High Court raises an additional point. One submission pointed out that the AUSFTA requires Australia to provide patent protection for new uses or methods of using a known product.<sup>88</sup> This highlights the distinction between a new use of a known product using the known properties of the product, which is not patentable, and a new use that takes advantage of a previously unknown property, which is patentable.<sup>89</sup>

### General inconvenience

Section 6 of the *Statute of Monopolies* specified that patents did not extend to any manners of new manufacture that are ‘contrary to the law nor mischievous to the state by raising prices of commodities at home or hurt of trade or generally inconvenient’.

As discussed in our Issues Paper, prior to 1960 the focus of the ‘generally inconvenient’ exclusion had been on problems caused to society by insubstantial inventions such as analogous uses. From 1960 to 1994, the courts started to imbue the term with social policy concerns. In the 1990’s, the Federal Court stated that it was for Parliament, not the courts or the Patent Office, to decide whether matters of ethics or social policy are to have any impact on what is patentable. The Court expressly rejected an argument that methods of medical treatment were excluded from patentability due to general inconvenience.

The contemporary view appears to be that the ‘generally inconvenient’ exclusion has provided the policy rationale for specific provisions within the legislation. For example, Menzies J agreed that if a specification failed to sufficiently define the invention the patent would be to the hurt of trade and be generally inconvenient. The High Court has also said that the ground of inutility was developed in decisions construing the phrases ‘mischievous to the State ... or generally inconvenient’. In *Welcome Real-Time SA v Catuity*, Heerey J rejected general inconvenience as a stand-alone ground of invalidity.<sup>90</sup>

A recent Federal Court decision relating to copyright is of incidental interest here. The case related to an alarm system for taxis that played the message “Help-Help-Driver-in-Danger-Call-Police-Ph.000”. Emmett J held that the message was not a literary work. He concluded:

It would be inappropriate for the Help Words not to be available for use by anybody without the consent of Pacific Technologies, lest infringement occurred by a taxi driver or a passer-by using the words.<sup>91</sup>

This rationale is not unlike that provided in *Rolls Royce Ltd’s Application* to refuse patent protection to a method of operating an aircraft:

The responsibility of a pilot of an aircraft in flight carrying scores of passengers is already sufficiently onerous without adding to his burden the task of avoiding infringement of a statutory monopoly in the operation of his standard engine controls unless the justification for the grant is reasonably manifest.<sup>92</sup>

New Zealand courts have taken a different approach to that taken by the Federal Court in Australia. The NZ Court of Appeal ruled that while methods of medical treatment may be inventions, it is generally inconvenient to protect them with patents. The

court added a caveat that they envisage little if any scope for exclusion on the basis of general inconvenience of inventions other than methods of medical treatment.<sup>93</sup>

The Australian High Court has referred to general inconvenience a number of times as a possible ground of invalidity, but has neither applied that proviso to revoke a patent nor extinguished the concept. A number of submissions said that there was clear authority that the general inconvenience exclusion remains available under the Patents Act. These submissions viewed general inconvenience as a valuable measure of last resort.<sup>94</sup> According to the submission by IPTA, there is clear authority that decision makers should not use general inconvenience to place blanket bans on patents across broad areas of subject matter, such as medical treatments. General inconvenience is based on a specific judicial perspective that the granting of a patent for a specific subject matter under consideration would create a burden that is not in the public interest.

Others saw the general inconvenience test to be outdated and in need of replacing or removing.<sup>95</sup> The terms carried a history of interpretation that was not necessarily consistent with the modern intent of the system. The provisions of novelty, inventive step and usefulness were better adapted to deal with insubstantial inventions. Clearer and more specific provisions were preferable for dealing with social issues.

## **Defining Invention**

### **Broad alternatives**

Most submissions preferred a combination of flexible and proscriptive tests to define the field of patentable subject matter. Almost half of the submissions were in favour of retaining manner of manufacture as the primary test for patentable subject matter. These submissions argued that the manner of manufacture test worked and supported the economic objectives of the system. On the other hand, many submissions believed the concepts of manner of manufacture and general inconvenience were unclear and were misaligned with the economic objectives of the patent system.

These contrary viewpoints present four main options for defining patentable subject matter. The first is to retain the current definition of invention tied to section 6 of the *Statute of Monopolies*. A subset of this option is to enhance the current system by reforming the requirements for inventiveness, usefulness and general inconvenience. This may remove some of the overlap and uncertainty of these provisions.

The second option is to capture the essential characteristics of the current test in clear and modern language. This approach would modernise and clarify the language of the law without changing key underlying principles.

The third option is to replace the current definition of invention with the language from the TRIPS Agreement that patents be available for any invention in a field of technology.

A fourth option is to have no definition of invention. Instead, the legislation would rely on the objective tests of novelty, inventive step and industrial applicability to

define the field of patentable subject matter. Specific areas of concern such as mere discoveries could be dealt with by express exclusions.

### **Retain manner of manufacture**

Submissions in favour of retaining the manner of manufacture test argued that it was not necessary to modernise the test as an extensive body of case law supported it. Despite the antiquity of the manner of manufacture test, it had enabled patent law to keep up with and adapt to radical changes in technology. Support for retaining the manner of manufacture test was strongest among the patent attorney and legal professions.<sup>96</sup>

Many of those in favour of retaining manner of manufacture pointed to previous reviews by IPAC and IPCRC. These reviews found that the law that has developed around the statutory language has provided legal certainty and has demonstrated sufficiently flexible to deal with the kinds of invention that were beyond comprehension in 1623.

An argument made by some submissions and repeated in the public forums was that there was no evidence that the manner of manufacture test was unreasonably interfering with the efficiency or administration of the patent system in Australia. The alternative view was that the open-endedness of the test had led to patents being granted in Australia for subject matters that were not patentable in other jurisdictions. Some of the available economic evidence suggests that it is not in Australia's interests to provide patent protection beyond international norms.

Among those who favoured keeping the manner of manufacture test, many still saw an opportunity to improve the law. Some preferred retaining the current manner of manufacture approach without adding further exclusions, and possibly removing some limitations or making other adjustments. Others suggested that adding express exclusions would allow Parliament to effect policy without changing the underlying basis for the law. Some believed additional exclusions were necessary to address existing problems or to restore policies overturned by the courts or IP Australia.

### **Update archaic language**

A number of submissions indicated that the manner of manufacture test should be replaced. These submissions generally preferred a flexible test together with objectively applied standards for novelty, inventive step and industrial applicability. Among the submissions that favoured retaining the manner of manufacture test, many justified this on the basis that the test had been clearly interpreted by the High Court in the *NRDC* decision. One option is to codify the *NRDC* requirement that an invention be an artificially created state of affairs in a field of economic endeavour.

Adopting the language of *NRDC* would provide a two-limbed definition of invention:

1. There must be an artificially created state of affairs. This means that an invention must have steps or properties that create an artificial effect in the physical world. There must be some physical effect, in the sense of a concrete effect or phenomenon or manifestation or transformation.<sup>97</sup>
2. The value of the creation must be in a field of economic endeavour. This means that the invention must be in the useful arts rather than the fine arts.<sup>98</sup>

This reflects the economic purpose of the patent system. An invention must have an industrial or commercial or trading character.

Adopting a definition of invention based on the *NRDC* decision provides some advantages over the current manner of manufacture test. The key features of an invention are set out directly in the legislation, providing greater transparency in the law. Although the *NRDC* decision dates from 1959, the words are relatively contemporary and do not suffer the problems of archaic language levelled at the manner of manufacture test and the *Statute of Monopolies*.

A test based on the words of *NRDC* is largely a restatement of the law in the words currently being applied by the courts. It does however simplify the law compared to the manner of manufacture test. The requirements that the subject matter of a patent not be contrary to law, mischievous to the state or generally inconvenient would be separated from the definition of invention. Social policy issues could be dealt with separately rather than bundled up in the definition of invention. Issues of newness would be dealt with directly by the requirements for novelty and inventive step. Similarly, utility would be dealt with under the specific ground that an invention be useful. This may require a further change to the patents legislation to capture the ALRC recommendation that an invention have a specific, substantial and credible utility.

One criticism of the *NRDC* definition is that it may be too wide. Justine Pila submitted that it was oriented less around encouraging and rewarding inventive activity than granting property for ideas of commercial value. Pila suggested that ‘invention’ should mean any artificial combination of steps (method) or properties (product) that creates an effect in the physical world.

### **Inventions in a field of technology**

The language of the TRIPS Agreement requires patents to be available for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Some submissions felt that the Australian legislation should adopt this structure.

A field of technology test provides a modern, and perhaps minimalist, approach to patentable subject matter. It possibly restates the *NRDC* requirement that an invention belongs to the useful arts rather than fine arts. It would have some of the same advantages as codifying the *NRDC* principles. The legislation would deal with matters of novelty, inventive step and utility directly rather than being incorporated partly in the manner of manufacture test. This may lead to a simplification of the law and greater clarity in administration of the law.

This option would also have the advantage of using internationally recognised language. It closely follows the TRIPS Agreement framework of setting out a general principle in favour of patentability for inventions and allows for separate provisions for social policy exclusions.

There is no general agreement as to the meaning of ‘field of technology’ within the TRIPS Agreement. Participants at some of the public forums felt that a ‘field of

technology’ test would run into problems of definition, even though there are definitions that seem clear. The Macquarie Dictionary defines technology as:

the branch of knowledge that deals with science and engineering, or its practice, as applied to industry; applied science.<sup>99</sup>

While this approach restricts patents to inventions in a field of technology, it does not provide a definition of ‘invention’. The European Patent Office requires inventions to be of a technical character or have a technical effect. There were suggestions to include a definition of invention including requirements of physicality and technicality, or to specify these requirements in guidelines.

In Europe, the legislators defined a list of subject matters that were not inventions, effectively defining invention by exclusion. Article 52 of the EPC states that the following subject matters, *per se*, are not inventions:

- discoveries, scientific theories and mathematical methods;
- aesthetic creations;
- schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- presentations of information.

Some submissions considered that providing a similar list would provide greater certainty in the law. While these submissions recognised that there would be issues with some subject matter at the boundaries of these exclusions, this was implicit in any market regulation and could be managed. Providing a list of exclusions would allow the government to set guidelines within established public policy. Greater certainty would offset any reduction in flexibility.<sup>100</sup>

Many other submissions were vehemently opposed to a list of exclusions. A common view was that the proscriptive approach in Europe had failed, and had merely promoted creative claim drafting. This resulted in obscure language in patent claims. Prohibiting certain areas of technology was seen as having failed to achieve its objectives in Europe.

### **Remove manner of manufacture**

A small number of written submissions suggested that there was no economic justification for placing limits on patentable subject matter beyond the requirements that the subject matter be new, inventive and have industrial applicability. Developments at or outside the margins of patentable subject matter tended to be among the faster growing areas of economic activity in Australia. The retention of the reference to the *Statute of Monopolies* was an unnecessary restraint on the patenting of these new areas of economic activity.<sup>101</sup>

An option is to remove the manner of manufacture requirement and rely on the objective tests of novelty, inventive step and usefulness to do the economic work of the patent system. The legislation could deal with any social policy issues separately, by specific or general exclusions. One suggestion was to have some broad, concept-based limitations such as excluding ‘mere discoveries’, together with positive requirements such as novelty, inventive step, industrial applicability and the disclosure requirements in section 40 of the Patents Act.

The counter argument to removing the manner of manufacture requirement is that intellectual property rights are an exception to the law's general abhorrence of monopolies.<sup>102</sup> Several submissions made the point that it is the patentability of subject matter, not the exclusion of subject matter from patentability, that requires justification on economic grounds. Removing the threshold requirement for invention may expand the field of patentable subject matter in Australia.

New Zealand has previously considered the option of removing the definition of invention and relying on the criteria of novelty, inventive step and usefulness. The New Zealand Government concluded that there was no guarantee that the industrial applicability criterion of the TRIPS Agreement would exclude those inventions currently excluded as not being a manner of manufacture. New Zealand decided to maintain the manner of new manufacture test, partly because it maintained harmony with Australian law.<sup>103</sup>

In the UK, the House of Lords considered that “in virtually every case” patentability could be decided by satisfying the grounds of novelty, inventive step, industrial applicability, and the specific exclusions from patentability in the UK Patents Act. Lord Hoffman qualified this by saying:

... one cannot say with certainty that one might not come across something which satisfied all the conditions but could not be described as an invention.<sup>104</sup>

## Social Exclusions

The objectives set out in the TRIPS Agreement promote the protection and enforcement of intellectual property in a manner conducive to social and economic welfare and to a balance of rights and obligations. Article 8 of the TRIPS Agreement allows members to ‘adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this agreement’.

The TRIPS Agreement allows members to exclude inventions from patentability where the prevention of the commercial exploitation of the invention ‘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’. Members may also exclude ‘diagnostic, therapeutic and surgical methods for the treatment of humans or animals’.<sup>105</sup>

## Submissions against social policy exclusions

A significant number of responses believed that patent law was an inappropriate mechanism for dealing with social or ethical issues. These views were often framed around the nature of the rights attached to a patent grant. A patent allows the patent owner to prevent others from using the patented invention, but does not provide an unimpeded right for the patent owner to exploit their invention. A patent owner may only use their invention subject to national and state laws and subject to any earlier

patent rights that may exist. If there is no patent, anybody may use the invention subject to existing laws.

Several submissions argued that patent law was a blunt instrument for dealing with social issues and that direct regulation of the targeted behaviour was vastly superior. The argument was put that ethical issues do not arise simply because a patent is granted; they arise in the manner in which the invention is used. It was therefore more appropriate to regulate use of inventions rather than exclude inventions from patentability.

Some submissions referred to the transient and subjective nature of morality and the resulting uncertainty of the scope of any ethical filter. Several submissions, including that of IP Australia, believed that patent examiners were not equipped to deal with ethical issues or that it was not appropriate for IP Australia to decide matters of social policy administratively.

Apart from the problems of definition and scope, there were also concerns expressed that limiting subject matter on ethical grounds may have a real impact on reducing innovation, particularly in areas of human health. The Enlarged Board of Appeals of the EPO decided in November 2008 that it is not possible to grant a patent in Europe for an invention which necessarily involves the use and destruction of human embryos. Such inventions were considered by the EPO to be contrary to *ordre public* or morality. Some participants to this review believed that such inventions were better dealt with by specific legislation, such as the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*. A morality exclusion was seen as being contrary to the vision of the Lockhart review of the stem cell legislation.<sup>106</sup>

Another argument put forward was that other real and intellectual property laws do not regulate ethics. For example, copyright is not denied because a film might be obscene, or an owner is not prohibited from having title to a house that may be used for illicit activities. The morality of the activity is dealt with by direct regulation rather than through real or intellectual property law.<sup>107</sup>

While a significant number of stakeholders felt that the patent system was the inappropriate place to regulate social behaviour, there was minimal support for removing all of the existing social filters from the patents legislation.

The ALRC also discussed ethical issues in its review of gene patents. The ALRC did not believe the Patents Act should be amended to expand the circumstances in which social and ethical considerations are taken into account in decisions about granting patents.<sup>108</sup>

### **Submissions in favour of social policy exclusions**

An equally significant number of submissions considered that social and ethical considerations were paramount and reflected the primary goal of the patent system to benefit society. It was said that all law had a social context and the suggestion that the patent system is somehow outside the social aspects of the economic infrastructure are misconceived.

It was argued that the patent system is only a small part of the overall economic structure of Australian society. The failure to obtain a patent is not catastrophic. An invention will be exploited if it has value and usefulness, whether patented or not. Therefore, the effect on innovation of excluding inventions on ethical grounds may be overstated.

A number of submissions felt that patents could have an adverse impact on healthcare by limiting access to technology by health providers and downstream researchers. The ability of governments and health professionals to maintain the public health of Australians is vital and some saw it as essential that patents take account of ethical issues. Some believed that patents on biological materials are contrary to fundamental principles of human dignity.

A further point made was that granting a patent may be seen as the government putting its imprimatur on the invention. Therefore, excluding socially undesirable inventions would protect the integrity of the patent system. It is not appropriate that the Government provide the incentive of exclusive rights for inventions that are socially abhorrent, regardless of whether other laws prevent their use.

To counter the argument that judges and examiners could not deal with ethical issues, it was argued that they are not asked to judge ethics *per se*, but whether public concerns are such that granting a patent may not be appropriate. In any case, there were mechanisms available to deal with this problem. For example, several submissions supported a panel to advise examiners on social exclusions. We deal with this suggestion below.

### Possible social filters

We are not persuaded by submissions that the patent system is or should be ethically agnostic. The patent system is often referred to as a social contract between the innovator and the state. It seems incongruous that an innovator be awarded a patent for an invention that is socially unacceptable. Social and ethical considerations have always been a part of Australian patent law.

We acknowledge that there are differences in values within and across society. There are ways of dealing with these differences, as there are in many other areas. For example, the Classification Board must take account of community concerns when classifying films and computer games. The Gene Technology Ethics & Community Consultative Committee may provide advice on matters of general concern to the community, including ethical issues relating to gene technology. IP offices in other regions have mechanisms for dealing with social policy issues.

We see a number of options for excluding subject matter on social grounds:

- Retain the exclusions currently provided in the Patents Act, including the requirement that the patented invention not be generally inconvenient (assuming that general inconvenience is part of the manner of manufacture test).
- Add specific exclusions to deal with particular issues. For example, the legislation currently excludes human beings. There was some support in the submissions for explicitly excluding discoveries.<sup>109</sup>

- Apply a general social exclusion, such as excluding inventions that are generally inconvenient or implementing the TRIPS Agreement provision allowing exclusion where the use of the invention would be contrary to *ordre public* or morality.

A combination of these options is also possible.

### **Retain current social exclusions**

One option is to retain the current exceptions:

- Patents are not available for inventions that are generally inconvenient.
- Human beings, and the biological processes for their generation, are not patentable inventions.
- 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.

The legislation also includes a discretion for the Commissioner of Patents to refuse patents that claim:

- an invention the use of which would be contrary to law;
- a substance that is capable of being used as a food or medicine (for humans or animals) and that is a mere admixture of known ingredients;
- a process for producing such a substance by mere admixture;
- a person's name as the name of the invention in a claim.

We have discussed the 'generally inconvenient' exclusion in detail above. If the manner of manufacture test were replaced, this would also omit the 'contrary to law, mischievous to the state, or general inconvenience' provisions from the threshold test. In this case, the legislation would need amending to expressly incorporate a 'generally inconvenient' exclusion if it was considered preferable to retain this provision.

There was generally little controversy expressed in submissions on the exclusion of human beings, except perhaps from some who saw it as illogical to exclude human beings but allow patents for human gene sequences. There was, however, a concern expressed that IP Australia had interpreted the exception to human beings and biological processes for their reproduction to exclude legal and widely accepted methods, such as methods of *in vitro* fertilization.<sup>110</sup>

Section 18(3) of the Patents Act excludes plants and animals from innovation patents. The Australian Seed Federation (ASF) contended that this exclusion should be removed to encourage investment in Australian agriculture. The ASF view was that the *Plant Breeder's Rights Act* does not provide sufficient protection to encourage investment in plant breeding.

ACIP conducted a review in 2004 of the exclusion of plants and animals from the innovation patent. A significant proportion of plant varieties eligible for a Plant Breeder's Right (PBR) would also be eligible for the innovation patent. The innovation patent system does not have the numerous balancing features (in particular, the exceptions from infringement) found in the PBR system. Thus, it was

considered that allowing innovation patents to be granted in relation to plants would provide excessive rights for the patent owners. Although there is no PBR-type system for animals, the status quo of free competition was retained due the absence of a clear need for innovation patent protection for animals. Our recommendations were that the exclusions should be maintained at that time.<sup>111</sup> We are not aware of any new evidence of sufficient weight to overturn those recommendations. Regarding deficiencies with the PBR system, ACIP is currently reviewing the enforcement of PBR. We expect to report to the Minister for Innovation, Industry, Research and Science shortly with recommendations for improvements to the system.<sup>112</sup>

A number of submissions and participants at public forums said that the ‘not contrary to law’ provision was a sufficient filter for social and ethical issues. It has the advantage of being relatively clear. It is also justified on broad public policy grounds that encompass social and ethical considerations.

A limitation of the ‘not contrary to law’ provision is that technology often outpaces the law, so that Parliament can only deal with these issues reactively. As submitted by Luigi Palombi (in relation to removing ethical limits on patentable subject matter):

Secondly, it would impose upon the Australian Parliament a greater burden to monitor the impact of technological developments on Australian economy and society and to respond legislatively in a proactive manner. Unfortunately, Parliament is not in the best position to predict or react to technological innovations that may bring economic, moral or ethical considerations into the assessment of patentability. Therefore, Parliament is more likely to be reactive and not proactive.

A number of submissions supported removing the Commissioner’s discretion to refuse applications relating to mere admixtures capable of being used as a food or medicine. This provision was introduced into UK law in 1932 to prevent patents for mere prescriptions or recipes. Australia introduced the provision in the *Patents Act 1952*.<sup>113</sup> A common view in submissions was that the provision was redundant in view of the inventive step requirements for an invention. Alternatively, it was seen as contrary to the TRIPS Agreement requirement that inventions be available without discrimination as to fields of technology.

Subsection 50(2) of the Patents Act is a curious provision that allows the Commissioner to refuse to accept a specification containing a claim that includes the name of a person as the name of the invention. This provision seems to be unique to Australian patent law. Anecdotally, we understand this provision may have arisen from concerns about a claim to the “Dolly Parton” rose.<sup>114</sup> However, we have not been able to verify its origin and the explanatory memorandum to the Patents Act 1990 merely restates the provision.

### **Specific exclusions**

The Patents Act currently includes several specific exclusions from patentable subject matter, such as human beings (and, with respect to the innovation patent, plants and animals). We have discussed these above. Several submissions also saw need for an explicit exclusion of discoveries.

It is always an option for Parliament to legislate specific exclusions, just as it did with the human being exclusion. In fact, the Federal Court has expressed the view that this is the preferred mechanism for excluding inventions on social policy grounds. The rider is that any further exclusion would need to fall within the provisions of the TRIPS Agreement.

The TRIPS Agreement allows members to exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Most countries place some limitation on methods of medical treatment or diagnosis of the human body. New Zealand and Canada exclude these methods on the basis that they are not inventions. The EPC includes a specific provision excluding medical methods, which has been adopted by European countries. Japan, China and Korea also limit patents on medical methods. In fact, in a survey of members states by the WIPO, almost all countries except Australia, the US and members of the Eurasian Patent Organisation<sup>115</sup> indicated some restriction on the patentability of diagnostic, therapeutic and surgical methods for treating humans and animals.<sup>116</sup> The US provides a defence against infringement for medical practitioners. Several submissions suggested that there should be a specific exclusion of methods of medical treatment, or at least further analysis of the issue. Others felt that excluding medical treatments would have a detrimental effect on medical research in Australia.

The ALRC was concerned that such an exclusion would have adverse effects on investment in biotechnology, medical research and innovation in healthcare. The ALRC also rejected the possibility of introducing some form of medical treatment defence.<sup>117</sup> ACIP is not aware of any additional evidence supporting such an exclusion.

### **General social filters**

One option for excluding inventions from patentability on social grounds is to provide a general public policy exclusion. The TRIPS Agreement allows countries to exclude inventions where the commercial exploitation of the invention would be contrary to *ordre public* or morality.<sup>118</sup> The Patents Act currently provides the Commissioner of Patents with a discretion to exclude inventions the use of which would be contrary to law, and has previously provided the Commissioner a discretion to exclude inventions the use of which would be contrary to law or morality.<sup>119</sup> Under the manner of manufacture test, inventions may be excluded for being generally inconvenient.

Providing an option to exclude inventions that are contrary to public policy or morality removes an incentive to innovate in areas deemed socially undesirable. The practical effect would be to prevent patents being granted for inventions that the public would find abhorrent.

Morality could be assessed against the standards of a reasonable person. There is a substantial body of case law providing well-established interpretations on who is a reasonable person.<sup>120</sup>

There are two situations where ethical objections to patenting tend to arise. The first is where the invention is unethical or immoral. In this situation, the objection is that patenting condones the invention. The second is where the invention is particularly

beneficial. In this situation, the objection is that patenting restricts the availability of the invention.<sup>121</sup>

In our view, any exclusion for social reasons would apply only in the former situation. Article 27(2) of the TRIPS Agreement allows exclusion from patentability only where the prevention of the commercial exploitation of an invention is necessary to protect *ordre public* or morality – that is, only where the *use* of the invention is objectionable. It is likely that very few inventions would fail such a general public policy or morality test.

The EPC includes a contrary to *ordre public* or morality exclusion. Under European Patent Office examination guidelines, this excludes:

... inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour. Obvious examples of subject matter which should be excluded ... are letter-bombs and anti-personnel mines. In general 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 the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.<sup>122</sup>

In the case of biotechnological inventions, the EPC rules provide that the following inventions are not patentable as they are contrary to *ordre public* or morality<sup>123</sup>:

- (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.

Australia would be free to develop its own guidelines or regulations on the types of subject matters to be excluded under such a provision.

The current exclusion allows the Commissioner of Patents to refuse to accept an application or to grant a patent if the use of the invention would be contrary to law. This mechanism is only available prior to grant of a patent, although it could be argued that a court could revoke a patent on the ground that such an invention would not fall within section 6 of the *Statute of Monopolies*. One mechanism to implement a general filter would be to amend section 50 to allow the Commissioner to refuse to accept an application or to grant a patent on inventions the use of which would be contrary to *ordre public* or morality, or would be generally inconvenient.

Another possibility is to state that such inventions are not patentable inventions. In this case, courts could also assess whether the use of the invention was contrary to *ordre public* or morality or was generally inconvenient. We note that the Australia-US Free Trade Agreement provides that a patent may only be revoked on grounds that would have justified a refusal to grant the patent. Thus, it is not an option to have the social filter applied by a court only.

## Other issues

### Inventiveness

We have already discussed the confusion resulting from the definition of invention and dual reference to manner of manufacture in the Patents Act. We propose the option of amending the legislation to ensure that decision makers deal with such considerations under the specific provision that an invention involves inventive step rather than as a separate threshold requirement for inventiveness.

There may be a small risk that this would increase the evidentiary burden on a party seeking to have a patent revoked, given the constraints on inventive step set out in section 7 of the legislation. However, the cost of the current uncertainty is likely to be greater. We note that the High Court expressed difficulty with the proposition that something could have an inventive step despite not having the necessary quality of inventiveness according to traditional principles.<sup>124</sup>

We also note that IP Australia is currently considering ‘raising the bar’ for inventive step.<sup>125</sup> The IP Australia proposal includes a test that allows decision makers to consider whether it was ‘obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success’. The US Supreme Court has recently reinstated a similar test in that country. A submission to the Senate Gene Patent Inquiry by several US Law Professors has suggested that these developments in the US law are likely to call the validity of many patents for gene sequences into question, now that the methods of DNA isolation are conventional.<sup>126</sup>

### Usefulness

The ALRC recommended that the Commonwealth should amend the *Patents Act 1990* to provide that an invention will satisfy the requirement of ‘usefulness’ only if the patent application discloses a specific, substantial and credible use. The ALRC also recommended that the usefulness of an invention should be a ground considered during examination of a patent application.<sup>127</sup>

As the ALRC noted, the United States requires a patent applicant to demonstrate a utility for an invention that is ‘specific, substantial and credible’. Australia’s trade agreement with the United States (the AUSFTA) states:

17.9.13 Each Party shall provide that a claimed invention is useful if it has a specific, substantial, and credible utility.

The New Zealand Patents Bill, which received its first reading in New Zealand Parliament on 5 May 2009, provides that an invention is useful if it has a specific, substantial and credible utility.<sup>128</sup>

The UK Intellectual Property Office and the EPO have also applied a requirement for ‘specific, substantial and credible utility’ in the past. More recently, both the UK Intellectual Property Office and the EPO have moved away from this test. Recent EPO case law has considered whether the industrial application of an invention is plausible and has a sound and concrete technical basis.<sup>129</sup>

We have proposed a specific option to implement the ALRC recommendations on usefulness. There is currently considerable overlap between the manner of manufacture test and the test of usefulness. Patent examiners cannot comment on the usefulness of an invention under paragraph 18(1) (c) of the Patents Act. However, examiners do have regard to the use to which an invention is put under the requirement that an invention be a manner of manufacture.<sup>130</sup> The ALRC recommendations would resolve some of the uncertainty that results from this overlap. We note that IP Australia is also proposing to implement these recommendations.

### Advisory panel

An argument made against including a social filter in the patents legislation was that examiners are ill-equipped to decide on social or ethical issues, or that these are matters that should not be decided administratively. The ALRC discussed a possible ethical advisory body, but dismissed the idea because it would add to the cost and complexity to the system.<sup>131</sup> A number of submissions thought that this suggestion was worth revisiting.

There are several models in other countries of advisory bodies that provide advice on social issues relating to intellectual property. These broadly fall into two categories:

1. Bodies that advise broadly on social or ethical issues related to science or technology, including issues arising from patents. An example is the *European Group on Ethics in Science and New Technologies*.

The European Group on Ethics in Science and New Technologies reports on both specific IP matters, such as ethical aspects of stem cell patents, and on IP issues arising in reports on particular technologies that are not specifically focused on IP.

2. Bodies that provide advice to IP offices on specific applications for a patent or trade mark. Two examples are the Norwegian *Ethics Committee in Patent Cases* and the New Zealand *Māori Trade Marks Advisory Committee*.

In Norway, patent applications being examined or under opposition, or under court proceedings, can be referred to the Ethics Committee in Patent Cases for advice on whether the invention is contrary to *ordre public* or morality.<sup>132</sup> The Norwegian Ethics Committee has been in operation for five years, but only one application has been referred to the Committee in that time. The application related to an Atlantic salmon that had been genetically modified to accelerate growth. Despite advice from the committee to refuse the application due to presumed sufferings of the animal and environmental problems, the Norwegian Industrial Property Office granted a patent for the invention.<sup>133</sup>

In New Zealand, a trade mark that contains Māori text or imagery is provided to the Māori Trade Marks Advisory Committee. The committee provides non-binding advice on whether the trade mark would cause offence to Māoris.<sup>134</sup> The New Zealand Patents Bill, which was introduced into Parliament recently, has provision for a similar body to advise in respect of inventions. The Bill has provision for the NZ Commissioner of Patents to seek advice from a Māori Advisory Committee or any other person that the Commissioner considers

appropriate for the purpose of making a decision as to whether an invention is contrary to public order or morality.<sup>135</sup>

In Australia, ACIP provides the Government with advice on the role of intellectual property and its contribution to the development of Australian industry. For example, we have previously advised the Government on patenting of business systems, the exclusion of plant and animal subject matter from innovation patents, and on patents and experimental use. However, ACIP does not provide advice on legal, technical, social or ethical issues in relation to specific patent applications.

There are examples outside of intellectual property of regulators obtaining advice. Under the *Gene Technology Act 2000*, the Gene Technology Regulator is required under the Act to seek advice from the Gene Technology Technical Advisory Committee (GTTAC) on all applications for dealings involving intentional release of Genetically Modified Organisms into the environment.<sup>136</sup> GTTAC provide scientific advice on risk assessment and risk management.

As discussed in our issues paper, patent applications received by IP Australia are reviewed by appropriately classified staff to see whether a prohibition order may be necessary. Advice is then sought from the Department of Defence, as needed. Therefore, IP Australia already has mechanisms in place for seeking advice on subject matters relating to national security. There may be scope for a similarly cost-effective mechanism for IP Australia to obtain advice on social or ethical issues relating to a patent application.

An advisory panel may be particularly valuable if a general social exclusion was introduced. Arguments advanced against having such a panel relate to difficulties of implementation and the potential for additional costs and delays to the processing of patent applications. There are also concerns about the composition of a panel and the possibility that inconsistent positions may be taken by differently constituted panels.

The ALRC considered that any determination about the possible social and ethical implications of a particular invention is likely to be contested, and thus new review or appeal mechanisms may be needed. The ALRC felt that the introduction of some new ethics advisory body would have uncertain consequences for the efficiency of the patent system.<sup>137</sup>

We have not, at this stage, given detailed consideration to a preferred implementation model for such a panel. We note that both the Norwegian and New Zealand models provide for an external body to provide non-binding advice. Both models also regulate timeframes for providing the advice. In the case of the Norwegian model, documents become part of the public record from the time the patent application is published.

We would like to obtain further public input on this issue. We have included an option to establish an advisory panel to advise the Commissioner of Patents on the application of social filters to the patentability of inventions (such as a contrary to *ordre public* or morality filter, or a ‘generally inconvenient’ exclusion).

## Appendix 1 Terms of reference

In its broad ranging 2004 review of gene patenting and human health *Report 99 Genes and Ingenuity: Gene Patenting and Human Health*, the Australian Law Reform Commission (ALRC) considered that the manner of manufacture test was obscure and difficult to understand. The ALRC also found that it was unclear whether the test had the ability to consider social and ethical issues according to the traditional principle that an invention not be “generally inconvenient”. The ALRC believed that an independent review should be undertaken of the appropriateness and adequacy of the manner of manufacture test.

Such a review should focus particularly on the generally inconvenient requirement, including the extent to which this requirement has been invoked by patent examiners and in challenges to patent rights, and whether there are alternative and preferable ways to formulate a threshold requirement for patentable subject matter. Any reform of the manner of manufacture test should take into account the recommendations of this Inquiry, including those relating to the requirement of usefulness (see Recommendations 6-3 and 6-4).

The ALRC made the following recommendation:

Recommendation 6-2. The responsible Minister should initiate an independent review of the appropriateness and adequacy of the ‘manner of manufacture’ test as the threshold requirement for patentable subject matter under Australian law, with a particular focus on the requirement that an invention must not be ‘generally inconvenient’.

Recommendations 6-3 and 6-4 relate to the criterion of ‘usefulness’. Currently this is a test of whether an invention fulfils its promise. IP Australia does not specifically assess usefulness. However, patent examiners assess the concept of utility as part of the manner of manufacture test. The ALRC recommended that IP Australia examine and report on the usefulness of an invention as a separate requirement, and that such use must be specific, substantial and credible.

Due to the high degree of overlap between 'manner of manufacture' and other criteria for patentability, in order to be effective the scope of the review was broadened to encompass 'patentable subject matter'.

The Minister for Innovation, Industry, Science and Research requested ACIP to:

inquire, report and make recommendations to the Australian Government on patentable subject matter. The review will include the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law, and the historical requirement that an invention must not be 'generally inconvenient'.

## Appendix 2 The review process

In May 2008, the Advisory Council on Intellectual Property (ACIP) advertised its review of patentable subject matter in Australia's major state and national newspapers. ACIP then published an Issues Paper in July 2008, seeking written comments from the public on a number of issues. ACIP received thirty-seven submissions, as set out in Appendix 3. Copies of the Issues Paper and the submissions received are published on the ACIP website ([www.acip.gov.au](http://www.acip.gov.au)).

ACIP held public forums in Canberra, Melbourne, Sydney and Brisbane in March 2009 to discuss the issues. Seventy-four people attended these forums (Appendix 4). ACIP also held a public reception in Adelaide on 23 June 2009, presenting the issues and potential options to approximately 40 stakeholders.

ACIP considered the submissions received and the matters discussed in the public forums. It believes the most constructive way forward is to release this options paper for further comment. This options paper considers the responses received and discusses a number of possible options for action.

In putting forward possible options, ACIP has tried to capture both the perceived positive and negative effects of the options based on the available evidence. Following consideration of these effects, ACIP has decided on several options as those most likely to satisfy the terms of reference of this inquiry.

Public comments are invited on the options proposed by ACIP in this paper. After consideration of any comments and possible consultations regarding this options paper, ACIP will submit a final report to Government.

## Appendix 3 List of submissions

1. Mike Lloyd
2. Chris O'Sullivan
3. Dr Luigi Palombi
4. Michael Kraemer
5. Humanist Society of Victoria
6. NZ Institute of Patent Attorneys
7. Dr Ian Turnbull
8. Dr Kerry Hubrick
9. Dr Vivian Santer
10. AMPICTA
11. Dianne Nicol & Jane Nielson on behalf of the Centre for Law and Genetics, University of Tasmania
12. Justine Pila
13. Microsoft Corporation
14. Australian Association of Pathology Practices (AAPP)
15. Doug Calhoun
16. The Institute of Patent and Trade Mark Attorneys of Australia (IPTA)
17. Yannick Chaumier
18. Davies Collison Cave
19. FB Rice & Co
20. Royal College of Pathologists of Australia (RCPA)
21. David Brennan
22. Anton Hughes
23. ResMed
24. Human Genetics Society of Australasia
25. Anna George
26. Hazel Moir
27. Intellectual Property Research Institute of Australia (IPRIA)
28. Cancer Council of Australia
29. Australian Seed Federation (ASF)
30. F P Old
31. FICPI Australia
32. Matthew Rimmer
33. Law Council of Australia
34. IP Australia
35. Department of Innovation, Industry, Science & Research
36. Medicines Australia
37. Australian National University

## Appendix 4 Public forums

ACIP held public forums in Canberra, Melbourne, Sydney and Brisbane in March 2009 to discuss the issues of whether and, if so, how the patent system should exclude subject matter from patent protection, for economic or other reasons. Seventy-four people attended these forums. The attendees represented a range of interests, including State and Federal Government, the legal and patent attorney professions, inventors, patent owners, research and commercialisation organisations, academics, health-care and medical associations, and ethical organisations.

### Canberra 2 March 2009

Fatima Beattie	IP Australia
Belinda Brown	Department of Environment, Heritage & Water
Karlie Brown	Department of Health and Aging
Miranda Bruyn	NHMRC
Geoff Burton	Genetic Resources & Management, Jean Shannon & Associates
Michael Curtotti	University Legal Office, ANU
Anna George	Murdoch University
Will Goldsby	Australian Seed Federation
Kristina Huyn	IP Australia
Hazel Moir	ANU
Dianne Nicol	University of Tasmania
Leo O’Keeffe	IP Australia
Luigi Palombi	ANU
Matthew Rimmer	ANU
Adrian White	Department of Health and Aging

### Melbourne 3 March 2009

Michael Caine	IPTA
Jason Coonan	Melbourne Ventures Pty Ltd
Karen Hallenstein	Telstra
Kerry Hubick	
Peter Huntsman	FICPI Australia
Ivan Lakatos	BHP Billiton
Matthew Lucas	Davies Collison Cave
Mathew O’Keefe	Foster’s Group Limited
Ian Pascarl	Law Council of Australia
Bob Phelps	Gene Ethics
Vivian Santer	Registered Patent Attorney, Consultant
Matthew Swinn	Corrs Chambers Westgarth
David Thornburn	Human Genetics Society of Australasia
Adrian Trioli	Callinans Patent & Trade Mark Attorneys
Stuart Wallace	Australian Institute for Commercialisation
David Webber	Davies Collison Cave
Beth Webster	IPRIA
Tim Wilson	Institute of Public Affairs

**Sydney 9 March 2009**

Yannick Chaumier	Schneider Electrics
Paul Green	ResMed
Philip Griffith	Law Council of Australia
Paul Grogan	Cancer Council Australia
Siew-Lee Hew	FB Rice & Co
Brett Kensett-Smith	AMPICTA / Ventracor
Joseph Kwok	Hodgekinson McInnes Patents
Chris O’Sullivan	FB Rice & Co
Fraser Old	Fraser Old & Sohn
Nadia Pece-Barbara	FB Rice & Co
Natalie Stoianoff	Faculty of Law, University of Technology, Sydney
Alan Tomlinson	Good Questions Research Pty Ltd
Tamsin Waterhouse	Royal College of Pathologists of Australasia
Paul Whenman	FB Rice & Co

**Brisbane 10 March 2009**

Michael Angliss	UniQuest
Victor Argæet	Davies Collison Cave
Sue Coke	Dept of Tourism, Regional Development & Industry
Alan Collier	Business, Management & Legal Consultant
Paul Davies	Fisher Adams Kelly
Anne Fitzgerald	Faculty of Law, Queensland University of Technology
Brian Fitzgerald	Faculty of Law, Queensland University of Technology
Martin Gellender	Environmental Protection Agency
Julio A Gomez	Inventors Association of Australia (Qld) Inc
Carolina Gomez	School of Medicine, University of Queensland
Josh Henderson	DLA Phillips Fox
Madhu Jogia	Patent & Trade Marks Attorney
Ben McEniery	Faculty of Law, Queensland University of Technology
Kathryn Morris	Davies Collison Cave
Ken Philp	Bennett & Philp
Fred Potgeiter	DLA Phillips Fox
Lillian Rizio	
Neil Sadler	DLA Phillips Fox
Mark Smith	Pizzeys Patent and Trade Mark Attorneys
Alistair Smith	Davies Collison Cave
Anna Stines	Pizzeys Patent and Trade Mark Attorneys
John Swinson	Mallesons Stephen Jacques
Miriam Taylor	School of Medicine, University of Queensland
David Tong	Inventors Association of Australia (Qld) Inc
Nicole Turner	Dept of Tourism, Regional Development & Industry
Michael West	Alchemia Ltd

## Abbreviations

ACIP	Advisory Council on Intellectual Property
ALRC	Australian Law Reform Commission
AMPICTA	Australian Manufacturers' Patents, Industrial Designs, Copyright and Trade Marks Association
ANU	Australian National University
ASF	Australian Seed Federation
AUSFTA	Australia-United States Free Trade Agreement
BIE	Bureau of Industry Economics
EPC	European Patent Convention
EPO	European Patent Office
FICPI	Australian Federation of Intellectual Property Attorneys
GTTAC	Gene Technology Technical Advisory Committee
IPCRC	Intellectual Property and Competition Review Committee
IPRIA	Intellectual Property Research Institute of Australia
IPTA	Institute of Patent and Trade Mark Attorneys of Australia
NHMRC	National Health and Medical Research Council
NZ	New Zealand
OECD	Organisation for Economic Co-operation and Development
PBR	Plant Breeder's Rights
PCT	Patent Cooperation Treaty
SABIP	Strategic Advisory Board on Intellectual Property Policy (UK)
TRIPS	World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property
UK	United Kingdom
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

## Notes

### ***Format of this paper***

<sup>1</sup> Advisory Council on Intellectual Property (ACIP), *Patentable Subject Matter, Issues Paper*, July 2008.

### ***Promoting innovation to benefit society***

<sup>2</sup> World Intellectual Property Organization (WIPO), *Why are patents necessary?* [http://www.wipo.int/patentscope/en/patents\\_faq.html#patent](http://www.wipo.int/patentscope/en/patents_faq.html#patent) (accessed 9 September 2009).

<sup>3</sup> *National Research Development Corporation v Commissioner of Patents* [1959] HCA 67 (“NRDC”). The High Court also expressed a need for some material advantage in the sense that the invention belongs to the useful arts as distinct from the fine arts – its value must be in the field of economic endeavour; and a requirement of utility in practical affairs.

<sup>4</sup> As of May 2009, there were almost 95,000 standard patents in force in Australia. An Australian resident entity was the first-named owner for 10% of these patents. Source: IP Australia.

<sup>5</sup> *Venturous Australia: Building Strength in Innovation*, Cutler & Company, 2008, page 85.

<sup>6</sup> Intellectual Property and Competition Review Committee, *Review of intellectual property legislation under the Competition Principles Agreement*, Final Report, September 2000 (“IPCRC Final Report”) page 139.

<sup>7</sup> *Powering Ideas, An Innovation Agenda for the 21<sup>st</sup> Century*, Commonwealth of Australia, 2009.

<sup>8</sup> ACIP, *Report on a Review of the Patenting of Business Systems*, September 2004.

<sup>9</sup> Details of the Senate Community Affairs inquiry into gene patents, including its full terms of reference, are available at [http://www.aph.gov.au/senate/committee/clac\\_ctte/gene\\_patents/index.htm](http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents/index.htm) (accessed 9 September 2009).

<sup>10</sup> The IPCRC included a draft recommendation in its Interim Report that the Patents Act should have a statement that more clearly sets out its objectives. See IPCRC *Interim Report* April 2000, page 54. The IPCRC’s Final Report omitted the recommendation. It may be desirable for an express statement of objectives to be included in the legislation.

<sup>11</sup> TRIPS Agreement Article 7.

<sup>12</sup> A standard patent has a maximum term of 20 years, extendable by up to 5 years for certain pharmaceutical products. Innovation patents have a maximum term of 8 years. While the inventor obtains an exclusive right to exploit their invention, the government retains the right to use or acquire the invention or to grant licences to others to use the invention in certain circumstances. There is no guarantee that a patent is valid, and third parties may challenge the patent at any time.

<sup>13</sup> Schedule 1, *Patents Act 1990*.

<sup>14</sup> *National Research Development Corporation v The Commissioner of Patents* (1959) 102 CLR at 252.

<sup>15</sup> The requirement that an invention be for a manner of manufacture applies to both standard patents and innovation patents. Unless specifically stated otherwise, the discussion throughout this paper applies to both standard patents and innovation patents.

<sup>16</sup> Innovation patents must be novel and have an innovative step.

<sup>17</sup> IPCRC Final Report, page 135.

### ***Retain, clarify, replace, delete or enhance?***

<sup>18</sup> Australian Law Reform Commission (ALRC), Report 99, *Genes and Ingenuity: Gene Patenting and Human Health*, June 2004, page 131.

<sup>19</sup> ALRC, *Genes and Ingenuity*, pages 120-132.

<sup>20</sup> IPCRC Final Report, pages 146-154.

<sup>21</sup> IPCRC Final Report, page 148.

<sup>22</sup> Although explicit reference to “inventions in all fields of technology” was first included in the revised European Patent Convention (EPC 2000), this amendment left the law substantially unchanged.

<sup>23</sup> IP Australia, *Getting the Balance Right: Towards a Stronger and More Efficient IP Rights System*, Consultation Paper, March 2009.

### ***Patentable subject matter – the issues in detail***

<sup>24</sup> Section 6 of the *Statute of Monopolies* 1623 (21 Jac. 1, c.3) (modern English version).

<sup>25</sup> A footnote to Article 27 of the TRIPS Agreement states that ‘capable of industrial application’ is synonymous with ‘useful’.

<sup>26</sup> Article 17.9 of the AUSFTA.

<sup>27</sup> Submissions by Calhoun, Nicol & Nielson, Hughes.

<sup>28</sup> The term *ordre public* is used in the TRIPS Agreement as the concept is derived from French law and not easily translated into English. It encompasses the protection of public security, the physical integrity of individuals as part of society and the protection of the environment. However, there is no generally accepted definition. See, for example, Jill McKeogh and Andrew Stewart, *Intellectual Property in Australia*, LexisNexisButterworths, 3<sup>rd</sup> Edition, 2004, at page 341.

<sup>29</sup> Article 27.2 of the TRIPS Agreement. See also Daniel Gervais, *The TRIPS Agreement. Drafting History and Analysis*, third edition, Sweet & Maxwell, 2008; and submission by Doug Calhoun.

<sup>30</sup> Submissions by Calhoun, Davies Collison Cave, IPTA, FB Rice, FICPI.

<sup>31</sup> Submission by Nicol & Nielson.

<sup>32</sup> Patents (World Trade Organization Amendments) Bill 1994, Explanatory Memorandum.

<sup>33</sup> US Free Trade Agreement Implementation Bill 2004, Explanatory Memorandum.

<sup>34</sup> The New Zealand Commissioner could previously refuse an application where the invention was frivolous in that the invention was contrary to a law of nature, where the use of the invention would be contrary to law or morality, or where the invention was a food or medicine produced by mere admixture. See Kenneth B Polewell, Commissioner, New Zealand Patent Office, *The TRIPS AGREEMENT: Implementation and Enforcement*, APEC Industrial Property Rights Symposium, Tokyo August 1996.

<sup>35</sup> Mark Jennings, *Practical Treaty Making: The Relationship Between Treaties and Domestic Law*, Department of Foreign Affairs and Trade Workshop, 6 November 2003.

<sup>36</sup> Standing Committee on the Law of Patents (SCP), *Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights*, WIPO, SCP/13/3, 4 February 2009.

<sup>37</sup> The members of the Eurasian Patent Organisation are Turkmenistan, Belarus, Tajikistan, Russian Federation, Kazakhstan, Azerbaijan, Kyrgyz Republic, Moldova, and Armenia.

<sup>38</sup> *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 and *Pfizer Inc v The Commissioner of Patents* [2005] NZLR 362

<sup>39</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383 and *Bristol-Myers Squibb Company v FH Faulding Co Ltd* [2000] FCA 316.

<sup>40</sup> Canadian Intellectual Property Office, *Utility and Subject Matter*, Manual of Patent Office Practice Chapter 12, revised February 2005. See also the consultation draft of revised Chapter 12 dated 4 February 2009.

<sup>41</sup> Case G3/08: Referral under Art 112(1) (b) EPC by president of the EPO (Patentability of programs for computers) to the Enlarged Board of Appeal. <http://www.epo.org/patents/appeals/eba-decisions/referrals/pending.html> (accessed 9 September 2009).

<sup>42</sup> See SCP, *Report on the International Patent System*, WIPO, SCP/12/3 Rev.2, 3 February 2009, Annex II, pages 65-96 for a list of exclusions from patentable subject matter by country.

<sup>43</sup> For example, see submissions by Pila, IPRIA, Medicines Australia, ANU, and ResMed.

<sup>44</sup> In recent years, US courts have reinstated an ‘obvious to try’ consideration in obviousness (*KSR v Teleflex, In re Kubin*) and have restricted inventions for business methods (*In re Bilski, In re Comiskey*) and signal claims (*In re Nuijten*).

<sup>45</sup> New South Wales introduced the first Patent Act in Australia in 1852 (coming into force on 10th January 1854). Prior to the Colonies enacting their own legislation in the mid 19th Century and forming their own Patent Offices, inventors applied to England for patent registration and protection. See *Patents Registered in Australia - from the mid 1800's to the present day*, State Library of Victoria <http://guides.slv.vic.gov.au/patents> (accessed 9 September 2009).

<sup>46</sup> See SCP, *Report on the International Patent System*, pages 8-12.

<sup>47</sup> Submission by Dianne Nicol and Jane Nielsen on behalf of the Centre for Law and Genetics.

<sup>48</sup> For example, sections 118, 119 and 119A of the *Patents Act* exempt certain uses of an invention from infringement. Chapter 12 of the Act provides for compulsory licensing or revocation of patents where the patent owner has not met the reasonable requirements of the public or where the patent has been used in a way that contravenes competition law. Chapter 17 of the Act allows for Crown use or acquisition of a patent.

<sup>49</sup> See the Secretary’s Advisory Committee on Genetics, Human Health and Society, *Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (the SACGHS Report) at page 63:

The NRC, Nuffield, OECD, and ALRC reports share an analytical framework, as does most of the literature on the patenting and licensing of genetic diagnostics. The reports accept the value of the patent system and cite its positive impacts on innovation generally. None of the reports make a compelling case that patenting was either necessary or sufficient to develop a particular genetic test. ... In these areas, a track record of more extensive litigation suggests that the patent system has been used to protect inventions, but it is not clear that patents are needed in order for innovation to move forward.

<sup>50</sup> Submissions by Moir and Palombi.

<sup>51</sup> Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, 29 August 1984.

<sup>52</sup> T.D. Mandeville, D.M. Lamberton, and E.J. Bishop, *Economic Effects of the Australian Patent System*, AGPS, 1982.

<sup>53</sup> Bureau of Industry Economics, *The Economics of Patents*, Occasional Paper 18, AGPS 1994.

<sup>54</sup> IPCRC Final Report.

<sup>55</sup> ACIP, *Report on a Review of the Patenting of Business Systems*.

<sup>56</sup> *Grant v Commissioner of Patents* [2006] FCAFC 120 (18 July 2006).

<sup>57</sup> *Venturous Australia*, page 85.

<sup>58</sup> James Bessen and Michael Meurer, *Patent Failure. How Judges, Bureaucrats, and Lawyers Put Innovators at Risk*, Princeton University Press, March 2008.

<sup>59</sup> On 30 October 2008, the US Court of Appeals for the Federal Circuit handed down its decision in *In re Bilski*, a ruling that limits the patentability of software and business methods in the US. Bilski’s patent application was for a method of hedging risk in the field of commodities trading. The Court ruled that “[a] claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” *In re Bilski* 2007-1130 USFC 30 October 2008. The US Supreme Court has decided to review this decision.

<sup>60</sup> Steven Seidenberg, *Bilski ruling moves US closer, narrower to global patenting norms*, Intellectual Property Watch, Vol 5 No 11, November 2008, pp. 7-8; and Amanda McBratney, *Bilski restricts*

*business method, software, diagnostics patenting*, Intellectual Property Focus, McCullough Robertson Lawyers, 21 November 2008.

<sup>61</sup> Elizabeth Webster and Paul H Jensen, *Do Patents Matter for Commercialisation?*, IPRIA Working Paper No. 03/09, March 2009; and Paul H Jensen, Russell Thomson and Jongsay Yong, *Estimating the Patent Premium from the Australian Inventor Survey*, IPRIA Working Paper No. 11/09, May 2009.

<sup>62</sup> Bronwyn H Hall, *The Use and Value of Patent Rights*, Prepared for the UK IP Ministerial Forum on the Economic Value of Intellectual property, 10 June 2009. For additional papers and further discussion from the forum, see <http://www.sabip.org.uk/home/forum.htm> (accessed 9 September 2009).

<sup>63</sup> According to IPRIA, dead-weight losses are the benefits foregone by people who cannot, or are not willing, to buy the innovative output at the patent-induced monopoly price but are prepared to pay at the cost-of-production price.

<sup>64</sup> Submission by Nicol & Nielsen; and 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).

<sup>65</sup> The *Patents Regulations 1991* state that a complete specification must not contain or consist of scandalous matter (Item 14 of Schedule 3). Under regulation 3.2A, the Commissioner may direct an applicant to do anything necessary to ensure the specification complies with these requirements. The application will lapse if the patent applicant does not comply with such a direction. Note, however, that regulation 3.2A does not apply to applications filed under the Patent Cooperation Treaty (PCT). For applications filed under the PCT, Article 21 of the PCT allows the International Bureau to omit any expressions or drawings that are contrary to morality or public order from its publications.

<sup>66</sup> These views were predominately expressed in submissions from the patent attorney and legal professions. For example, see submissions by Palombi, Santer, IPTA, Davies Collison Cave, FB Rice & Co, Brennan, FICPI Australia, and Law Council of Australia.

<sup>67</sup> For example, see submissions Kraemer, Hubick, Pila, AMPICTA, Nicol & Nielsen, AAPP, Chaumier, RCPA, Hughes, Moir, IPRIA, Cancer Council Australia, IP Australia, and ANU.

<sup>68</sup> Submissions by Palombi, Turnbull, Humanist Society of Victoria, AAPP, RCPA, Human Genetics Society of Australasia, Moir, Cancer Council Australia.

<sup>69</sup> IPCRC Final Report, pages 151-153.

<sup>70</sup> *NRDC*

<sup>71</sup> ALRC, *Genes and Ingenuity*, page 130.

<sup>72</sup> Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005.

<sup>73</sup> Submission by Nicol and Nielsen.

<sup>74</sup> Submission by Department of Innovation, Industry, Science and Research and IP Australia to the Senate Community Affairs Committee Inquiry into Gene Patents, paragraph 4.28.

<sup>75</sup> [http://www.aph.gov.au/senate/committee/clac\\_ctte/gene\\_patents/submissions/sublist.htm](http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents/submissions/sublist.htm) (accessed 25 August 2009).

<sup>76</sup> The SACGHS Report acknowledged the ALRC report as having devoted more attention to gene patents than any other government group. The SACGHS public consultation draft report is available at [http://oba.od.nih.gov/SACGHS/sacghs\\_documents.html#GHSDOC\\_011](http://oba.od.nih.gov/SACGHS/sacghs_documents.html#GHSDOC_011) (accessed 9 September 2009).

<sup>77</sup> A copy of the complaint is available at [http://www.aclu.org/images/asset\\_upload\\_file939\\_39568.pdf](http://www.aclu.org/images/asset_upload_file939_39568.pdf) (accessed 9 September 2009).

<sup>78</sup> The phrases ‘merely a new use of an old product’ and ‘analogous use’ mean that the subject matter is for the use of known materials in the manufacture of known products for the purpose of which their known properties make those materials suitable. See *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 252.

<sup>79</sup> *Philips v Mirabella* [1995] HCA 15; (1995) 183 CLR 655.

<sup>80</sup> Richard H Stern, *Being Within the Useful Arts as a further Constitutional Requirement for US Patent-Eligibility*, European Intellectual Property Review, Vol. 31(1) 2009. See also footnote 33 where Stern states:

When the triviality of implementation is neither conceded nor facial, the invention may nonetheless be obvious, but it cannot be determined summarily at the outset on grounds of patent-eligibility. Such a determination would instead require a detailed analysis of the scope of the prior art and the difference between it and the implementing devices.

There has been some judicial criticism in the US of this ‘commingling of distinct statutory provisions which are conceptually unrelated’. See *In re Bergy* 596 F.2d 952 (US Court of Customs and Patent Appeals 1979).

<sup>81</sup> *Biogen Inc v Medeva PLC* [1996] UKHL 18 at [42] – [46].

<sup>82</sup> Submissions by IPTA and FICPI. See also the submission by Brennan: ‘Preserving this limited merit role seems neither controversial nor undesirable’.

<sup>83</sup> *Lockwood Security Products v Doric Products* (2007) 235 ALR 202.

<sup>84</sup> See submissions by O’Sullivan, Hubick, Nicol & Nielsen, Davies Collison Cave, FB Rice & Co, Hughes, ResMed. See also Lawson, Charles, *Evolution of “inventive step”-like elements in Australian patent laws*, Australian Intellectual Property Journal Vol. 18 No. 3, August 2007, pp 130-148.

<sup>85</sup> *Dura-Post (Aust) Pty Ltd v Delnorth Pty Ltd* [2009] FCAFC 81 (30 June 2009) and *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2009] FCA 595 (3 June 2009).

<sup>86</sup> Jeremy Blum, *Why “invention” should be removed from New Zealand patent law*, Intellectual Property Forum No. 64, March 2006, page 31.

<sup>87</sup> Common general knowledge is referred to in section 7 of the *Patents Act 1990* but is not defined in the Act. The meaning has been discussed in numerous court cases. For example, see *ICI Chemicals & Polymers Ltd V Lubrizol Corp* 45 IPR 577:

The common general knowledge is the technical background to the hypothetical skilled worker in the relevant art. It is not limited to material which might be memorised and retained at the front of the skilled workers mind but also includes material in the field in which he is working which he knows exists and to which he would refer as a matter of course.

<sup>88</sup> Submission by Medicines Australia, and article 17.9.1 of the Australia-United States Free Trade Agreement.

<sup>89</sup> Australian Patent Office Manual of Practice and Procedure, part 2.9.2.17.

<sup>90</sup> See *Interlego AG v Toltoys* [1973] HCA 1; *Advanced Building Systems v Ramset* [1998] HCA 19; *Welcome Real-Time SA v Catuity* [2001] FCA 445 (17 May 2001) at [131-132]; and submissions by Brennan and IPRIA.

<sup>91</sup> *State of Victoria v Pacific Technologies (Australia) Pty Ltd (No 2)* [2009] FCA 737 (10 June 2009).

<sup>92</sup> *Rolls Royce Ltd’s Application* [1963] RPC 231.

<sup>93</sup> *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104 (28 June 2004)

<sup>94</sup> Submissions by O’Sullivan, Palombi, Santer, IPTA, FB Rice & Co, and FICPI Australia.

<sup>95</sup> Submissions by Nicol & Nielson, Chaumier, ResMed, Moir, IPRIA, Old, IP Australia.

<sup>96</sup> Submissions by IPTA, FICPI, NZ Institute of Patent Attorneys, Law Council, Santer, FB Rice, DCC, Old (noting that if there is any change, it should be to delete the concept of ‘generally inconvenient’), NZIPA, Brennan, O’Sullivan (though notes ‘manner or manufacture’ is not clear to lay persons), Palombi (noting problems with certain Federal Court decisions), Microsoft.

<sup>97</sup> *Grant v Commissioner of Patents*

<sup>98</sup> The terms ‘useful arts’ and ‘fine arts’ are somewhat antiquated themselves but are still commonly referred to in patent law to distinguish inventions from discoveries, abstract ideas, aesthetic creations,

schemes, rules and plans. Hazel Moir submitted these terms provide little guidance because they ignore the ‘liberal professions’ like accounting, medicine and law.

<sup>99</sup> The Macquarie Dictionary Online © 2009 Macquarie Dictionary Publishers Pty Ltd.

<sup>100</sup> Submissions by Chaumier, Moir, IP Australia.

<sup>101</sup> See submissions by Lloyd, Kraemer,

<sup>102</sup> The High Court recently referred to this ‘general abhorrence of monopolies’ when discussing copyright in *Ice TV v Nine Network Australia* [2009] HCA 14 (22 April 2009) at [28].

<sup>103</sup> NZ Ministry of Economic Development, *Boundaries of the Patents Act 1953: Boundaries to Patentability, A Discussion Paper*, March 2002; and NZ Cabinet Paper, *Review of the Patents Act 1953 Stage 3: Part 1*, 6 August 2003. See

[http://www.med.govt.nz/templates/ContentTopicSummary\\_5876.aspx](http://www.med.govt.nz/templates/ContentTopicSummary_5876.aspx) (accessed 9 September 2009).

<sup>104</sup> *Biogen v Medeva*, [1997] RPC 1 at page 41. See also the opinion of Lord Mustill at page 31.

<sup>105</sup> TRIPS Agreement, Article 27

<sup>106</sup> The Lockhart review refers to the independent review in 2005 of *The Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* chaired by the Hon John Lockhart.

<sup>107</sup> Regarding copyright, see Ricketson’s *Law of Intellectual Property: Copyright, Design and Confidential Information* at 7.420

While the *Copyright Act 1905* (Cth) provided that copyright could not subsist in any "blasphemous, indecent, seditious or libellous work or matter", there was no similar provision in earlier imperial legislation or in the *Copyright Act 1911* (UK), and the same is true of the *Copyright Act 1968* (Cth). Accordingly, copyright now subsists in all original works that satisfy the necessary connecting factors under s 32 of the 1968 Act, without exception. There is no reference to any further ethical or moral criterion which must be fulfilled before protection is accorded. There is, however, a thread of authority, both before and after the 1911 Act, that equitable and/or legal relief may be denied in respect of works of this kind. While some of these decisions contain judicial assertions that copyright does not subsist in such works, it is probably more accurate to say that in these cases the courts have refused to enforce the copyright on the ground of public policy. As some of these decisions represent the values and views of a different age, their applicability remains an open question.

<sup>108</sup> ALRC, *Genes and Ingenuity*, pages 178 – 191.

<sup>109</sup> Discoveries are excluded from patentability primarily for economic reasons, as discussed by the IPCRC. However, social reasons for their exclusion are also often advanced. Several submissions raised ethical arguments against patenting naturally occurring substances.

<sup>110</sup> Submission by V Santer.

<sup>111</sup> ACIP, *Should plant and animal subject matter be excluded from protection by the innovation patent?*, November 2004.

<sup>112</sup> For details on the ACIP review of enforcement of plant breeders’ rights, see <http://www.acip.gov.au>.

<sup>113</sup> An amendment to UK law in 1919 allowed patents for substances produced by chemical processes or intended as food or medicine only if the claims to the substance were made dependent on their method of manufacture. The 1932 amendment to UK law made it clear that ‘mere admixtures resulting only in the aggregation of the known properties of the ingredients’ would not be deemed to be a method of manufacture under this provision. The mere admixture provision was added to Australian law in the *Patents Act 1952* without the earlier limitation to products in UK law. See Lord Marks and R.A. Wolstenholme, *The Patents and Designs Acts*, Sweet & Maxwell, London, 1933; *Patents and Designs Acts Final Report of the Departmental Committee*, London 1947 (Swan Committee Report), paragraphs 92-101; and the *Patents Act 1952*, section 155;

<sup>114</sup> Petty Patent 567,071, titled *Rose plant – cultivar Dolly Parton*. Claim 1 reads:

A new and distinct variety of Hybrid Tea rose plant named Dolly Parton, substantially as illustrated in the accompanying photograph and described, characterized particularly by (a) attractive very large fully double blossoms of orange-red colouration, (b) outstanding blossom fragrance, (c) excellent blossom form, (d) strong sturdy stems, (e) exceptional vigor which forms a well-branched broad and upright plant, and (f) above average disease resistance.

<sup>115</sup> The regulations to the Eurasian Patent Convention exclude inventions contrary to public order or morality but do not explicitly exclude diagnostic, therapeutic or surgical methods.

<sup>116</sup> SCP, *Report on the International Patent System*, Annex II, pages 65-96.

<sup>117</sup> ALRC, *Genes and Ingenuity*, pages 174 – 178 and 507 – 517.

<sup>118</sup> The United Kingdom has implemented this provision by excluding inventions the commercial exploitation of which would be contrary to public order or morality. UK *Patents Act 1977* section 1(3).

<sup>119</sup> *Patents Act 1903*, section 118.

<sup>120</sup> See the definition of ‘reasonable person’ in *Encyclopaedic Australian Legal Dictionary*, LexisNexis Australia, 9 September 2004:

The ordinary person; a person with the characteristics of an ordinary person in the defendant's position; a fictitious, imaginary, or hypothetical person of ordinary prudence, intelligence, and skill under the circumstances: *Heaven v Pender* (1883) 11 QBD 503 ; *King v Phillips* [1953] 1 All ER 617 ; [1953] 1 QB 429 . Formerly known as ‘reasonable man’.

<sup>121</sup> See ALRC, *Genes and Ingenuity*, page 190 and the submission by ResMed for further discussion of these two alternatives.

<sup>122</sup> *Guidelines for Examination in the European Patent Office*, Part C, Chapter IV, paragraph 3.1.

<sup>123</sup> *Implementing Regulations to the Convention on the Grant of European Patents*, Rule 28.

<sup>124</sup> *Philips v Mirabella* [1995] HCA 15 at [4].

<sup>125</sup> IP Australia, *Getting the Balance Right, Towards a Stronger and More Efficient IP Rights System*, Consultation Paper, March 2009.

<sup>126</sup> Supplementary submission to the Senate Gene Patent Inquiry by Professors Sarnoff, Kahn and Andrews; *KSR International Inc v Teleflex Corp* 127 S. Ct. 1727 (2007); and *In re Kubin* 2008-1184 (Fed. Cir. 3 April 2009). The protein in question in the *Kubin* case had already been identified and the prior art suggested that the protein plays a role in human immune response.

<sup>127</sup> ALRC, *Genes and Ingenuity*, recommendation 6-3.

<sup>128</sup> *Patents Bill*, New Zealand Government Bill 235-1, section 10.

<sup>129</sup> UK Intellectual Property Office, *Examination Guidelines for Patent Applications relating to Biotechnical Inventions in the Intellectual Property Office*, April 2009, paragraph 54.

<sup>130</sup> Paragraph 18(1) (c) of the Patents Act 1990 states that a patentable invention must be useful. Section 45 of the Act sets out the grounds for examination of a patent application. Paragraph 18(1) (c) is not included in these grounds for examination. See *Australian Patent Office Manual of Practice and Procedures*, Vol 2, paragraph 2.9.4.

<sup>131</sup> ALRC, *Genes and Ingenuity*, pages 185-189.

<sup>132</sup> The Norwegian Patents Act provides an exception to patentability for inventions contrary to *ordre public* or morality (section 1b). The Act also provides for an Ethics Committee in Patent Cases appointed by the King. The ethics committee may be consulted during examination (section 15a), opposition (section 25) or in legal proceedings or administrative review of grant (sections 52a and 52d). The Norwegian Patent Regulations set out the rules for the committee in chapter 15.

<sup>133</sup> Jostein Sandvik, Senior Legal Advisor, Norwegian Intellectual Property Office, *Patent ethics in Norway*, and Dag E. Helland, Chair, The Norwegian Committee on Ethics of Patenting, *Patenting and ethical questions: What are the problems?*, presentations given to the Wellcome Trust Workshop “Is there a Future for Patent Ethics Committees?”, Manchester, 13 May 2008, available at

<http://www.shef.ac.uk/law/sible/projects/wellcome/workshop.html> (accessed 9 September 2009). See also the website for the Norwegian Advisory Board on the Ethical Aspects of Patenting - <http://www.etikkom.no/In-English/Patent-Board/> (accessed 9 September 2009).

<sup>134</sup> The Māori Trade Marks Advisory Committee was established under section 177 of the New Zealand *Trade Marks Act 2002* to advise the NZ Commissioner of Trade Marks as to the likely offensiveness of trade marks containing Māori text and imagery. The committee comprises 5 appointed members. Trade marks which contain Māori text or imagery are provided to the committee, which meets every three months. The committee advises on whether the trade marks would cause offence to Māoris. The advice is not binding on the Commissioner. In the first year, the Committee assessed 333 trade marks and considered that 8 needed more information or were likely to be offensive.

See [http://www.med.govt.nz/templates/ContentTopicSummary\\_1290.aspx](http://www.med.govt.nz/templates/ContentTopicSummary_1290.aspx) (accessed 9 September 2009) and, *Brandscape*, AJ Park newsletter, 7 October 2005, [http://www.ajpark.com/newsletters/brandscape/BRANDSCAPE\\_OCT\\_05.htm](http://www.ajpark.com/newsletters/brandscape/BRANDSCAPE_OCT_05.htm) (accessed 9 September 2009).

<sup>135</sup> The New Zealand Patents Bill 235-1 (2008), designed to replace the NZ Patents Act 1953, had its first reading in the New Zealand Parliament on 5 May 2009. See sections 14 and 275-278.

<sup>136</sup> Sections 50 and 51 of the *Gene Technology Act 2000*.

<sup>137</sup> ALRC, *Genes and Ingenuity*, page 203. The ALRC report discusses a mechanism to provide expert advice to patent examiners on technical issues on pages 202-205 and discusses an ethics advisory body on pages 185-189.