

SUBMISSION

**TO THE ADVISORY COUNCIL ON
INTELLECTUAL PROPERTY**

**Patentable Subject Matter
ISSUES PAPER**

**Dianne Nicol and Jane Nielsen
On behalf of the
Centre for Law and Genetics
Law Faculty, University of Tasmania**

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Question 1 – Economic objectives of limiting patentable subject matter

Can placing limits on inherently patentable subject matter be justified on economic grounds?

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?

We agree that questions need to be asked about whether the current patent system, which has essentially remained unchanged for centuries, is properly adapted to facilitate the development of new areas of technology. One such question is whether the patent system properly distinguishes between patentable and unpatentable subject matter. As noted in the *Patentable Subject Matter Issues Paper*, limits have always been imposed on patentable subject matter. In particular, a distinction has been drawn between the useful and fine arts. There are sound economic as well as other social and practical reasons for making this distinction.

We approach this question and the other questions raised in this *Patentable Subject Matter Issues Paper* from the perspective that the objective of the patent system is the promotion of innovation and dissemination of technology. Despite arguments being raised in support of alternative rationales for the patent system, we submit that it is difficult to challenge the dominant paradigm, given that this is so clearly enunciated in TRIPS. However, it is important to acknowledge that Article 7 of TRIPS goes on to state that patent rights should operate in a manner that is conducive to social and economic welfare.

As such, TRIPS does not just provide an economic rationale for the patent system; social considerations also need to be taken into account. For example, biomedical technologies have healthcare implications, agricultural biotechnologies have food supply implications, climate change technologies have environmental implications, and so on. It would be wrong to focus solely on economic grounds in setting the limits on patentable subject matter. The issue should be cast in terms of innovation and dissemination of knowledge rather than economy.

We recognise that the relationship between patenting, innovation and dissemination of knowledge is complex. There is conflicting evidence as to whether or not innovation is best served by a system that grants monopoly rights, or one that encourages a competitive environment. It is therefore vital that full advantage is taken of an opportunity such as this to evaluate the patent system and criteria for assessment of patentable subject matter. An optimally functioning patent system will properly balance the innovation advantage provided to patent holders with the concomitant risk of innovation blockage for follow on users. With the advent of high technology, the pace and complexity of the innovation process has increased dramatically. Complex webs of primary and follow-on innovators are emerging.

There is a large, but conflicting, body of theoretical economic literature on optimal intellectual property strategies in such areas of cumulative innovation. The messages from these analyses are mixed. There are those that provide compelling arguments as to why the availability of patents for subject matter at the upstream end of the research-development continuum encourages investment in research and development.¹ Others provide equally compelling arguments as to why this level of protection might not be optimal in areas of cumulative innovation.²

One risk is that broad patents claiming foundational technology may result in hold ups and patent thickets could cause anticommons effects. Hold ups can occur when the owner of a patent over foundational technology refuses to deal with a developer of downstream technology. Anticommons effects can occur both where there are numerous overlapping property rights and also where reach-through licence agreements lead to licence and royalty stacking.³ The risk is that the timely delivery of new products and processes could be significantly hindered in these new areas of technology, which has both economic and social consequences.

Questions relating to optimal strategies for innovation and dissemination of knowledge cannot be answered solely by imposing limitations on inherently patentable subject matter. We doubt whether excluding entire fields of technology from patenting would solve the innovation conundrum in those fields. One risk is that there would be no incentive for research and development. Another is that such exclusions could be circumvented by creative claims drafting. Rather, we suggest that each individual invention that satisfies the requirement of being an invention in a field of technology should be rigorously examined in accordance with the usual criteria of novelty, inventive step and industrial applicability. The disclosure and claiming requirements should also be rigorously examined. We submit that there are also strong grounds for limiting patents to use-bound claims and that this issue warrants much deeper analysis.

In making this submission, we recognise that patent offices around the world suffer from a serious lack of resources to rigorously examine patents, particularly given the pace of technological development. There are repeated criticisms in the literature of the time it takes for patent offices to examine patents and the quality of examination.⁴ One option might be to take heed of Mark Lemley's 'rational ignorance' argument.⁵ He presents a persuasive case as to why it would be irrational to pay increased attention to validity and to put increased resources into the assessment of patent applications. He argues that a

¹ Suzanne Scotchmer, 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law' (1991) 5 *Journal of Economic Perspectives* 29.

² For example, Robert Merges and Richard Nelson, 'On the Complex Economics of Patent Scope' (1995) 90 *Columbia Law Review* 839.

³ Michael A Heller and Rebecca S Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698 at 698-699.

⁴ See, for example, Adam B Jaffe and Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress, and What To Do About It* (Princeton: Princeton University Press; 2004), particularly 'The Slow Starvation' Chapter 5.

⁵ Mark A Lemley, 'Rational Ignorance at the Patent Office' (2001) 95 *Northwestern University Law Review* 1495.

massive increase in resources would be required to ensure validity of issued patents and that challenging the validity of questionable patents in court is more efficient. However, Lemley's views are not universally shared.⁶ There are legitimate fears that bad patents will impact negatively on innovation. In our view, it is not clear that enough questionable patents are challenged in Australia, and this lessens the strength of the rational ignorance argument to a large extent. We submit that it is hard to find an adequate substitute for rigorous examination of patent practices.

As noted in *Venturous Australia: Building Strength in Innovation*, which reviewed the national innovation system in Australia, patent law should be reviewed to ensure that the inventive steps required to qualify for patents are considerable and that resulting patents are well defined.⁷ But we agree with the Report that it is not clear that a revision of patentable subject matter in isolation can address the fundamental problems. We submit that it is asking too much to expect that blanket bans on particular subject matter will address concerns about the role of the patent system in facilitating innovation and dissemination of knowledge.

It is important to acknowledge that there are statutory tools for alleviating hold up and anticommons risks post-grant, such as compulsory licensing, Crown use, competition law as well other initiatives such as patent pooling and clearinghouse mechanisms. It is equally important to recognize that ex-ante policy decisions must to be made by governments, funding agencies, universities and other research institutions and industry as to whether or not patenting is the optimal strategy for innovation and dissemination of knowledge, both for fields of technology and for individual inventions.

Nevertheless, we do recognise that the patentable subject matter requirement has a legitimate role to play in facilitating innovation and dissemination of knowledge and that more guidance may need to be provided to patent examiners with regard to satisfaction of this requirement, particularly in emerging fields of technology. Satisfaction of the technicality and physicality invention requirements are particularly problematic under current Australian law. The difficulty in Australia is that there is an insufficient body of case law to guide examiners in new areas of technology.

We submit that assistance could be provided in the form of guidelines rather than specific legislative exclusions. We submit that further assistance may need to be provided to patent examiners in difficult cases. For example, patent examiners could be provided with the option of sending difficult cases to an expert review panel or sending them out for peer review. We return to these matters later in our submission in response to Question 12.

⁶ See, for example, Arti K Rai, 'Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform' (2003) 103 *Columbia Law Review* 1035 at 1080–4.

⁷ Cutler & Company Pty Ltd, *Venturous Australia: Building Strengths in Innovation* (2008) Recommendation 7.2.

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?

If the rationale for the patent system has any basis in fact, then the availability of patents for particular subject matter must encourage some innovation by providing an incentive for research and downstream product development. However, it is difficult to measure the extent to which the patent system actually achieves this end.⁸ One way might be to correlate the expansion in numbers and sizes of firms in new areas of technology with the availability of patents for relevant subject matter.

In biotechnology, relaxation of the thresholds for patenting of gene sequences and other research tools in the late 20th century occurred in parallel with a surge in the number of firms entering the field. While the extent to which the availability of patent rights is actually causative of the growth in numbers of these small to medium enterprises in biotechnology is difficult to assess, the views of participants in the industry clearly support the notion that patenting is vital to their success.

Views of this nature were often expressed by biotechnology industry participants in interviews that we conducted in 2002-2003.⁹ However, the mantra that this increase in patent protection was a necessary pre-condition for the biotechnology boom has been heavily criticised.¹⁰

We recognise that there are genuine concerns about the potential for patents to detrimentally impact on the primary research conducted in universities and other public research organizations that feeds in to the innovation cycle. Patenting will not always be the optimal mechanism for disseminating university knowledge. Concerns about hold up and anticommons impacts on innovation also need to be taken seriously, even though the evidence that these are actually eventuating is mixed.¹¹ However, these concerns need to be balanced against the positive role that patents can play in encouraging innovation, particularly for small, specialised firms and their licensees.¹²

⁸ Indeed, a major report recently released in Canada expressed frustration about the lack of empirical data on critical questions as to whether and how IP increases investment in research and development; encourages or retards development in low- and middle-income countries; and facilitates or hinders the dissemination of new products and services: International Expert Group on Biotechnology, Innovation and Intellectual Property, *Towards a New Era of Intellectual Property: from Confrontation to Negotiation* (September 2008) at 35 (hereafter the Canadian IP Report).

⁹ Reported in: Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (Hobart: Centre for Law and Genetics Occasional Paper No. 6; 2003), available at: <http://www.lawgenecentre.org/pub.php>

¹⁰ See the Canadian IP Report at 35.

¹¹ Timothy Caulfield, Robert M Cook-Deegan, F Scott Kieff and John P Walsh, 'Evidence and Anecdotes: an Analysis of Human Gene Patenting Controversies' (2006) 24 *Nature Biotechnology* 1091

¹² One of us makes a case for the need to recognise and protect the contribution made by small specialist biomedical firms that have grown up around strong patent rights: Dianne Nicol, 'Strong Patent Rights, Weak Patent Standards and Innovation in Biomedicine' in: Chris Arup and William van Caenegem (eds), *Intellectual Property Policy Reform: Fostering Innovation and Development* (Cheltenham, UK: Edward Elgar) in press, which can be made available on request.

We emphasise that the focus of inquiry should be on innovation and dissemination of knowledge, and the extent to which they are conducive to BOTH social and economic welfare.

Question 3 – Ethical reasons for limiting patentable subject matter (Part 4)

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?

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

We submit that there should be scope for dealing with ethical concerns in patent law, provided that these concerns relate solely to exploitation of the invention, as prescribed in TRIPS. It is important to separate out ethical concerns relating to patenting of technology and ethical concerns relating to the technology itself. The latter should not be dealt with through the patent system but through direct regulation of research and development activities. But there will be some instances where it would be contrary to morality to allow the patent system to be used to facilitate the commercial development of certain technologies. Later in this submission we explain why we believe that the general inconvenience provision does not adequately deal with this matter.

We expect that, as a general rule, few patent applications will fall foul of an exclusion centred on ethical grounds. Nevertheless, it is appropriate that such an exclusion is explicitly provided for in our patent legislation. Article 6 of the European Biotechnology Directive provides some useful examples of the types of subject matter that should be considered to be unpatentable on ethical grounds:

- (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.

We emphasise that this list provides examples only and is not intended to be exhaustive. Some of the examples provided above may fall within the ‘human beings’ exclusion in section 18(2). However, we suggest that Section 51 of the *Patents Act 1990* (Cth) should be amended to include inventions that are contrary to morality as well as law, as was the case in the 1903 Act. It is not clear to us why this provision was omitted from the 1952 and 1990 Acts.

We suggest that the types of subject matter that would fall within this exclusion should not be specified in the legislation. Ultimately it should be for the courts to determine such matters on a case-by-case basis. However, we submit that guidelines should be provided to patent examiners on the types of subject matter that should be excluded on the morality ground. Furthermore, an expert review panel could assess such complex issues as morality and public order, as well as the notion of invention. We explore these issues later in this submission in response to Question 12.

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?

As previously stated, we believe that, in general, it will only be in the most exceptional circumstances that a patent application is refused on ethical grounds. However, in Europe at present there is a great deal of confusion as to the patentability of human embryonic stem cells as a result of the application of the *ordre public*/morality exclusion by the European Patent Office to patent claims filed by the Wisconsin Alumni Research Foundation and differences in interpretation of the law across European jurisdictions.¹³ The European Patent Office Enlarged Board of Appeal heard the appeal against rejection of the patent on 24 and 25 June 2008 but is yet to hand down its decision.¹⁴ There is concern that rejection of the patent could impact detrimentally on innovation and research in this important area of technology.

Despite these concerns, we support the inclusion of a morality provision in Australian law. We believe that appropriately formulated guidelines and expert evaluation should ensure the right balance is achieved and should address concerns associated with detrimental impacts on innovation and research.

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?

As previously mentioned, we believe that it is wrong to focus exclusively on economics when considering the rationale for the patent system. Rather, the language of innovation and dissemination of knowledge should be used, and it should be acknowledged that these have social as well as economic consequences.

As such, we submit that it is necessary to consider factors other than economics, ethics and national security, particularly the broader social perspective. This does not equate with ethics, which should be addressed by a new morality provision. The question with

¹³ Laura Bonetta, 'European Stem Cell Patents: Taking the Moral High Road?' (2008) 132 *Cell* 514.

¹⁴ European Patent Office, 'Enlarged Board of Appeal To Review WARF Stem Cell patent Application in Public Hearing at the European Patent Office' (11 June 2008) available at: <http://www.epo.org/about-us/press/releases/archive/2008/20080611.html> (last accessed 9 September 2008)

regard to social concerns is whether placing limits on inherently patentable subject matter provides the optimal environment for promoting innovation and disseminating knowledge, for the social and economic benefit of Australia.

Question 6 – Content and structure of current Australian law (Part 7)

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?

Is the current law clear to decision makers and users of the system? Does the content or structure of the current test cause you any significant problems?

To a large extent we believe that current Australian law meets the objectives of the patent system, insofar as it provides for appropriate standards of patentability, in line with international obligations and legislation in other jurisdictions. This is not to say that the application of those standards is always optimal. For example, there are legitimate concerns about the application of the inventive step standards, as highlighted in the Report *Venturous Australia*.¹⁵

However, there is a greater level of uncertainty about the manner of manufacture test and the role of the general inconvenience proviso and there is some lack of clarity about the industrial applicability/utility standard. The Full Federal Court decision in *Grant v Commissioner of Patents* [2006] FCAFC 120 (18 July 2006) and business method patent decisions in other jurisdictions have added to this lack of certainty. In particular, the ‘physical effect’ requirement lacks clarity. For this reason, we submit that it is timely to review Australian law and to move beyond the ancient manner of manufacture test. We explore this matter further in our response to Questions 7 and 11.

Question 7– Issues with current Australian law

Do you have any comments on issues A to H identified in Part 11.3.1?

- combination of flexible and proscriptive tests
- value of existing body of case law
- general inconvenience, mischievous to the state and hurt of trade
- archaic language
- threshold of inventiveness
- threshold of utility
- scope of rights awarded
- requirement for grant

A. We submit that a combination of flexible and proscriptive approaches works well in the Australian context. We believe that sole reliance on a proscriptive approach will cause confusion and is likely to lead to increased litigation. We agree that an explicit provision relating to mere admixtures of food and medicine is no longer required. However, the exclusion of inventions that are contrary to law should be proscribed, as

¹⁵ See above n 7.

should an exclusion for those inventions which are contrary to morality. The extent to which the human beings exclusion actually adds anything is open to question.

B. We submit that the NRDC principles have served us well in the past. However, the lack of a sufficient body of case law considering the application of the NRDC test in new fields of technology is problematic and even when cases do come to the courts, they may not provide the courts with sufficient opportunity to canvass all relevant issues for that particular field of technology. For this reason, we recommend that there should be improved mechanisms for establishing guidelines to assist patent examiners in particular fields of technology (see our response to Question 12).

C. We agree that it is appropriate to remove the general inconvenience, mischievous to the state and hurt of trade elements. In particular, general inconvenience is not the appropriate avenue for canvassing ethical concerns. It should be replaced with an explicit morality provision. While there may be some ongoing scope for general inconvenience in relation to insubstantial inventions, it is difficult to see how this interpretation is compliant with TRIPS. Provided that an invention satisfies the Article 27 requirements it is patentable irrespective of its value to society. We recognize that this is problematic, because it may mean that patenting of such inventions does not facilitate innovation or dissemination of knowledge.

D. We submit that the language of the Australian provisions should be brought up to date. It is difficult to see why we continue to cling to ancient formulations, which have been expunged from patent law in most if not all other jurisdictions. If nothing else, it is becoming embarrassing to have to explain to experts in other jurisdictions that we still retain the manner of manufacture test as a key component of our law. It seems somewhat anachronistic that the notion of manner of manufacture originated in ancient English law, yet it was removed from UK patent legislation in 1977 but continues in Australian law.

E. In our view the threshold test enunciated in *Philips v Mirabella* no longer stands following the decision in *Lockwood v Doric*. To take this conclusion beyond doubt, we recommend that the definition of invention should be removed from Schedule 1 and the concept of manner of manufacture should be replaced, as canvassed in more detail in our response to Question 11.

F. We submit that a clearly enunciated test for industrial applicability/utility should be introduced. We deal with this further below.

G. We support the notion of limiting patents to use-bound claims. There is active discussion of this option in Europe at the present time. As such, Australia would not be totally out of step with the rest of the world to consider this option. However, we submit that this matter requires much deeper analysis and should be the subject matter of a separate inquiry.

H. We submit that both the subject matter and the industrial applicability/utility criteria should be assessed on examination and should be grounds for opposition and revocation.

We submit that it accords with TRIPS to require that subject matter satisfies all of the requirements of: invention in a field of technology, novelty, inventive step, and industrial applicability/utility before becoming patentable.

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?

We submit that best practice should be the goal. There is no one jurisdiction that provides an ideal model for Australia. Our submission brings together a mixture of European and US laws and international treaty obligations.

Question 9 – International compliance of current Australian law Is current Australian law compliant with our international obligations?

As noted above, we have some doubt as to whether the general inconvenience proviso is compliant with TRIPS, depending on its interpretation by the courts. While there is lack of clarity in Australian legislation about whether the industrial applicability/utility requirement specified by TRIPS has been properly implemented, it would appear to be applied in practice by patent examiners in compliance with our international obligations.

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?

As previously mentioned, we have some doubt as to the extent to which the imposition of proscriptions relating to inherently patentable subject matter will be a key driver for meeting the objectives of the patent system, given the constraints imposed by our international obligations and best practice. Issues of innovation and dissemination of knowledge are multifactorial.

Nevertheless, we acknowledge that satisfaction of appropriate threshold requirements of inventiveness will continue to be vital in meeting the objectives of the patent system. In particular, inventions should clearly satisfy the requirement of physicality and should be in a field of technology, and clear distinctions must be made between discoveries and inventions and moral and immoral inventions.

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 specific subject matters be used?

Should such provisions be expanded, such as by including the exceptions from patentability allowed under TRIPS?

We suggest the following legislative structure could be adopted for section 18(1):

- (1) Subject to subsection (2),^[1] a patentable invention must satisfy the following criteria for the purposes of a standard patent, so far as claimed in any claim:
- (a) it is an invention in a field of technology;^[2]
 - (b) when compared with the prior art base as it existed before the priority date of that claim:
 - (i) it is novel; and
 - (ii) it involves an inventive step;
 - (c) it has industrial applicability,^[3] and
 - (d) it was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

Notes:

^[1] We have some doubt that subsection (2) is actually needed. Subject matter of this nature would either fail to satisfy the requirement of being an invention or would fall foul of the contrary to law provision already existing in section 51 and/or the contrary to morality provision that we propose should be included in section 51.

^[2] We submit that the requirement for there to be an invention in a field of technology should be listed as one of the criteria for patenting so that patent examiners explicitly address this requirement when considering patentability. The existing body of case law relating to the manner of manufacture test should continue to provide guidance in this assessment task. We submit that it is important to continue to make the distinction between inventions and discoveries. While the option of including the requirement for the invention to be in a field of technology in Australian law was rejected in the *ACIP Report on a Review of the Patenting of Business Systems* (2003) we submit that this option should be revisited. In the first place, this is simple adoption of the language in the TRIPS Agreement. Secondly, in our view, the requirement that the invention is in a field of technology is not a major extension of the *NRDC* requirement that the invention belongs to the useful rather than the fine arts. There may be some business methods that do not satisfy this requirement, but in our view they will be rare and the extent to which patenting of such subject matter actually encourages innovation and dissemination of knowledge is highly uncertain.

^[3] We submit that the industrial applicability/utility requirement should be given explicit recognition in Australian patent law. At present, the manner of manufacture test incorporates this requirement in part, and the usefulness requirement adds gloss, but greater clarity is desirable. To avoid confusion with terminology between old and new laws, we suggest that the language of industrial applicability is adopted, rather than usefulness or utility. If Australian law includes an industrial applicability requirement, then the old usefulness ground becomes otiose and should be deleted.

We also submit that the definition of invention in Schedule 1 should be deleted and with it any reference to section 6 of the *Statute of Monopolies* and to the concept of general inconvenience. It may be appropriate to include a definition of invention that includes requirements of physicality and technicality, but it may be preferable to specify these requirements in guidelines that assist examiners in determining whether the invention requirement has been satisfied. As noted previously and dealt with in more detail below, we further submit that further assistance could be provided to patent examiners in the form of an expert review panel or peer review

As previously mentioned, we submit that a contrary to morality ground should be added to section 51 alongside the contrary to law ground.

With regard to the TRIPS exclusions, we submit that our proposed morality exclusion would be TRIPS compliant. The plant and animal exclusion allowed under TRIPS cannot be introduced for standard patents because this would not be compliant with the AUSFTA. The method of treatment exclusion has been canvassed fully by the courts and we see little justification for re-opening debate about their patentability.

Question 12

Do you have any other comments?

In this submission we have alluded to the need for guidelines to assist patent examiners in the process of considering whether the subject matter requirements have been satisfied. We recognize that IP Australia provides guidance to assist patent examiners in its *Manual of Practice and Procedure* and that this is regularly updated. We do not question the quality or accuracy of this document. However, we submit that additional guidance may be required for some areas of technology, particularly for fields of technology where there is little or no guidance from the courts. We strongly support recommendation 8-2 from the ALRC Report *Genes and Ingenuity* that:

IP Australia should develop examination guidelines, consistent with the *Patents Act 1990* (Cth), the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria of patentability apply to inventions involving genetic materials and technology.

We submit that this recommendation could be expanded to include other fields of technology, particularly business methods and software. The guidelines could cover all of the patent and disclosure requirements, particularly the new industrial applicability requirement which, we have submitted, should be explicitly provided for in section 18. We further submit that these guidelines should be formulated in consultation with stakeholders.

It may also be appropriate to open the guidelines for a period of public comment to improve transparency and consultation, as was done for the US Utility and Written

Description Guidelines. We note that under the US *Administrative Procedure Act*, agency rulemaking (including rulemaking at the USPTO) is usually subject to ‘notice and comment’ requirements - i.e., release for a period of public comment followed by final rulemaking. There may be some justification for including such a requirement in Australian law, either generally for all administrative decision making or more specifically for patent guidelines.

We have also noted above that even greater assistance could be provided to examiners in difficult cases. One option might be to provide an expert review panel, which could make decisions on such issues as physicality and technicality with regard to the invention requirement, the distinction between inventions and discoveries and the morality exclusion. The ALRC Report provides information on some precedents for specialized patent advisory bodies in other jurisdictions and specialized bodies in other regulatory regimes in Australia, but only with regard to ethical matters.¹⁶

While the ALRC reported that they saw some merit in the establishment of a new ethics advisory body as a better mechanism for addressing social and ethical concerns than leaving such matters to patent examiners, it was concluded that such a mechanism would inevitably add to the cost and complexity of the patent system. However, we submit that if an expert body were given a broader mandate to advise on invention, industrial applicability and other matters in controversial areas of technology as well as ethical considerations, then the benefit from the perspective of facilitating innovation and dissemination of technology would outweigh the cost of increased complexity of the patent system.

In the alternative, we have suggested that a peer review system could be used to resolve some difficult cases. The US-based Peer-to-Patent project may provide some guidance in this regard. This project was launched in June 2007 with the support of the USPTO. Applicants voluntarily publish their patent applications on the Web for peer review. Although the primary focus of the project is on determining prior art for the assessment of novelty, it could be expanded to allow for deliberations on patentable subject matter as well.

¹⁶ ALRC, *Genes and Ingenuity* (2004) at 185-186.