Submission to ACIP Review of Patentable Subject Matter

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I submit that there is no need to change the current test for patentable subject matter, and that the opinion of the reviews carried out in 1984 and 2000 should be followed. The Australian Law Reform Commission review of 2004, for which I was a member of the Advisory Committee, recommended that the test be reviewed, but did not present any real evidence that it had in fact caused significant confusion to patent applicants or practitioners, or had resulted in any other detriment.

The ALRC report discussed a number of submissions and academic articles, a number of which argued that naturally occurring genetic materials should not be patentable because they represented mere discoveries. However, the key factor in deciding patentability under the present law is whether a discovery or finding *has been applied to a useful purpose*, and this distinction between discovery and invention is well understood. As the ALRC acknowledged, many of these submissions demonstrated a poor understanding of the patent laws and how they are applied.

The present test has operated successfully for over 400 years, and despite its antiquity has enabled patent law to keep up with and adapt to radical changes in technology. For example, application of this test in the *Ranks Hovis McDougall* case (Ranks Hovis McDougall's Application [1976] 46 AOJP 3915) resulted in Australia being the first country to grant a valid patent for a living organism, several years before the seminal *Diamond v Chakrabarty* case in the United States (Diamond v Chakrabarty 447 US 303 (1980)).

The test is well understood by patent attorneys, legal practitioners, the Patent Office and the courts, and the landmark NRDC decision (*National Research Development Corporation v Commissioner of Patents*, (1959) 102 CLR 252) is internationally known and respected. To introduce any new test would introduce great uncertainty which could not be resolved until at least one test case had been litigated, possibly up to the High Court. Such uncertainty would increase costs and would be greatly unfavorable to innovation.

My comments on the specific questions posed in Section 11 of the Issues Paper are as follows:

Question 1

I do not consider that there is any evidence to suggest that there is any justification on economic grounds for placing any limitation on the scope of patentable subject matter. Indeed, the contrary may be the case. For example, the pharmaceutical industries in Italy and India have expanded enormously since these countries removed their prohibition of product patents for pharmaceuticals.

Assessing the subject matter of each individual patent application to determine whether that patent is necessary to encourage innovation would not be feasible, because patent examiners do not have the requisite knowledge to make such a determination, and because the number of applications would make the task unwieldy and cause undue delay in processing applications. Moreover, discrimination against any particular field of technology on this ground would be a violation of the TRIPS Agreement.

If an innovation is in a field in which being first to market is the most important factor in commercial success and in which market life is short, the cost of patenting is unlikely to be considered worthwhile, and any limitations on patentability will be irrelevant to the innovators.

Question 2

Imposing limits on patentability can stifle innovation, because the cost of developing new products or methods can be enormous, and companies will only undertake developments if they have a reasonable prospect of a period of exclusivity during which they can recoup their costs and hopefully make a profit. For example, it is notorious that the cost of bringing a new pharmaceutical product to market is in the region of 1 billion dollars. High costs are faced by the makers of any product which is subject to Government regulation.

The *Diamond v Chakrabarty* decision of the US Supreme Court, which removed the restriction on patentability of living organisms in that country, made the biotechnology industry possible. As stated above, in Italy and India the removal of the prohibition of product patents for pharmaceuticals provided, a great stimulus for the pharmaceutical industry.

Limitations on patentable subject matter, such as the “technical effect” criterion in Europe, are often difficult to interpret, and therefore create uncertainty. They also suffer the major disadvantage that they cannot cope with new fields of technology.

Question 3

Inventions which are contrary to law are already excluded from patentability. Imposing limitations on patentability on ethical or moral grounds is fraught with difficulty, because it always involves the questions "*whose* ethics", "*whose* morality". There is very little consensus on such matters other than in specific areas which are the subject of criminal law, eg murder. For example, inventions relating to methods of contraception used to be considered unpatentable, although the Statute of Monopolies does not mention morality.

If the subject matter of the invention is otherwise inherently patentable, and its sale and use is legal, then arguably neither the courts nor the legislature should interfere. If any individual has a conscientious objection to doing so, s/he can refuse to make, sell or use the invention. Imposing ethical limitations via legislation is open to political manipulation, as occurred with present Section 18(2).

Patent law is a completely inappropriate mechanism for dealing with ethical issues, particularly if patent examiners have to make judgements on such criteria, since they are not trained in this area.

Ethical limitations on patenting are often proposed because the limitations on the rights conferred by a patent are usually not appreciated by the general public. In fact, the grant of a patent confers the only the right to stop others from exploiting the invention without the patentee's authorization; it does not mean that the patentee is free to exploit the invention. A patent does not give an affirmative right to do anything; the patentee is subject to all normal national and state laws which relate to the subject matter of the invention, and is also subject to any relevant earlier patent rights which may subsist. The patentee cannot stop others from continuing activities which they started before the priority date of the patent. These limitations can be quite significant.

Question 4

Imposing limitations on patentability on ethical grounds has the consequence that one particular set of ethics may be imposed on the population at large, regardless of whether it supports that set of ethics. This is particularly difficult to remedy if the limitation is imposed by legislation.

For example, present Section 18(2) not only excludes human beings and human embryos from patentability; it has been interpreted by the Patent Office to exclude methods of *in vitro* fertilization. Such methods are legal and very widely used. Considering the amount of artificial intervention involved, it is difficult to see how they can be considered to be "*biological*" processes for generation of a human being. Given the wide acceptance of *in vitro* fertilization by the general

community, it is even more difficult to see how techniques for achieving it can be regarded as “unethical”

Other legislation such as the *Prohibition of Human Cloning Act* (2002) and the *Research Involving Human Embryos Act* (2002) governs the production of human embryos, and arguably makes redundant some of the ways in which Section 18(2) has been applied by the Patent Office.

Question 5

The only real justification for exclusion of otherwise patentable subject matter would be that the manufacture or use of the patented product would be contrary to law. This is covered under the present legislation Section 50 (1)(a)), and the interpretation of the statute is well understood. However, if such manufacture or use is illegal this provision appears to be redundant.

Exclusion from patentability on the ground that the claimed invention constitutes a mere mixture used in food or medicine is more difficult to justify. Many pharmaceutical formulations are “mere admixtures” in which no actual or potential physical or chemical interaction can be demonstrated, but which nonetheless provide a significant practical advantage. It is hard to see why such formulations should not be inherently patentable, subject to the normal requirements of novelty and inventive step.

Question 6

The content and structure of the current Australian test for patentability are generally appropriate, subject to the reservations expressed in my comments on Questions 3, 4 and 5, and do meet the objectives of the system. In particular, the present test has the enormous advantage of flexibility.

As a result of its long history and many interpretations by the courts, particularly in the NRDC decision, the current law is clear to decision makers and users of the system. Most users receive professional advice, and can therefore avoid any potential problems resulting from the form of their claims.

In my more than 23 years of professional practice as a patent attorney I have never had any difficulty in interpreting the manner of manufacture test and applying it to the cases I have dealt with. This is despite the fact that my practice has been in the field of biotechnology, which is at the cutting edge of scientific development and could be regarded as posing particular problems in assessing patentabilty.

Question 7

A. The combination of flexible and proscriptive tests does not cause any difficulty in practice, because they are well understood by practitioners and have been clearly interpreted by the courts.

The exclusion on the ground that the claimed invention constitutes a mere mixture used in food or medicine could certainly be abolished, as discussed under Question 5. Such formulations should be patentable, subject to the normal requirements of novelty, inventive step and usefulness.

The specific exclusions for human beings and for inventions contrary to law have been discussed under Questions 3 and 5.

B. It is generally considered by patent practitioners that the principles enunciated in the NRDC case do meet the objectives of the test, and have generally been well understood and followed in subsequent decisions.

C. One reason why the "generally inconvenient" element of the test appears to be "dormant" is because it is so well understood that practitioners advise their clients that innovations which fall foul of this criterion would not be patentable, and therefore applications claiming such developments are not lodged. Where as a result of changes in social attitudes a class of innovation is no longer regarded as inappropriate for patent protection, eg methods of medical treatment, this readily dealt with by the courts.

Applications for "insubstantial" inventions are all too common, but are rejected for lack of novelty or lack of inventive step, without the manner of manufacture test having to be invoked. If they are indeed insubstantial they will not survive in the marketplace, and any patents granted for them will not be maintained or readily enforceable.

While "mischievous to the state" and "to hurt of trade" may not be readily applied by examiners, there appears to be no need to remove these criteria, let alone to replace them by new concepts which may pose their own problems and which would require interpretation by the courts.

D. Despite its so-called "'archaic" language, the Statute of Monopolies is well understood by patent attorneys, legal practitioners, the Patent Office and the courts. Any change in language or in the nature of the test would create uncertainty until it had been judicially interpreted, which would increase costs and would be greatly unfavorable to innovation.

E. Again this does not cause any particular difficulty. It would be very rare for an innovation which fell foul of this criterion to be found to be novel and inventive.

F. At the time of the ALRC report, lack of utility was only available as a ground of revocation, and was not considered at the examination or opposition stage. Since then lack of utility has been added as a potential ground of opposition.

As set out in Section 2.9.4 of the Australian Patent Office Manual of Practice and Procedure, patent examiners are required to check whether a patent specification discloses a useful purpose for the claimed invention, and this purpose must be reasonably specific. In practice this is similar to the requirement in the United States that the specification must disclose "a specific, substantial and credible" utility.

G. The same exclusive rights in respect of any use apply also to inventions in other fields, eg electronics and mechanical devices, and cause no difficulty.

Any change to the scope of rights awarded in respect of chemical compounds, including pharmaceuticals and genetic materials would be contrary to the principles of international harmonization and to the AUSFTA. It would also discriminate against specific fields of technology and would thus violate the TRIPS agreement. Such a restriction of rights would completely contradict legislation and practice since Federation.

Moreover, since it is common for inventions in the pharmaceutical and biotechnology fields to take 10-12 years to reach the marketplace, if they do so at all, the practical period of exclusivity conferred by a patent for such an invention is in fact shorter than for inventions in other fields, even when the potential for extension of term is taken into account.

The inventor of any new and inventive use for a previously patented compound can obtain his/her own patent. The original patentee cannot use the compound for the new purpose without a licence from the new patentee; conversely the new patentee cannot do so without a licence from the original patentee. Such cross-licensing arrangements are extremely common in the pharmaceutical and biotechnology industries, and are negotiated in the light of market forces.

Again it appears that there is little if any evidence that the present law causes any detriment, and many of the arguments that it does so are put forward by academics rather than by the relevant industries.

H.

The present patent examination system has served this country, and others such as the United States, Europe and Japan which have broadly similar systems, very well over many decades.

One great advantage of the way in which the Australian Patent Office operates is the open communication and discussion between members of the examining corps. The Australian Patent Office Manual of Practice and Procedure is a comprehensive guide to examination, with detailed case law references. Difficult cases are referred to senior examiners who have the necessary experience to assess them. An applicant can request a hearing in respect of any maintained objection, and refusal of an application by the Commissioner of Patents can be appealed to the Federal Court, and ultimately to the High Court. Thus there is no need for assessment by any external expert panel.

Moreover it is difficult to see how any independent expert panel in Australia could be appointed without considerable delay and unacceptable costs being incurred. Costs would be greatly magnified if it were necessary to have recourse to overseas experts.

In contrast to the statement at page 66 of the Issues Paper, lack of usefulness is in fact assessed during examination, under the criteria of manner of manufacture (sec 18(1)(a)) and full description of the invention (sec 40(2)(a)). See Section 2.9.4 of the Manual of Practice and Procedure. The manner of manufacture criterion will not be satisfied if the “invention” constitutes a mere discovery or a scientific principle.

In the event of a decision by the Patent Office which is disputed by the applicant’s competitors, the present provisions for opposition and revocation are available. As stated with reference to item F, lack of utility is now available as a ground of opposition as well as of revocation.

Therefore there is no need for any new ground of opposition or of revocation.

Question 8

Australian patent law is already broadly harmonized with the laws of the other major patent jurisdictions, including the United States and Europe, both in the content of the legislation and in the practice of the Patent Office. Amendments have already been made to comply with AUSFTA, and to raise the standard of novelty and inventive step to be comparable with these criteria as they are applied in the United States and Europe. The standard of examination has also improved.

If any further harmonisation is to be effected in respect of what can be patented, the United States definition of patentable subject matter is much more flexible, and therefore is preferable.

Question 9

Australian patent law already complies with the international treaties to which Australia is a signatory, and with Australia's international obligations.

Question 10

It is vital to the development of Australian innovation that the patent system should be flexible, so that it can accommodate new technologies. Ethical considerations should not be part of any assessment of patentability. Thus the NRDC principles should continue to be applied.

Attempts to exclude particular subject matter, such as methods of medical treatment, are likely to case difficulty, as they did under the European Patent Convention. For example, second and subsequent medical uses are patentable in Europe via an exception to the exclusion from patentability under the Convention, and have to be defined in a convoluted form, along the lines

> "Use of compound X in the manufacture of a medicament for treatment of condition Y".

Moreover the practice of the European Patent Office is to apply a narrow interpretation of all exclusions from patentability.

Under the TRIPS Agreement it is forbidden to discriminate against any particular field of technology, such as biotechnology, and consequently our present law is compliant with Australia's international obligations. Although the TRIPS Agreement does allow for exclusion of certain subject matter, such as methods of medical treatment (Article 27(3)(a)), this particular exclusion appears to be based on an outdated idea that medicine was a field which was "altruistic and not economic in nature". Clearly medical services are very much part of the Australian economy, and there is a need for an incentive to develop new methods of treatment. The exclusion in Article 27(3)(b) is primarily directed at developing countries, and therefore is not appropriate for Australia.

Questions of "ordre publique or morality" (Article 27(2)) are discussed above. Any decision as to what would constitute subject matter which was objectionable under this heading should not be subject to political or religious considerations, because the lack of broad community consensus on what is or is not objectionable. There is no generally accepted view on many of the areas which are suggested by various groups to offend against ordre publique or morality". A "conscience vote" in Parliament may not reflect community views, and can be manipulated by pressure groups. Opinion polling is generally carried out on too limited a scale to be truly representative of the views of the general public, and can be manipulated by pressure groups. The only realistic way of determining

community views on such questions is a referendum, which is unlikely to be feasible.

Question 11

The present legislative structure, including the “manner of manufacture” criterion and the Statute of Monopolies, is appropriate to achieve the preferred content of patentable subject matter.

No foreign structure would serve as well as Australia’s present legislation.

No subject matter should be inherently unpatentable, provided that it constitutes a manner of manufacture according to the NRDC criteria. If any exclusion is stated, it should be interpreted as narrowly as possible.

The exceptions from patentability allowed under TRIPS Agreement should not be added to the Australian Patents Act.

Question 12 Other comments

In summary, the present system is not broken, and does not require fixing. No amendment to the Australian test for patentability is needed.

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