

This submission addresses specifically some of the questions and issues in chapter 11 of the Patentable Subject Matter Issues Paper of July 2008.

I would be interested in attending any meetings involving discussions of these issues.

#### 1. Questions 3 and 4

1.1 In my view "placing limits on inherently patentable subject matter [can] be justified on ethical grounds". Otherwise any aspect of our socio-legal structure that has an economic foundation or basis would also be allowed to avoid ethical or moral considerations. For example, hospitals could justify euthanasing patients they consider to be of no future economic value. Child labour or prostitution in schools could be justified because of the economic benefits to those involved including the victims. The concept of fiduciary duty and any attempt at ethical corporate governance would mean less than it does at present.

1.2 The patent system is only a small part of the overall economic structure of our society. Failure of a patent grant is far from catastrophic. Any invention, whether or not patented, will be exploited if it has inherent value and usefulness. The test is simple. What proportion of innovative products on the market today are not protected by patents (or other intellectual property rights)? My guess is well over fifty percent.

1.3 The suggestion that the patent system is somehow outside the social aspects of our economic infrastructure is misconceived, in my view. If patent grants were ethically neutral (or unethical) then would it not be hypocritical to argue that those who infringe patents, such as third world generic medicines manufacturers, or those who avoid paying royalties, act dishonestly or unethically?

1.4 In my view "patent law [is] an appropriate avenue for dealing with ethical issues" because all law does or should involve ethical considerations as do the roles of statutory regulators. Otherwise what is the point in trying to distinguish right from wrong in court or using statutory declarations, for examples?

1.5 The contra argument fails, in my view, because the Patent Office and any subsequent tribunal or court, is not asked to judge the ethical issue per se but rather only whether or not public concerns about it are such that granting a monopoly and financial benefit may not be appropriate. That is a scientific rather than a philosophical assessment and much easier.

1.6 By way of examples, consider a device designed to assist people to commit suicide (assuming legality); arguably not a "treatment" for the human body. Such devices exist. The issues of assisted suicide and euthanasia are current, topical and divisive. However, it would not be the issue of euthanasia that the Patent Office or court need consider. Is not the true "ethical" issue for them simply whether or not a financially beneficial monopoly over such a device should be granted in light of the controversy?

1.7 Again, a safe drug found to induce aggression in humans (methamphetamine if not addictive or illegal, for example). Clearly there would be a market of sports people, sales people, criminals and the like. Clearly it could be considered unethical

and against the ordre public since it would probably promote violent behaviour. Does anyone doubt that a monopoly over such an invention would be inappropriate?

1.8 What about a safe self help ultrasonic abortion inducing device. There are strongly held views on both sides of the abortion debate. On the one hand women needing the device would not wish to pay royalties to the inventor on top of their "misfortune" whilst on the other hand the device should be banned. Surely there is no dilemma for the Patent Office or court in denying it patentability?

## 2. Questions 7 and 11

2.1 Our system of inherent flexibility plus proscriptive inclusions and exclusions is the appropriate one, in my view. The disparate and confusing case law is the product of that flexibility and possibly reflects differences between adjudicators, as for example is assessing novelty or usefulness or infringing design or substantial part. That is part of intellectual property law as is judicial discretion in many other areas of law.

2.2 "Manner of manufacture" needs a significant proscriptive component.

2.3 The appropriate system is one which provides general guidance and specific exclusions and inclusions but where the Patent Office and ultimately the courts assess specific inventions.

2.4 First the courts have shown they consider the social, political, moral and ethical issues arising in patenting the responsibility of Parliament. Personally I think that is wrong, with respect to the judges, because Parliament has, as I read it, left it to the courts by not trying to spell it out or impose a code despite opportunity and reason to do so, over and above that in the Statute of Monopolies 1623 (UK).

2.5 Judges often ask for clear words from Parliament but here, in my view, by continuing to retain the 1623 provision (section 6), Parliament has asked the courts to apply contemporary thinking on social and ethical aspects of innovations that might not be contemplated at the time of enactment, effectively allowing a degree of judicial discretion on a case by case basis.

2.6 Secondly, Parliament can act more quickly than the courts. The court system has been rightly criticized for its slowness to respond to new technologies. It takes time for disputes to occur and cases to reach appellate courts. Speed of development, exploitation and commercialisation of new technologies is fundamental to commercial competitiveness in many areas.

2.7 Proscription by regulation could be a more rapid means of expanding or restricting the definition of "manner of manufacture".

2.8 Thirdly, many new areas of inventions are predictable early, in broad terms, even though the means of achieving the required outcome remain to be solved. For examples, increasing computer memory size and speed were easily predicted as fundamental to advancing computer technologies; fuel efficient motor vehicles using

non-carbon fuel; tougher yet flexible and heat resistant materials; and "thinking" robots, are predictably the next generation in those fields.

2.9 By way of examples where proscription ought to be used to exclude (or include) sub groups of developing technologies I raise the following two examples in the field of biotechnology, as now giving rise to problems.

### 3. Patenting Private Genetic Information

3.1 Patenting of genes generally raises significant issues. One that seems to have been largely ignored thus far is that of privacy of genetic information. The "uniqueness" of individuals and sub-groups of human beings is mostly genetic. Each individual or family or ethnic group or groupings based on appearance or skills or talents, for examples, could be defined by a set of unique genes. They are potentially valuable.

3.2 Consider though traits with identifiable phenotypes such as diseases or physical attributes such as eye colour, and their combinations. Examples of such genes already isolated, and hence patentable subject matter in Australia, include most obviously genes containing mutations that cause disease. Some claims are of thousands of genetic diseases (conditions) of which some are very rare. Many diseases actually have the name of the patient first identified.

3.3 The problems are first that the "inventor" gains a monopoly over use of that private, unique information, presumably at the exclusion of the owner. Secondly, that private (although the patient source may not be identified) information is published. Thirdly, there are consequences to genetic relatives who also have an interest in the information. Would anyone be happy with a government authority, without their permission, granting a monopoly to exploit the appearance of that person's face or that of their great grandmother's face?

3.4 As our privacy law now stands without information identifying the gene donor no infringement of personal privacy would likely occur. That is so even under a system incorporating the recent ALRC extensive recommendations, as I read it.

3.5 The monopoly must include any DNA fingerprint test for the mutations or gene combinations, and the protein product that might be administered therapeutically or beneficially as a drug.

3.6 My submission to the NHMRC inquiry regarding guidelines for disclosure to genetic relatives can be provided for background and completeness, if that would assist.

3.7 Human cloning is specifically prohibited. Human beings are specifically excluded from patentable subject matter. Should not the "essence" of a human being or sub-group of human beings also be excluded? Where should the line be drawn between one unique gene and the whole human being? After all it can only be the "unique" components that require the human being exclusion to be spelt out in the first place.

3.8 It is a very small and possibly even obvious step from the present state of affairs to the isolation of genes for what are considered desirable traits such as genes for:

"health" (for example involved in fat metabolism); "beauty" or other physical attributes; intelligence and talents and skills; or, of more concern, traits such as aggression or immorality. Obviously these are polygenic but recombinant DNA constructs containing more than one gene are common. All such genes and individuals with those genes are valuable in economic terms, to someone (for examples, over aggressive soldiers or extra strong labourers).

#### 4. Patenting Tissue and Organ Derivation from Stem Cells

4.1 A second issue is raised by stem cell technologies.

4.2 The purpose and highly publicized potential of stem cells is for them to be used to produce new tissues and organs. The idea is that freshly isolated adult stem cells can differentiate into specific tissues and organs whilst embryonic stem cells have the potential to differentiate into any tissue or organ under appropriate conditions (totipotent). The tissues and organs from adult stem cells will not be rejected by the donor or closely related individuals. Those from embryonic stem cells or stem cell lines, can be more or less tissue typed for use in "related" individuals or those with similar tissue types. That is to say a selection of organs of the different tissue types could be maintained "on the shelf" for use as needed.

4.3 The totipotent cell culture exception is relevant because it seems to exclude the stem cells and cell lines but, as I tried to point out to the NHMRC review of Alternative Reproduction Technology, once they are differentiated they are no longer stem cells and are no longer any more available for differentiation than other cells from the same tissue. The final guidelines did not address that issue despite increasing numbers of reports of successful differentiations.

4.4 My submission to the NHMRC inquiry on alternative reproduction technologies, particularly concerning stem cell research, can also be provided for completeness and background, if that would assist.

4.5 The problem I see is that apart from the issue of the stem cells and stem cell lines which raise additional intellectual property questions (and ethical problems particularly for embryonic stem cells) and which may or may not be caught by human tissue Acts and other relevant legislation, the resultant tissues or organs, through the processes for their production, fall into an unknown and unconsidered category.

4.6 The NHMRC Human Research Ethics Committee should have attempted to properly address the issue in their recently revised guidelines, since it was raised, because the sole potential of stem cell research is to produce new tissues and organs; it is the foreseeable consequence of successful research; and some specific tissue differentiations are currently being claimed. No doubt those guidelines are up for frequent reviews but unclear or incomplete guidelines are not helpful to those in the field. Guidelines should be ahead of the technology. What is the point of a map once the destination is in sight?

4.7 If, in the present context, the concepts of "generally inconvenient" and "ordre public" were intended to incorporate an ethics element, as seems to me certain, then

obviously guidelines from the NHMRC Human Research Ethics Committee would be taken to constitute the contemporary standard. Hence my concern.

4.8 That delay in providing advanced research guidelines is highly relevant to patenting and the present review because examples of the patent system lagging behind new technologies are not uncommon.

4.9 Adult stem cells are considered unipotent or pluripotent although that may change with improved technology. The totipotent provision is aimed at embryonic stem cells but should it not apply equally to adult stem cells in light of the concerns I have raised.

4.10 This submission is not concerned with the mainstream ethical issues raised by using human embryos for stem cells isolation but with the proprietary and other issues raised by product by process patents of the generated tissues and organs.

4.11 For example, a new heart generated from adult stem cells is equivalent to a cloned organ genetically equivalent to the donor. It is, in my view, equivalent to cloning a human being and removing the heart as a transplant organ and then throwing the remains of the "unique" human being into the bin. That is disturbing because the heart donor (hypothetical or virtual clone) has no say. Some hold the view that the essence of "humanness" does not reside solely in the brain but in other organs as well and the heart is a traditionally held source.

4.12 Tissues such as the heart, generated from embryonic stem cells are even more problematic because some hold the view that a new human being is created at fertilization. Hence a heart generated from embryonic stem cells is a transplantable organ from a hypothetical or virtual, but unique, human being (often named by the parents) with parents and siblings. It might be considered a still born or dead child of the age of the organ.

4.13 Are these human being or means of generating human beings?

## 5. Question 8

5.1 I also briefly address the question of which countries' system is preferred. Would Australia's long term best interests be served better by aligning with China, India, Asian and Eastern European countries which are clearly the major future markets for new technologies. In high tech but easy and cheap areas such as biotechnology, it is likely these countries that will also be developing the technologies, and with little or no regard to animal or tissue exploitation concerns or other ethical issues.

5.2 Predictably developing countries will largely be ignoring intellectual property rights (existing examples are: copyright and pirating in China; and generic medicines in India). They will undercut the United States, Australia and other countries that rely on those systems, in key areas of advancing technologies, in those developing countries that are the real markets. That undermines the economic rational for our patent system.

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Yours sincerely,

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