

DEST Submission on ACIP Options Paper on Patents and Experimental Use

Background

As part of its portfolio interests, the Department of Education Science and Training (DEST) has responsibility for ensuring Australia has a strong science, research and innovation capacity and is engaged internationally on science, education and training to advance Australia's social development and economic growth. The Department is responsible for implementing the Government's objectives through its investment in research, science and innovation to support the development and use of new knowledge, and to encourage utilisation and commercialisation of public sector research. In this DEST has an interest in assuring a vibrant research and patenting environment.

As well as researchers in universities and university related organisations (especially Cooperative Research Centres), portfolio agencies likely to be affected by any amendment of the *Patents Act 1990* include CSIRO, Australian Nuclear Science Technology Organisation (ANSTO), the Australian Institute of Marine Science (AIMS) and the Australian Research Council (ARC). We understand the ARC and CSIRO are making their own submissions in response to the ACIP Options Paper.

Links to Other Reports/Inquiries

As noted in the ACIP Options Paper (pp.1-2), the *Australian Law Reform Commission Inquiry into Gene Patenting and Human Health* (ALRC Report 99) raises the question of an experimental use exemption, especially in Recommendation 13-1 (see Attachment A). As part of the Government's response to the ALRC report, DEST has expressed the view that ACIP should include in its deliberations the issues raised in the ALRC report and consider the implications of recommendation 13-1 in the wider policy context of ACIP's examination of the issue of an experimental use exemption. The Government can then consider the issue in the context of both the ALRC report and the ACIP inquiry.

Response to Options Identified by ACIP

The primary policy concern from DEST's perspective is to ensure that, the propensity to innovate is encouraged. This objective is consistent with the objectives expressed in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, Article 7.

At the very least, innovation should not be impeded either by excessive uncertainty in the patent system or by the restrictive application of intellectual property (IP) rights. A balance therefore needs to be struck between the rights of the patent holder, the rights of other researchers, and the need for an effectively functioning innovation system. It is also important that policy and regulation in this area take into account international developments to ensure that Australia's arrangements are in harmony with international practice. This is important in encouraging international collaboration in research and potential overseas investors in Australian technology and innovation.

It is noteworthy in this context that publicly funded research organisations have interests both as patent holders and as research organisations that may wish to conduct experiments and research on patents. On the one hand, licensing-in patented technologies for experiments and investigations could become costly if an experimental use exemption were not available, or were too narrowly defined. On the other hand, these organisations

also recognise the need to ensure an appropriate level of protection to those inventions which have been granted patent protection when the invention's main market or application relates to research activities (e.g. new investigative tools or methods). Research organisations are also conscious that the greater the degrees of uncertainty, the greater the difficulty in ensuring that researchers properly understand the legal environment in which they are working.

'Research Tools' Illustration

An illustration of a legitimate interest of a patent holder is provided by the case of 'research tools'. These are materials and instruments that are sold commercially to customers who wish to use them in research. Patentees should be allowed to stop others from marketing these tools commercially without a licence from the patentee (unless, of course, the needs of the market are not being met). But this should not stop a researcher from making the material or the instrument purely for the purpose of his or her own investigations. If on the other hand, a reagent is being used for routine testing, such as in a commercial pathology laboratory, the patentee should be entitled to require the laboratory to have a licence to use the reagent.

DEST therefore agrees with the principle that researchers should have the explicit right to perform research on the content (form and function) of a patent. The Department supports the need to reduce the level of uncertainty that currently exists about the existence and potential scope of such an exemption in common law.

DEST notes that while this uncertainty has yet to be manifested in the form of litigation in Australia, the recent decision in the United States in relation to *Madey vs Duke* could provide a precedent. Depending on possible future US legal and/or policy interpretations of the *Madey vs Duke* decision, there is the risk that research and innovation among Australia's public sector research institutions and their researchers could be disrupted by Australian courts applying the uncertain *Madey vs Duke* test (originally established in an 1813 US case). At worst, researchers may be prevented from carrying out certain research because the patentee refuses to give them a licence. They could also face an additional financial burden in using patented rights expressly for experimental purposes. This uncertainty and/or financial burden could result in delays or the cessation of investigations and research.

IP ownership/benefit sharing issues where researchers in the public and private sectors form consortia and become joint patent holders is also an important consideration. In such circumstances it is desirable to have as great a level of certainty over IP ownership rights as possible.

DEST also notes that there is widespread debate among Organisation for Economic Cooperation & Development (OECD) countries on this issue, with a range of measures taken, including no regulatory action. Complicating consideration of the issues is the as yet unknown implications of harmonisation policies under trade related aspects of intellectual property rights by the World Intellectual Property Organisation. DEST believes that experimental use is a sufficiently important and contentious issue that it should be included as part of the international efforts to harmonise intellectual property laws. If at all possible, Australia should avoid adopting an approach that is not in broad accord with the laws and practices of the major countries with which it trades. In particular, we are also yet to see the full effects of recent bilateral agreements such as the Australia-United States Free Trade Agreement (AUSFTA), and emerging IP rights issues in areas such as bioinformatics and nanotechnology and future innovative technology services.

Against the background of this evolving policy environment, DEST makes the following specific observations on ACIP's preferred Options (page 17 of the Options Paper).

Option B

No Change

The primary effect of this option is that it leaves determining the nature and extent of the experimental use exemption to the courts, when and if the matter is brought before them. This would mean that decisions would be based on the specifics of the case and precedence.

The risk in this option is that the policy principles outlined above may not be given due weight in any judicial deliberation on a specific case. DEST therefore believes that formalising some form of experimental use exemption is desirable. The need is greater now than it perhaps was in the past because researchers and research organisations are increasingly aware of the potential value of their IP and are seeking to protect and exploit their inventions and ideas. More aggressive IP protection practices increase the risk that current research activity could be found by a court to be infringing the rights of patent holders, especially if the principles established by cases such as *Madey vs Duke* are applied indiscriminately or without full regard to the potential impact on the propensity to innovate.

As emergent technologies become increasingly dependant on scientific discovery, it seems likely that patent holders may seek to make claims on knowledge previously regarded as 'fundamental science' (e.g. biotechnology enterprises seek to patent genetic sequences whilst nanotechnology enterprises seek to patent molecular structures). Any existing implicit experimental use exemption is arguably becoming less effective as it fails to provide a means for demarcating 'fundamental scientific knowledge' from 'proprietary information' and a legal challenge to an implicit exemption seems increasingly likely.

Option C1

Modify the definition of exploitation to not include experimental use, without further defining the term.

Whilst this Option would serve to codify the experimental use exemption, it does not appear to provide much more certainty than Option B. It would still presumably require case law to define what 'experimental exemption' means, which could limit opportunities to identify which current practices infringe and make necessary adjustments to future practices/research approaches.

Option C7

Exemption for 'fair experimentation' with inclusive permitted uses.

This Option addresses both underlying principles and guidance regarding experimental use. It also provides an opportunity to make changes to current practices that are considered to be infringements in light of explicit defence of experimental use. In addition, by drawing on the copyright 'fair dealing' analogy it has the advantage of providing the courts with a further point of reference in interpreting 'fair experimentation'.

In addressing the details of Option C7, DEST suggests ACIP may wish to consider the following issues:

- The inclusion of ‘the commercial effect of the act upon the patent holder’ as one of the factors to be considered when determining whether an act is ‘fair experimentation’ may place an unreasonable burden on the experimenter. In most instances it seems unlikely that an experimenter would have any way of knowing the commercial status of the patent holder and attempting to fulfil this consideration could add uncertainty to the process. ACIP may therefore wish to consider removing the question of commercial impact.
- The factors and acts covered in Option C7, together with consideration of the public interest, could be specified in the Act as factors to be considered by (but not limiting) a court in deciding the relief, if any, to be granted under section 122(1) of the Act. The approach would be directed at placing the onus on the patentee to establish the actual or potential harm suffered by the patentee as a result of the experimental use, as opposed to placing the onus on the researcher to establish that the use in question falls within the allowed experimental use. This approach might also be more compatible with enforcement provisions such as TRIPS Articles 44 and 45 and AUSFTA Article 17.11, than would be the exclusion of ‘experimental’ activities as exceptions to the patentee’s rights under TRIPS Article 30 and 31 or AUSTFA Articles 17.9(3) and 7.9(7).
- There may also be merit in adding a form of compulsory licence to the remedies available to under section 122(1). ‘Reach-through’ licensing, for example, can allow for royalty-free use of the patent during the experimental stage, with a later obligation on the researcher to account to the patentee, according to the proportion of the ‘commercial value’ of the product or process developed (or some other measure of ‘value’ to the researcher, such as research grant(s) or research contract payments) that is attributable to the researcher’s earlier use of the invention. This might help avoid protracted licence negotiations in the early stages of experimentation where the ultimate product or process to be developed is possibly unknown and its ‘value’ indeterminate.

Option C8

Exemption for experimenting ‘on’ the subject matter of the invention, with inclusive permitted uses.

Option C8 is more specific C7, in that it seeks to provide some guidance on what is considered experimentation ‘on the subject matter of the invention’. However, as noted in the Options Paper, there is a risk that the notion of ‘subject matter’ may be too vague, leaving the way open for parties to a dispute to interpret it very widely or narrowly, as the case may be. Also, in practice it is likely that many experiments ‘on’ a patented technology would involve conducting the experiments ‘with’ that technology, rendering the distinction problematic at the very least.

Further Consideration of Options D1 and D2

In their current form, DEST does not consider Options D1 or D2 provide a solution to the experimental use issue. However, they may in their own right warrant further investigation with some amendments.

Specifically, DEST notes the concern expressed in the ACIP Options Paper that a restriction to 'the utility of the invention disclosed in the specification' might be in breach of TRIPS and AUSFTA because it might preclude the patentability of products where utility is unclear, or not, described in the specification. DEST would observe, however, that for the invention to be patentable, it is a statutory requirement that the invention be useful and that within the patent examination process, utility (along with several other parameters) has to be ascertainable from the specification, expressly or implied. That is, utility may not necessarily be 'disclosed' in the specification.

DEST notes that the utility of patented inventions was considered by the recent ALRC report on *Gene Patenting and Human Health*. Recommendation 6-3 proposes the Patents Act to be amended to include 'usefulness' as a requirement in the examination of a standard patent. A patent application would be judged to satisfy this 'usefulness' requirement only if the patent discloses 'a specific, substantial and credible use'. DEST sees potential for a modified form of Options D1 or D2 being used to address this issue of demonstrable utility, whilst simultaneously providing the courts with the means to determine fair experimental use.

Development of Guidelines

Regardless of whether an implicit experimental use exemption remains or the Act is amended to include an explicit exemption, DEST suggests there would be value in developing guidelines to provide indicative advice on what practices might attract a patent infringement claim. One vehicle for such guidelines (at least in the context of publicly funded research) could be the *National Principles of IP Management for Publicly Funded Research*. The *Principles* were developed in 2001 by a number of Commonwealth agencies and organisations concerned with public sector research, including the ARC, IP Australia and the National Health and Medical Research Council (copy available at: <http://www.nhmrc.gov.au/research/general/ipman.pdf>).

Although such guidelines would not be expected to be mandatory, they could be a valuable 'risk management' tool since they would assist researchers to assess whether practice is likely to infringe patent holder rights.

Conclusion

DEST considers that a legislated experimental use exemption would be a desirable innovation in Australian patent law. The specific form of that exemption (i.e. in terms of the choices between Options C1, C7 and C8) is probably best determined by consideration of the legal principles involved. On balance, and for the reasons outlined above, Option C7 would seem to have the greatest prospect of success in terms of providing certainty while balancing the interests of patent holders and researchers and promoting the propensity to innovate.

Further investigation of Options D1 and D2 in a modified form is also recommended.

**Department of Education, Science & Training
March 2005**

Australian Law Reform Commission Inquiry into Gene Patenting and Human Health (ALRC Report 99) Recommendation 13-1

13. An Experimental Use Exemption

13-1 The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention; for example, to investigate its properties or improve upon it. The amendment should also make it clear that:

- (a) the exemption is available only if study or experimentation is the sole or dominant purpose of the act;
- (b) the existence of a commercial purpose or objective does not preclude the application of the exemption; and
- (c) the exemption does not derogate from any study or experimentation that may otherwise be permitted under the *Patents Act*.