

**SUBMISSION TO THE  
ADVISORY COUNCIL ON INTELLECTUAL PROPERTY**

**PATENTABLE SUBJECT MATTER<sup>1</sup>**

**General Comment**

The just released Australian government review of national innovation system can only be described as scathing of the patent system. Such a critique should sound warning bells that the system is losing support among its users – and therefore seriously raises the question of whether the system is adequately meeting their needs.

For instance, the report states:

“There is mounting evidence that [the patent system] is impeding rather than stimulating innovation. There is widespread anxiety about whether a ‘patent thicket’ has developed in software as a result of software patenting with many large firms consciously developing ‘patent pools’ with which to defend themselves against other’s patent claims.”<sup>2</sup>

... “it is imperative that IP policy make the transition that competition policy made over a decade ago now, from a specialist policy area dominated by lawyers, to an important front of micro-economic reform.”<sup>3</sup>

From a university viewpoint, the patent system is not ideal. Universities are generators of “invention” and disseminators of knowledge. The patent system presents unreasonable costs to Universities in terms of protection of potentially large patent portfolio, and thus a barrier to dissemination of university innovation through commercialisation.

The rule of thumb figure required for the international patent protection of invention in the “usual markets” is in the order of \$100,000. It is easy to conclude that any university seriously engaged in innovation will not be able, itself, to meet the costs of fully protecting its intellectual property through the use of patents. Universities are not funded to hold patent portfolios, creating a situation either of vulnerability or of potential exploitation by commercial partners who are looked to, to fund such protection, (where appropriate). There appears to be no reason why the costs of patent protection should be of this scale: the cost is largely generated by redundant national fees required for protection in multiple jurisdictions. By comparison the cost of international copyright protection is close to zero - it automatically attaches to copyright matter.

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<sup>1</sup> Submission on behalf of the Australian National University prepared by Michael Curtotti, Senior Legal Officer, ANU Legal Office.

<sup>2</sup> Review of the National Innovation System p 84,  
<http://www.innovation.gov.au/innovationreview/Documents/NIS-review-web.pdf>

<sup>3</sup> Ibid p 85

Patents purport to be descriptions of property. It is questionable whether they effectively achieve this objective. Compared to a system such as Torrens title which does substantively achieve the objective of reliably, indisputably and disjunctively<sup>4</sup> describing an item of property, patents are manifestly inferior. A patent is not a tool that is easy to use, even for professionals engaged in the field. The proper management of a patent portfolio thus necessarily implies the repeated engagement of external professional expertise to assist in its management. The language of patents and patent law are problematic in this respect, to the point where significant change would be required to make them accessible to the key users who might reasonably expect to be able to interpret and apply the meaning and effect of a patent, say in the day to day operations of a university, without extensive training.

The number of patents now issued (with an implicit requirement that the patent field be searched when considering commercialisation), is overwhelming. There is no prospect that universities would either wish to, or have the resources to be able to repeatedly search through such bodies of patents to determine the “intellectual property landscape” in respect of its ongoing innovation and commercialisation activities. This significantly impedes a university and its innovators from planning strategically those innovations that might have a reasonable prospect of avoiding existing patents and therefore entering the market place.

Patent associated litigation is, to say the least, an unattractive option, if a university is faced with a need to protect its innovation or resist claims of patent infringement.<sup>5</sup>

The kinds of concerns that are expressed above and in the National Review of Innovation are of course also implicit in the questions raised by the ACIP in its discussion paper. Given the current climate of review of innovation and questioning of the role and effectiveness of the patent system, ACIP may wish to take the opportunity to consider more substantive reform of the patent system than might otherwise be contemplated. Given the international aspects of patent law, such reform might inevitably require international and well as national review. Universities need a system which can be used with reasonable facility in practical day to day operations without a burden of unnecessary costs (which must be drawn away from teaching and research).

### **Experimental Use Exception**

Before turning to the specific questions raised by ACIP, the University wishes to raise the experimental use exception. In February 2003 ACIP was asked to consider the question of an experimental use exception by the then Australian government. ACIP found that there was a greater need for certainty as to the existence and scope of the exception and

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<sup>4</sup> That is in a manner in which there is no overlap between “adjacent” patents

<sup>5</sup> The Review of the National Innovation System makes the observation that “many Australian innovators feel an acute lack of access to cost effective dispute resolution in the Australian system.” p 86.

made four recommendations for amendment of the Patent Act to embody the exception. The Australian government accepted all these recommendations.<sup>6</sup>

This is not merely a theoretical issue. The current ambiguity in law gives rise to situations where Universities must either accept the risk of legal ambiguity or invest resources in negotiating perpetual, irrevocable research and development licences whenever assigning or exclusively licensing patented intellectual property. Further commercial partners often seek to control the subsequent research activities of an assigning university. The proposals advanced by ACIP will not solve this problem as there is nothing preventing a contractual requirement of commercial partner consent to research activities. An additional provision is required to ensure that those universities most able to further advance innovation are not faced with demands for external control of their research: i.e. a provision which makes any purported contractual provision which restrains the experimental use of patented matter void.

**Recommendation:** That ACIP raise with the government implementation of previous recommendations concerning the experimental use exception and address the issue of contractual obligations which seek to restrain experimental use of patented matter by research bodies as outlined above.

## **RESPONSES TO ACIP QUESTIONS**

The following are additional comments on some of the specific questions raised by ACIP in its discussion paper.

### **Question 1 – Economic objectives of limiting patentable subject matter (Part 3) Can placing limits on inherently patentable subject matter be justified on economic grounds?**

In response to this question it may be observed that it is the *patentability* of matter that requires justification on economic grounds, rather than the limitation of patentability.

This is merely to observe that a patent, at its heart, is a grant of a monopoly, with consequent implications for limits on competition and increased pricing to the marketplace.

The traditional justification for the grant of patents is of course an exchange between society and inventors, in which inventors are provided with the potential for super profit in return for disclosure for their invention and eventual open availability of the invention to society. As observed in the ACIP discussion paper, this kind of rationale is reflected in article 7 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property.<sup>7</sup> This seems to us

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<sup>6</sup> Australian Government Response to the Advisory Council on Intellectual Property Report Experimental Use Exception <http://www.ipaustralia.gov.au/pdfs/news/20070708.pdf>

<sup>7</sup> ACIP Issues Paper *Patentable subject matter* p 7

to remain the pertinent *policy* test of whether patenting (or the patenting of any particular invention or subject matter) can be justified.

That the issue is more than theoretical is illustrated by the contested case of software patenting, in which there is real empirical evidence that there is no connection between the fostering of research and development and the ability to gain patent protection.

**Recommendation:** As far as possible patenting should not extend beyond those cases where in fact the desired exchange of value between society and inventor is achieved. The limitations of patentable matter (however conceptualised) should be tested light of this fundamental objective.

### **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?**

Ethical considerations apply in every field of human activity. There does not appear to be any inherent reason that patenting might by its nature exempt from such ethical considerations. The sciences, a field with which Universities are intimately concerned, has progressively improved its adherence to ethical standards because it is clear that such standards are necessary if unintended harm is to be avoided in particular circumstances.

In a democracy it is perfectly appropriate for Parliament to determine ethical limits in consultation with the public which it represents. Parliament is in fact designed for this role, while the courts are not. The courts are not inherently designed for the determination of questions of policy or ethics (although in many cases they display considerable expertise in dealing with such questions).

Nonetheless, their role is to determine disputes between persons bringing specified causes of action. Their rulings turn on a multitude of fact issues that any case may raise and strictly speaking the only parties bound by a court decision are the parties to the proceeding. While the courts should in accordance with their mandate be free to take into account what policy or ethical/equitable consideration they determine appropriate, this is not incompatible with legislation which determines (as has been done by Australia) that certain forms of patenting are ethically flawed and should therefore be excluded from patentability. An undesirable aspect of court decisions is that they may be mutually contradictory, difficult to apply to different fact situations and inaccessible to the general public.

**Recommendation:** As far as possible any ethical limitations on patentable subject matter is better stated in legislation rather than left to the courts.

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

Patent law cannot be considered to be exempt from ethical issues. It would be irresponsible for patent law to fail to deal adequately with ethical issues that arise in its operation.

One area where patent law has contributed to what might reasonably be concluded to be “ethical” failure is in respect of access to medicine for the poor in developing countries. While patent law is only one element of the economic systems involved, it is nonetheless an important and influential element.

The most notorious instance of this issue is the AIDs pandemic and drug availability for its treatment. AZT, one of the early treatments for AIDs was patented by the pharmaceutical company Burroughs Wellcome (BW). Their asking price for a year’s supply of the treatment (the difference between life and death for sufferers) was US\$10,000. The pricing was justified by reference to ‘research efforts’, claims disputed by public agencies which contributed to the development of the drug. Efforts to have the patent revoked were unsuccessful although the patent expired in 2005. Current day treatments rely on a combination of drugs to overcome HIVs capacity to mutate around any single drug. Such a combination is now available in generics produced in the developing world including India and Brazil and the pricing has been brought to US\$137 per year’s supply. The patent system hindered rather than contributed to the global response to AIDs.<sup>8</sup> It is well known that the impact of the AIDs pandemic has been dire. In sub-Saharan Africa life expectancy has been reduced by 20 years and 12,000,000 children under the age of 18 have lost one or more parents to the disease. Its economic impact on those societies has also been dire. 25 million people have died from AIDs related causes. Even today the number of new cases of the disease is increasing at a greater rate than the spread of antiviral treatments to combat it. Nonetheless global deaths are stabilizing at the extraordinary figure of 2,000,000 deaths per annum.<sup>9</sup> Sensibly the international community has set the goal of universal access to antiviral treatment as a key strategy in combating the disease.

That patenting remains an issue is illustrated also by the most recent UNAIDS report on the disease.

*“In settings where health resources are so limited, many medications are deemed too expensive for routine use in resource-limited settings (Steinbrook, 2007). Historically, this has been particularly true for new, patented medications, developed by pharmaceutical companies in high-income countries.*

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<sup>8</sup> Human Rights and the WTO The Case of Patents and Access to Medicines Holger Hestermeyer Oxford University Press p 5 et seq

<sup>9</sup> 2008 Report on the Global Aids Epidemic UNAIDS pp 13-15

*As in many other arenas, the HIV response has helped forge new ways of improving access to essential medications in low- and middle-income countries. Due to activist pressure, the emergence of competition from generic manufacturers, and direct negotiations with pharmaceutical companies by UNAIDS and other partners, prices for the leading antiretroviral drugs have fallen sharply during the last ten years. What has emerged is a pricing regime that has long been advocated by global health experts but seldom put into practice; that is, “tiered” pricing, whereby companies charge different prices depending on a country’s ability to pay. The new approach to drug pricing has freed up substantial resources for health services in low- and middle-income countries. For example, it is estimated that Brazil saved approximately US\$ 1 billion between 2001 and 2005 as a result of its domestic generic manufacture of eight antiretroviral drugs and its negotiation of price reductions from manufacturers (Nunn et al., 2007). National governments in 94% of countries with generalized epidemics, as well as in 61% of countries with concentrated epidemics, report having national policies for using generic drugs or parallel importation of medications to promote antiretroviral access (UNGASS Country Progress Reports 2008).”<sup>10</sup>*

HIV-AIDS is only one case in which the access of medical treatment for the poor is restricted for reasons similar to the foregoing. An issue is whether Australian patent law enables manufacturers in Australia to produce generics for developing country markets where a critical drug treatment may otherwise be practically unavailable. This is significant because many developing countries lack the infrastructure to undertake manufacture locally.<sup>11</sup> Another issue is whether the patenting system promotes or tends to marginalise research effort and the dissemination and application of solutions that are specifically directed to addressing the medical issues facing a significant proportion of the human population. The absence or relative paucity of commercial mechanisms fostering and enabling the application of such research effort can reasonably be concluded as contributing to the significant disparity in health outcomes between developed and developing countries.<sup>12</sup> This raises unavoidable ethical questions such as whether patent law is “ethical” in respect of innovation which it tends to reward as opposed to that which it does not, and in respect of the additional expense it may imply in circumstances such as the above.

Thomas Pogge examines these issues and seeks to propose alternative mechanisms that might lead to the same results. One option he presents involves three components:

- Public licensing of new *essential* drugs to all pharmaceutical companies
- Inventor firms would still receive what he describes as a “multiyear patent”, but would be rewarded out of public funds in proportion to the impact of their invention on the global disease burden. This would reorient incentives in a manner that would promote the creation of drugs

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<sup>10</sup> UNAIDS report 157

<sup>11</sup> Hestermeyer 150

<sup>12</sup> Malaria, pneumonia, diarrhoea and tuberculosis is said to account for 21 percent of the global disease burden but receive a mere 0.31 percent of all public and private funds devoted to health research. See *Human Rights and Global Health: A Research Program* Thomas W Pogge Blackwell Publishing Metaphilosophy Vol 36 No 1 / 2 January 2005, p 189

for the poor. In such a scheme copying of the drug by generic suppliers would reward the innovator by additional public funding. The aim would be to align moral and prudential issues so that an investor is not forced to choose between recouping investment and addressing global health needs.

- The third component would concern the design of workable rules for the implementation of such a system.<sup>13</sup>

Whether one agrees with Pogge's proposal, it seems undeniable, given the scale of *preventable* human suffering involved that serious consideration of the ethical dimensions of innovation and patentability is required. Universities are of course centrally concerned with innovation. ANU has endorsed a document prepared under the auspices of the Association of University Technology Managers titled *In the Public Interest: Nine Points to Consider in Licensing of University Technology*.<sup>14</sup> It also observes that millions around the world are dying from preventable diseases,<sup>15</sup> and urges universities as follows:

*"We recognize that licensing initiatives cannot solve the problem by themselves. Licensing techniques alone, without significant added funding, can, at most, enhance access to medicines for which there is demand in wealthier countries. Diseases that afflict only the global poor have long suffered from lack of investment in research and development: the prospects of profit do not exist to draw commercial development, and public funding for diseases suffered by those who live far away from nations that can afford it is difficult to obtain and sustain. Through thoughtful management and licensing of intellectual property, however, drugs, therapies, and agricultural technologies developed at universities can at least help to alleviate suffering from disease or hunger in historically marginalized population groups."*

It is a reminder that no single element of the innovation system is solely the cause of such outcomes and that research organisations have a role to play. ANU is seeking to implement the Nine Points, but universities are in a relatively weak position to pursue such outcomes, without broader structural changes that might incentivise commercial agencies in respect of such issues.

**Recommendation:** That consideration be given to changes that might be undertaken through the patent system to remove current disincentives to research and dissemination of research to meet health and other basic needs of the global poor.

**Question 7– 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

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<sup>13</sup> Pogge pp 188 - 192

<sup>14</sup> [http://www.autm.net/aboutTT/Points\\_to\\_Consider.pdf](http://www.autm.net/aboutTT/Points_to_Consider.pdf)

<sup>15</sup> Nine Points to Consider, p 8.

- **threshold of inventiveness**
- **threshold of utility**
- **scope of rights awarded**
- **requirement for grant**

Obscurity is to some degree an inevitable consequence of a system which seeks to encourage innovation by equating the product of innovation with property: i.e. with a set of concepts designed to deal with the ownership of physical objects or land.

Nonetheless patent law might reasonably be regarded as excessively arcane and containing avoidable and unnecessary regulatory burdens on industry and innovation.

Whatever merits the system of precedents and common law may have, one of them is not clarity and ready accessibility of law. If the central content of patent law must be sifted from lengthy (and often mutually inconsistent) judicial pronouncements, one may conclude that the codification of these principles is called for. In a democracy, any citizen should be able to ascertain the law without the need of a lengthy, specialist education. This far from possible in respect of patent law, and is not even possible for central users of the patent system. While such ideals are honoured more in breach than observance, nonetheless regulators have an ongoing obligation to ensure that the law strives for this ideal and attains it wherever possible.

For a university there are a number of user categories who must apply the patent system:

- a. academics who may generate inventions;
- b. commercialisation officers who are responsible for interface with industry and for enabling the process of technology transfer;
- c. lawyers responsible for advising on the application of law;
- d. management responsible for decision making in respect of management of complex intellectual property portfolios.

In respect of clarity and ease of application, Universities are not well served by the patent system. The costs of ascertaining the patentability of an invention are high, and the ability to determine whether new innovation may infringe an existing patent is low and beyond practicability in the day to day operation of a university. Generally the University must meet the costs of patenting up front, with only the potential to recoup these costs down the track. The figure often cited for patenting across relevant jurisdictions is in the order of \$100,000. Most of this figure is generated essentially by multiple government imposts imposed by each national jurisdiction. A better arranged system would avoid such multiple taxation.

**Recommendation:** The University does not advance a specific recommendation but notes that the language of patent law is arcane, difficult to access, is excessively costly and does not serve users well. Its improvement is warranted.

## **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?**

Knowledge is not limited by boundary. The current international patenting system carries the burden of multiple jurisdictional registration – the only apparent benefit of which is to finance the operation of a multiplicity of national filing regimes. The PCT system eases the administrative burden to some degree. It does not remove the cost.

The current system is not of course a true international system – such a system would consist of a single cross jurisdictional registration within one national or international bureau without the need to traverse multiple jurisdictions, or to pay multiple fees.

Harmonisation of our law with that of others therefore seems an inadequate goal, if the patent system is to be significantly improved in this respect.

**Recommendation:** Consideration be given to steps to enable a true international patent registration system, with registration fees similar to those that might be incurred to file in a single jurisdiction. Given the problems that have been identified, the University considers that Australia should not move closer to the U.S. patent system. Any new international system should preferably not have the characteristics of the U.S. patent registration system.

**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?**

The ANU considers that it is preferable that software not be patentable and more generally that patentability not be further extended. Reforms should not result in the further extension of patentable material.

There is an inherent tendency for the scope of intellectual property rights to grow over time. For instance when first created, copyright lasted only 20 years and was a far more restricted concept – it now extends over a far broader range of subject matter and the standard adopted by Australia is the life of the author plus 70 years.

This is relevant for instance in respect of software which attracts copyright protection and which arguably does not constitute an invention: at least not in the same manner that would have been imagined when systems of patenting were first created.

In terms of the dissemination of knowledge and its free use, this tendency is a matter of concern. For instance, Albert Einstein's copyright work is currently not in the public domain in Australia. Given that the theory of special relativity was written in 1905 serious questions must be raised as to dangers to the dissemination of knowledge

represented by the urge to continuously extend intellectual property rights and the difficulty of going in the opposite direction.

Following Australia's adoption of AUSTA, Australia extended its term of copyright to the life of the author plus 70 years, in line with the United States. In the United States the extension was derisively referred to as the Mickey Mouse extension due to the extensive lobbying of the commercial owners of such cartoon characters. Proponents of the Bill made no secret of the fact that they would have liked to see copyright protection extended "forever".

In terms of the patent system a similar recent extension that cannot be grounded in the basic policy rationale of patenting is the extension of patenting to software. Software development has been a flourishing area of innovation extending well before it began to attract patent innovation. It has thus been an area of particular study around the question of whether patenting has assisted or impeded further innovation in the system.

For instance the economic analysis of software patenting by Bessen and Hunt concludes that the dramatic increase in patenting of software in the United States (after court decisions made it possible in that jurisdiction) cannot be explained by the traditional incentive theory of patenting: i.e. the use of patents does not encourage research and development in respect of software. "The vast majority of patents are obtained by firms outside the software industry with little investment in the inputs (computer programmers) required to develop software inventions. ... Industries known for prodigious patenting in general account for the vast majority of software patents obtained."<sup>16</sup> Conversely they conclude that "The patent thicket explanation is consistent with the observed rise in patent propensity and the negative relationship between changes in software patent share a research intensity in certain industries ... If, ... the legal changes have encouraged strategic patenting, then the end result might be less innovation."<sup>17</sup>

Further the National Innovation Review, citing Bessen and Meurer notes that software patents are four times as likely as other patents to attract litigation.<sup>18</sup>

These kind of findings seriously suggest that patenting of software is unjustifiable in terms of the economic theories on which patenting is justified.

The concern is strengthened if we consider the manner in which software is produced. Software is both a product creation industry and a service industry. A product in one context may freely be interchanged with a tool in another. For instance computer code for the rapid sorting of a collection of data is a utility which may be incorporated into other code to achieve a more direct result, such as the provision of a database that can be operated in real time in some practical context. The software engineering industry has responded to the challenges of the creation of increasingly complex software artefacts by

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<sup>16</sup> The Software Patent Experiment James Bessen and Robert M Hunt, 14

<sup>17</sup> Bessen and Hunt, p 15

<sup>18</sup> National Innovation Review, p 84

creating massive public access “tool libraries”<sup>19</sup> which form modular components of yet more complex software artefacts. For instance a program providing a graphical calendar facility can be considered a separate product, it readily becomes a sub-component of more complex software to which a calendar is ancillary. So far from patenting and seeking to monopolise such material, the industry recognises that it shares an interest in making available to software creators increasing bodies of code that constitute re-usable components – in most cases freely and without charge.

The result, as might be expected, is enhanced innovation, and interoperability of software and an increased ability of software engineers to work on each others code. Cost of both creation of code and its maintenance is reduced and speed of innovation is increased. At least such beliefs drive the behaviour of software developers.

The patenting of software represents a serious threat to the operation of an industry founded on such tenets, and which has amply demonstrated it has no need of patent protection to encourage innovation. There is thus a case for legislative reversal of court decisions which have extended patentability to software.

**Recommendation:** That consideration be given to the legislative reversal of the patentability of software.

**Would your preferred content be compliant with Australia’s international obligations?**

Australia should comply with its international obligations.

## **Question 12**

**Do you have any other comments?**

We ask the committee to note our general comments, and particularly our comments and recommendations on the Experimental Use Exception.

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<sup>19</sup> An example is the extensive java development kit created and distributed by Sun Microsystems <http://java.sun.com> which provides software code enabling rapid development of business applications, graphical interfaces, database tools, input/output utilities to name just a few. Similar libraries are provided by Microsoft, and the proponents of most of the major programming languages in which software is actually created.