

**SUBMISSION**

**to the  
Advisory Council on Intellectual Property**

**Patentable Subject Matter  
OPTIONS PAPER**

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The authors are both members of the Law Faculty at the University of Tasmania and members of the Centre for Law and Genetics. The Centre developed out of a project funded by the Australian Research Council (ARC) from 1994-1997. The primary focus of the project was the ethical and legal implications of advances in genetic technology. Since then, the Centre has had three further ARC and has expanded its areas of research to include broader issues associated with commercialisation of genetic technology, access to healthcare and biobanking.

Professor Dianne Nicol teaches in the areas of intellectual property law, equity, media law, IT law and biotechnology and the law. She is the Associate Dean for Research in the Law Faculty and Graduate Research Coordinator. Professor Nicol has a PhD in cell and developmental biology from Dalhousie University in Canada and an LLM in intellectual property law from the University of Tasmania. Her research interests particularly focus on the interface between innovation, research and access to healthcare in biomedicine. She has undertaken ARC funded research on cooperative strategies for managing intellectual property in biotechnology with colleagues from the Australian National University. She is currently in receipt of funding from the ARC for a project on patent pooling in biotechnology, in collaboration with Dr Nielsen and colleagues from Swinburne University and Japan. Dianne was appointed to the Advisory Board for the Australian Law Reform Commission (ALRC) inquiry into gene patenting and human health and was a consultant to that inquiry. Together with other members of the Centre for Law and Genetics, Dianne regularly makes submissions to public inquiries. She made joint submissions with Dr Nielsen to the ALRC inquiry and the Advisory Council on Intellectual Property (ACIP) inquiry into patents and experimental use.

Dr Jane Nielsen teaches primarily in the areas of competition law and torts. She has a PhD from the University of Tasmania. Her thesis focused on the interaction between intellectual property and competition law in the biotechnology area. Her research interests continue to consider the intellectual property/competition law divide, and how innovation in biomedicine may be optimised. She also has a keen interest in issues associated with compulsory licensing and access to medicines. Jane has commenced work on the authors' ARC funded patent pooling project, and her research will now examine this aspect of innovation in biotechnology. With Dianne, Jane has regularly made submissions to public inquiries, including to the ALRC inquiry into gene patenting and human health, and to the ACIP inquiry into patents and experimental use.

The authors made a submission to the ACIP Patentable Subject Matter Issues Paper (submission #11) and Nicol appeared at the Canberra public consultation

## The ACIP approach

We endorse the ACIP approach of separating out three distinct steps: economic test; social filters and enhancements. This is a logical way of dealing with the issues. However, we stand by our earlier submission that the threshold subject matter requirement has social as well as economic consequences. Its role is to mark out the boundaries of what subject matter is patentable and what is not. Discoveries, algorithms and laws of nature are not patentable because there is no social justification for allowing them to be (accepting that there are also economic reasons for their exclusion). Patenting of such subject matter is likely to have detrimental consequences in terms of the dissemination of knowledge, which is a social concern more than an economic concern. Hence, we prefer to refer to the first step as the subject matter test rather than the economic test. Social filters and enhancements flow on from this.

### Subject matter test: options A to D

The view that we expressed in our submission to the Patentable Subject Matter Issues Paper was that the manner of manufacture test should be **replaced** with an ‘invention in field of technology’ test. However, in the alternative we would support **clarification** of the test by adoption of the language of ‘artificially created state of affairs in the useful rather than the fine arts’. Contrary to the view expressed in the Options Paper at page 14, we are not of the view that the field of technology test would broaden the scope of what may be patentable. In our view, ‘invention’ means essentially the same as ‘artificially created state of affairs’ and ‘field of technology’ means essentially the same as ‘useful rather than fine arts’. While there will always be scope for judicial interpretation of any legislative provision, we do not see why the ‘invention’ test would be any more problematic than the ‘artificial state of affairs’ test. However, we can accept that there may be some support for retaining the vestiges of the NRDC test to keep a unique Australian flavour in the language of our patent law. Hence, we do not think it is out of the question to use the words ‘artificially created state of affairs’ and ‘useful rather than fine arts’.

In our view, there are a number of benefits in **removing** rather than **retaining** the manner of manufacture test. This test has served us well in the past, but it is becoming less relevant as the distinct set of patent criteria that together made up the manner of new manufacture test in 1623 become more and more separated. Novelty was the first criterion to become clearly separated out from the manner of new manufacture test, followed by inventive step and then utility/ industrial applicability (in many jurisdictions). Article 27(1) of TRIPS clearly illustrates this evolutionary process. Once manner of new manufacture is stripped of novelty, inventive step and utility it becomes a pure subject matter inquiry.

Retaining the language of manner of manufacture and manner of new manufacture in section 18 and Schedule 1 *Patents Act 1990* is apt to cause confusion, as illustrated in the *NV Philips* High Court case. See further discussion on this point below in relation to Option H. Removal of the language of manner of manufacture and manner of new manufacture will remove this uncertainty.

Removal of the manner of manufacture requirement will also clarify the distinction

between the subject matter inquiry and the utility/ industrial applicability inquiry in Australian patent law. The distinction between subject matter and novelty and inventive step is clear in the legislation. The same clarity should exist with regard to subject matter and utility/ industrial applicability.

Finally, removal of the manner of manufacture requirement will (should) take with it reference to general inconvenience and the other provisos in section 6 of the *Statute of Monopolies*. In our view, if we are to have a social filter in our patent law, it is far more appropriate that explicit language is used. Much has been written about the role of the general inconvenience requirement, but we still have no real knowledge as to how it might be interpreted by the courts, if they are ever given the opportunity to do so.

As such, our submission strongly favours replacement or clarification of the manner of manufacture test. We are strongly opposed to the view that the subject matter requirement should be **deleted**. It is not sufficient just to focus on the technical patent criteria of novelty, inventive step and utility/ industrial applicability. There **must** also be appropriate subject matter. Policy debates and court proceedings indicate that subject matter requirements are very much live issues in other jurisdictions as well as Australia.

## **Social filters: options E to G**

As noted above, we are not in favour of retention of the general inconvenience proviso or the other provisos from section 6 of the *Statute of Monopolies*. If the language of manner of manufacture and manner of new manufacture is removed from the *Patents Act 1990*, these provisos will die a natural death as well. We believe that this would be an appropriate outcome.

The ‘human beings’ exception in section 18(2) could be retained, but if an ordre public/ morality exclusion is added this exception is unlikely to serve any additional useful function. The plant and animal exception has been the subject of a separate ACIP inquiry. While there may be some justification for retaining or removing this exception, this issue will not be canvassed more fully at this stage in this submission. It is also questionable whether the discretionary considerations in section 51 serve any really useful purpose.

One other point that we believe needs to be raised is that if we are to retain any of these provisions in the Australian *Patents Act 1990*, they should be referred to as exclusions rather than exceptions, to distinguish them from the defence-type exceptions envisaged as permissible under Article 30 TRIPS.

We also see little value in adding a list of specific exclusions. If the subject matter inquiry is working as it should, then discoveries and the like will be filtered out based on their failure to satisfy this requirement. The addition of a specific list of exclusions is apt to cause confusion and invites litigation, particularly if words like ‘as such’ are included. The European experience does not instill confidence in the use of specific exclusions.

As noted in our submission to the Issues Paper, we support the inclusion of some sort of ordre public/ morality exclusion. While there will inevitably be some uncertainty as to the applicability of this requirement, we suspect that it is more likely to be under-utilised rather than over-utilised. A list of the types of subject matter that would be considered to be contrary to ordre public/ morality (similar to the list provided in the European Biotechnology Directive) would assist. This is precisely the type of issue where advice

could be sought from the proposed Advisory Panel, which would be able to evaluate contemporary public perceptions on issues of morality and make determinations as to the patentability of certain inventions based on its findings.

## **Enhancements: options H to J**

We strongly support the suggestion that the legislation should explicitly deal with inventiveness under the requirement that a patentable invention involves an inventive step. In our view it is undesirable for a patent application to be refused or a patent held to be invalid as a result of a threshold inquiry into absence of novelty or inventive step on the face of the specification, independent of the novelty and inventive step inquiries. We note that admissions as to lack of novelty or inventive step in the specification are relevant in ascertaining whether the novelty and inventive step requirements have been fulfilled and our submission is that they are only relevant to those inquiries. It was only because of the unique circumstances in *NV Philips* that it was necessary for the High Court to consider whether lack of novelty or inventive step could be raised as threshold requirement.

Our submission to the issues paper strongly endorsed the view that there should be greater clarity with regard to the utility/ industrial applicability requirement and that specific reference should be made to the requirements for specific, substantial and credible utility. We reiterate our view that it would be sensible in all the circumstances to adopt the language of utility or industrial applicability rather than retaining the language of usefulness. Presently, the usefulness requirement does not equate with the specific, substantial and credible utility requirement in US law. We argue that retaining the language of usefulness is apt to cause confusion, given that there is a body of case law that has interpreted the existing usefulness provision in quite a different way from the US utility requirement.

We strongly support the proposal for there to be an Advisory Panel to assist the Commissioner on Patents, not just on the social filters, but also on the subject matter requirement and other related matters. We suggest that the Advisory Panel should be given a wide mandate to consider any contentious patent matters. It would be unduly restrictive to limit the Advisory Panel to consideration of social filters. Further, we submit that the Panel should not be restricted to consideration of specific patent applications, but should be able to provide advice to the Commissioner on any contentious patent issues, as they arise from time to time.

In this respect, setting up a panel in the form of a statutory body like the National Competition Council (NCC) might be considered. The NCC has as its primary roles the provision of advice about competition policy matters, and recommendations to the Australian Competition and Consumer Commission as to whether access declarations under Part IIIA of the *Trade Practices Act 1974* (Cth) should be made. The main roles of the NCC have changed over time, with its original function being the provision of advice to State and Territory governments concerning the opening up of government agencies to competition.

Establishing an Advisory Panel with a statutory basis would allow the functions of the Panel to be reviewed and if necessary, altered over time. Expanding the remit of the Panel to matters outside the social filters would reduce the administrative burden of

establishing such a Panel. Allowing the Panel to research patent issues and provide non-binding advice to the Commissioner of Patents would also seem to us to be sensible given the number of inquiries conducted in respect of patent law issues over the previous decade, and the ever-changing nature of patentable subject matter.