

## ACIP Patentable Subject Matter Response to Issues Paper

### Question 1 - Economic Objectives of Limiting Patentable Subject Matter

#### (i) Can Placing Limits on inherently patentable subject matter be justified on economic grounds?

While economic considerations do apply to the patent system as a whole, to use purely economic grounds to define what is patentable subject matter is not appropriate.

The existing framework has led to a delineation between what is considered suitable subject matter for patent protection and what is not. For example, pure business schemes have systematically been rejected as not constituting patentable subject matter. Such schemes could be detrimental on an economic level but this is not the appropriate consideration for determining patentable subject matter. Rather the framework in Australia has consistently found that such schemes do not constitute patentable subject matter on the ground that they fail the *NRDC* test - see *Grant v Commissioner of Patents* (2006).

While it is feasible that the grant of patents for certain subject matter may be detrimental economically to the community at large, we argue that the current tests and framework are sufficiently robust and fluid to appropriately exclude this subject matter.

To limit patentable subject matter based purely on economic grounds would introduce a further and more stringent test. Economic issues are already part of the rich framework of our system and to further carve out subject matter based purely on economic considerations would potentially unfairly restrict protection of innovation.

#### (ii) Should the subject matter of each individual invention be assessed to determine whether a patent is necessary to encourage innovation, or should such an assessment be done for entire fields of technology?

"No" to both parts of this question.

(a) on an individual assessment, we do not see how this is practical or even relevant. This is taking innovation and its encouragement to a "micro" level when in fact it should be looked at on a "macro"-scale. Encouragement of innovation is a cornerstone of the patent system and is multi-faceted. To review each individual invention on the basis of encouraging innovation would, in our opinion, not have much, if any, impact on the desired increase in encouragement of innovation. It would also potentially unnecessarily burden the system with an additional consideration.

(b) much the same argument as set out in (a) applies to whether entire fields of technology should be subject to such an assessment. While not on such a "micro" level and perhaps not giving rise to quite such a procedural burden, this system is

questionable, potentially unworkable and would likely not achieve the desired increase in the encouragement of innovation above and beyond that already provided by the patent system.

### **Question 2 - Economic Effect of Inherent Patentability Test.**

**What would be the consequences on innovation of imposing or removing limits on patentable subject matter? Are you aware of any empirical data on such consequences?**

Imposing Limitations.

In answering this question, we assume that it relates to imposing limitations over and above those already in place within the statutory and judicial framework. In this case, the consequences would be to further restrict the benefits of the patent system for the subject matter that is so limited. Imposition of further limitations would economically benefit some while others would suffer.

To give an example, we believe one can compare and contrast the European and US approaches to protecting software patents. Where there is an imposition of a limitation in regard to software, one might imagine we would see more nimble IT developers (organisations or individuals) using that freedom from concern of infringing patent rights to bring software-based innovations more quickly to the marketplace than is the case where software patents are allowed. On the other hand, in countries where software patents are not allowed, many software developers may well suffer from the fact that they are not in a position to create a patent position that allows them to licence or otherwise sell their development.

While we are unaware of any empirical evidence, we can say with respect to software, that it is by no means clear that European IT developers (or Europeans in general) are in some way economically better off than US-based developers (or US citizens in general) that are required to abide in a system that allows such patents. Given this, we would err on the side of arguing against limitations in this field. As the same argument could be put for other fields, and given the inherent uncertainty of technological development, we do not believe additional limitations should be imposed in Australia.

Removal of limitations.

Again, we assume that the proposal concerns removal of limitations currently in place. Some may argue that removal of restrictions would not have much effect for the majority of currently excluded subject matter on the basis that they would be caught by other provisions in the legislature. There is, however, an argument to remove certain exclusions such as "contrary to law" and the food and medicine exclusion - see comments below.

On the whole, however, with any amendments one must be careful not to upset the balance which could potentially lead to unintended consequences.

### **Question 3 - Ethical Reasons for Limiting Patentable Subject Matter**

**Can placing limits on inherently patentable subject matter be justified on ethical grounds? Is it appropriate for legislation to predetermine ethical limitations on patentable subject matter or is it more appropriate for courts to determine such limitations on a case-by-case basis?**

The patent system should *reflect* public policy/standards relating to ethical issues (which are transient). While it has a place in reflecting ethical considerations, we do not believe the patent system is an appropriate forum to decide or dictate such issues.

Certain subject matter is not patentable in Australia including human beings and the biological processes for their generation; inventions that are contrary to law; inventions falling within the ambit of "generally inconvenient"; and food and medicine where a mere mixture of known ingredients. It is argued that this framework adequately covers ethical considerations.

The "last resort" provision of "generally inconvenient" does appear to provide a mechanism to prevent the patenting of any previously unforeseen subject matter that may subsequently be deemed inappropriate subject matter for ethical reasons.

In relation to the current exclusions, it is argued by some that removing the exclusions of contrary to law and the food and medicine exclusion would have little, if any, real impact. The grant of a patent to an invention that is otherwise unlawful could not then be lawfully exploited. The issue of the food and medicine exclusion is discussed below and we believe could be appropriately dealt with under s 18(1)(b).

As different ethical issues arise in the future then this is a matter for the legislature and not for the judiciary. Indeed, the Australian courts have been loathe to rely on ethical concerns as a basis for overturning patents which are otherwise directed to patentable subject matter - see *Bristol-Myers Squibb v FH Faulding* (2000) FCA 902.

**Is patent law an appropriate avenue for dealing with ethical issues? If not, what is an appropriate avenue?**

While the patent system may reflect the ethics of the day, it is a matter for Parliament to deal with overarching ethical concerns.

**Question 4 - Ethical Effect of Inherent Patentability Test.**

**What would be the ethical consequences of imposing or removing limits on patentable subject matter? Are you aware of any examples of such consequences?**

The patent system is not the forum to deal with ethical issues but rather, and as noted above, these should be dealt with under the broader umbrella of public policy and *reflected* in the patent system. The patent system as a tool to address ethical concerns is a blunt instrument.

Looking at the extreme of removing say the provision "contrary to law" and thus allowing the grant of "unlawful patents" would arguably have no ethical impact as such patents would be almost certainly un-exploitable. The area of "exploitation"

seems the more appropriate focus for regulation of inventions which give rise to ethical concerns.

If use of an invention is deemed unethical then it is the role of Parliament to legislate to protect society from its use and exploitation.

If the patent system defines patentable subject matter based on ethical considerations but Parliament has not legislated against particular inventions of ethical concern then the fact that a patent could not be granted to exploit the invention will not prevent its use and exploitation.

Methods of Treatment of Humans - Historically, patents for methods of treatment were denied in Australia because they did not constitute patentable subject matter on the grounds of general inconvenience. Barwick CJ, in *Joos v Commissioner of Patents* (1972) 126 CLR 611, found that methods of treatment were patentable subject matter but for an assumed public policy that patents not be granted for such inventions. On this basis, the subject matter was deemed "generally inconvenient". However, in reality there was no such public policy and subsequent decisions have affirmed the inherent patentability of methods of treatment.

Therefore, to impose a limit on patentable subject matter to exclude methods of treatment would require a specific act of legislation. We would argue that such a restriction is not required on the ground that it potentially curbs innovation and research in the field of medicine (an area in which Australia excels) and does nothing to address the perceived concerns. We have not seen a flood of cases where a practitioner has been sued for performing a patented method. On the other side, the system enables a patentee to ensure all aspects of their invention are appropriately claimed without the need necessarily of having to resort to more convoluted drafting styles, e.g. "Swiss-style" claims.

Therefore, we do not see ethical considerations constituting a justification to impose or remove the current limitations on patentable subject matter.

**Question 5 - Other reasons for limiting Patentable Subject Matter  
Other than economics, ethics and national security, can placing limits on inherently patentable subject matter be justified on any other grounds?**

No. For example, we do not believe special provisions should be introduced in relation to traditional knowledge. Appropriate application of current principles, including the manner of manufacture test, novelty and inventive step should be sufficient.

**Question 6 - Content and Structure of Current Australian Law.  
Does the content of current Australian law meet the objectives of the system?  
Are decision makers focusing on the appropriate principles? Is the legislative structure of current law appropriate for the content?**

Yes if the objective of the system is to allow the grant of patents to appropriate subject matter and prevent the grant of unacceptable subject matter.

There is scope to address some areas which have been arguably misread or at least the intent misinterpreted by the courts. The goal of any amendment should be to avoid disturbing the fine balance afforded by the current system and, further, ensuring that the amendments do not result in unintended consequences.

As evidenced by the findings in *Grant v Commissioner of Patents* and *Bristol Myers Squibb*, the courts do appear to be focusing on appropriate principles.

## **Question 7 - Issues with Current Australian Law**

### 11.3.1

#### *A - Combination of flexible and proscriptive tests*

The current combination of provisions generally works well.

Although, we question the continued existence of s50(1)(b) that a substance capable of being used as food or medicine and which is a mere mixture of known ingredients may not be afforded the grant of a patent. Given the restriction on patentability set out in section 18, this provision seems superfluous.

#### *B - Value of existing body of case law.*

The decision of the High Court in *NRDC* is rightly viewed as a leading authority on manner of manufacture and provides, to date, a flexible and instructive approach to determining patentable subject matter. Subsequent decisions have built on this strong foundation to provide us with the current, valuable body of case law. The case law is so solid that there is no over-riding need to attempt to change the current system.

#### *C - General Inconvenience, mischievous to the state and hurt of trade*

As touched on above, the role of "general inconvenience" does seem to have been used historically to prevent the grant of patents to subject matter deemed "unethical". The fact that it is so rarely utilised suggests that the measures in place to determine patentable subject matter are almost always sufficient without resorting to this safety net provision. However, it is just that, a safety net which allows for a degree of fluidity and enables the *NRDC* approach to be morphed to meet changing needs.

#### *D - Archaic Language*

Presumably the question has arisen from terms such as "*mischievous to the state and hurt of trade*". We believe the terms are not so archaic as to cause confusion to the modern reader. The rich body of case law has dealt with this language and set guidelines for users of this system. While there is a perhaps a small risk that courts will in future have problems with the language, attempts to modify the language pose far greater risks to upsetting the balanced system that is currently in place.

#### *E - Threshold of Inventiveness*

The whole concept of the threshold of invention appears to fly in the face of the legislative intent and has resulted in confusion surrounding the test to be applied. While it would appear that the High Court in *Lockwood Securities Products Pty Ltd v Doric Products Pty Ltd* (2007) has gone a long way in clarifying that there is probably not a discrete threshold test of inventiveness, it would be desirable to clarify this matter through appropriate modification of the legislation.

While one means to achieve such clarification would be to remove the dictionary definition of "invention", we would highlight that any proposed change must ensure that all of the integers of s6 of the *Statute of Monopolies* are still incorporated within our legislative structure eg the provisions of generally inconvenient *etc.* should be retained.

#### *F - Threshold of Utility*

We see no need for amendment/modification of the manner of manufacture provision. The requirement that an invention be useful is clearly set out in s18(1)(c).

#### *G - Scope of Rights Awarded*

The scope of rights should not be considered in the present forum of reviewing patentable subject matter. The balance between claiming and teaching is addressed by the provisions relating to written description and fair basis. It is not a matter to be addressed under the guise of manner of manufacture.

There should be a clear delineation between manner of manufacture and other provisions such as those relating to sufficiency of description, including best method and fair basis.

#### *H - Requirement for Grant*

Manner of manufacture should be considered pre-grant by the patent examiners as a check against the grant of patents to unsuitable subject matter. It is not the sole role of the Patent Office to grant patents but to also act as a guardian to safeguard against the undesirable impacts of invalid patents in the marketplace.

### **Question 8 - International Integration**

**Is it more important to achieve best practice or to harmonise with a major jurisdiction? Are any jurisdictions preferable over others?**

All major jurisdictions face the same hurdles as Australia when attempting to balance the rights of the patentee with those of the public at large. In relation to manner of manufacture we submit that Australia does appear to have a most flexible and transparent test that is not so inconsistent with overseas practice that it requires amendment or abolition.

Compare this to the US. In §101, the use of the words "new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof" was considered to provide a framework to cover "everything under the sun made by man". However the specific words of the legislation have been the subject

of intense review and scrutiny which arguably has led to a state of uncertainty, particularly in the field of business methods and signal processing.

In Europe, the proscriptive approach led to claim constructions such as the "Swiss-style" claim which navigated around the specified exclusion to methods of treatment for second medical use of a known drug. Concerns relating to this approach led to the changes of the convention embodied in the EPC 2000.

### **Question 9 - International Compliance of Current Australian Law Is current Australian law compliant with our international obligations?**

TRIPS Article 27 states:

1. *Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*
2. *Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*
3. *Members may also exclude from patentability:*
  - (a) *diagnostic, therapeutic and surgical methods for the treatment of humans or animals;*
  - (b) *plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.*

We question whether the exemptions relating to mere admixtures and the name of a person in s50 of the *Patents Act* 1990 comply with Australia's obligations under TRIPS.

### **Question 10 - Preferred Patentable Subject Matter According to what you believe are the appropriate objectives and constraints of the patent system, what sorts of subject matters do you think should be inherently patentable and what should not? Would your preferred content be compliant with Australia's international obligations?**

By attempting to mandate specific subject matter that *is* patentable would be to risk the very rigidity warned against in *NRDC*.

What is not patentable is suitably addressed (bar the mere admixture provisions) in the current legislation.

**Question 11 - Legislative Structure**

**What sort of legislative structure would be appropriate to achieve your preferred content identified in Question 10? Are any foreign structures preferred? In principle, when should statutory provisions excluding subject matters be used? Should such provisions be expanded, such as by including the exceptions from patentability allowed under TRIPS?**

Given that we do not see the need to change the current system bar the specific example raised above, we believe the current legislation provides a good framework. We do not see any advantage in pursuing a foreign structure.

We see no benefit to introducing any of the exceptions to patentability allowed under TRIPS. It is also important that Australia meets its obligations under TRIPS and recently negotiated free-trade agreements and does not bring in limitations that are not compliant with TRIPS or those agreements. In this regard, we would comment that it is by no means settled that the exclusion in the EPC of software patents is compliant with TRIPS.

With reference to introducing and/or removing limitations on patentable subject matter (see questions 1 and 2) an over-riding consideration is, therefore, Australia's international obligations.