Current Issues Facing Australian IP Law With Regard To Living Matter
By Tim Doty II

I. Introduction

Since the inception of the plant breeder’s rights regime, the Australian Government has attempted to harmonize the patent system with plant breeder’s rights.1 The Australian Government established The Advisory Council on Intellectual Property (ACIP) in 1994 to fulfill this goal, among others, while executing its advisory functions regarding intellectual property matters and the strategic administration matters of IP Australia.2 The ACIP operates under “a broad strategic view of the role of intellectual property and its contribution to the development of the Australian industry.”3

The ACIP is an independent body created to supply guidance to IP Australia and the Minister for Industry, Tourism and Resources on matters of policy and administration of intellectual property law in Australia.4 The council is comprised of a cross section of the intellectual property industry including members of the large and small business sectors, attorneys and legal professionals and academics.5

Two issues which impact Australia’s intellectual property law with regard to living matter have recently come under consideration by the ACIP. First, the ACIP considered the impact of the exclusion of plant and animal subject material from the innovation patent.6 Secondly, the ACIP is currently conducting a review of whether patent rights may be inhibiting research and development in certain industries, particularly in regards to biotechnology.7

II. Consideration of the Exclusion of Plant and Animal Subject Matter From the Innovation Patent

In November 2004, the ACIP completed a review which considered the exclusion of plant and animal subject material from the innovation patent. The review process began with the
release of an issues paper seeking written comments from interested parties, followed by an analysis of these comments, a round table discussion by the ACIP, and a final report with recommendations of the ACIP.8

The ACIP introduced innovation patents to the Australian Government in 2001 to provide inexpensive second-tier patent protection as a safeguard for small, incremental innovations.9 The innovation patent provides for a lower inventive threshold than the standard patent while retaining many of the same protections as the standard patent.10 While the ACIP suggested that the innovation patent be available to all subject matter available for a standard patent, the Australian Parliament had concerns for the implications of innovation patents for plant and animal subject matter.11 Thus, Parliament excluded plant and animal subject matter, and the biological processes for their generation, from patentable subject matter for an innovation patent.12 This exclusion is the subject of the November 2004 report in which the ACIP was asked “to assess the implications of the exclusion and to determine whether the exclusion is in the national interest.”13

A. Plants

Plant breeders are allowed to apply for protection under both the plant breeder’s right and the standard patent system.14 A standard patent is more advantageous than plant breeder’s rights for a plant breeder who wants to obtain protection over the process and not just the final product.15 The standard patent also allows the breeder a more extensive monopoly right, which protects against a wider range of conduct which may be viewed as infringement.16 Conversely, a breeder may prefer to obtain plant breeder’s rights over a standard patent because plant breeder’s rights are less expensive, easier to obtain, and may cover material which is not patentable such as discovery.17 The innovation patent exception disallowing the granting of an innovation patent
for plants and the processes for their generation leaves a gap in protection where a breeder may not obtain a lower threshold of protection for the plant processes or the exclusive rights granted by the standard patent for a plant that does not meet the inventive step criterion for a standard patent.  

The gap in protection between plant breeder’s rights and the standard patent would be minimized through the allowance of innovation patents for plants and processes for their generation.  

The innovative patent would retain the same protections of the standard patent, such as protection of the process for plant generation and a stronger stance against infringement, while requiring a lower innovative threshold. It would be easier to secure and less expensive and, therefore, similar to plant breeder’s rights.

Because innovation patents would provide patent protection to a larger proportion of plant varieties, “[r]emoving the innovation patent exclusion for plants would, in theory, create an overlap in rights between plant breeder’s rights and the innovation patent.” The potential overlap of plant varieties which satisfy the criterion for both the innovation patent and plant breeder’s rights has the potential to “cause complexity and confusion of operating parallel protection” and is a major concern of the industry.

Plant breeder’s rights contain “exceptions for breeding, experimentation and farm saved seed which are crucial to the success of the [plant breeder’s rights] system.” These exceptions bear importance in the discussion because they are not provided for innovation patents. The absence of the exceptions to innovation patents creates the potential to be a significant detriment to the industry if there is a high degree of overlap of plants qualifying for both the innovation patent and plant breeder’s rights.
The ACIP determined that the similarity in the patentability criteria of innovation patents compared to plant breeder’s rights led to the conclusion that many plant varieties eligible for plant breeder’s rights would satisfy the innovative step requirement of the innovation patent. Therefore, a significant overlap exists between the two causing concern that innovation patents could eventually replace the plant breeder’s rights system. This would serve as a highly detrimental cost to the industry because of the lack of exceptions for breeding, experimentation, and farm saved seed within the innovative patent law.

The ACIP determined that the costs to the industry of removing the innovation patent exception outweigh the benefits of such removal and recommend that “the current exclusion form the innovation patent of plants and biological processes for their generation should be maintained at this time.” The ACIP identified that only minor benefits in increased protection would accrue from the removal of the exclusion. It found that the benefits would pertain to only the protection of a proportion of lower level inventions which “require significant investment and are particularly vulnerable to competition.” Thus, because the high potential costs of allowing innovation patents for plants, and biological processes for their generation, are high, the ACIP recommended maintaining the innovation patent exclusion.

B. Animals

The gap in protection for animals and the processes for their generation is more significant than that of plants and plant varieties because there is no lower-level protection available. Plant breeder’s rights allow a lower-level protection for plants while there is no such protection for animals and the processes for their generation. Despite this gap in protection, significantly less concern has been expressed on this issue and the comments on this issue tend to be speculative.
Advocates of removal of the exclusion of animals and processes for their generation from innovation patents centered their arguments on economics. The lack of an innovation patent may act as a barrier to entry to smaller industry players by shifting the focus of research and development from small projects to larger projects. Currently, economic returns cannot be secured through patent protection for lower level innovations of animals and processes for their generation because protection is not available unless an inventive step can be demonstrated. Advocates of removal of the exclusion argue that the overall rate of innovation industry may decrease because focus will remain on larger projects with longer time frames. Additionally, research projects involving genetic manipulation typically produce technological developments with varying levels of innovation which could benefit economically from use of the innovation patent. The innovation patent could prevent the potential for economic loss and provide researchers in the industry protection of the animal varieties and methodologies producing such results.

Promoters of maintaining the current status of exclusion focused their argument on the nature of animal breeding and claim that the innovation patent will have little use in the animal industry. The innovation patent may be impractical for animals because of the difficulties which exist in distinguishing breeds against an innovative step. The innovation patent could also prove to be of little use in the animal breeding industries because “it is a long-held convention that ownership of an animal implies ownership of breeding rights.” Animal breeding is based on a type of creeping innovation which may be adversely effected through the relative ease of obtaining an innovation patent granting the patent holder rights to restrict further innovation. The lax examination requirements and the relative ease of obtaining an innovation patent allows for the potential abuse of intellectual property rights of animals because protected or commonly
known animals may be accessed and falsely represented creating a large number of invalid
patents.\textsuperscript{44}

Upon consideration of the arguments discussed above, the ACIP recommended that “the
current exclusion from the innovation patent of animals and biological processes for their
generation should be maintained at this time.”\textsuperscript{45} Although no changes were made, the ACIP
provided that changes may become necessary in the future due to the development of more
costly forms of breeding, such as genetically modified organisms, or if new evidence of
innovation in animal breeding being discouraged is found.\textsuperscript{46}

\textbf{III. Conflicts Created by Patent Rights and Experimental Use}

The ACIP is currently conducting a review considering the effect of patent rights on research
and development, particularly in biotechnology.\textsuperscript{47} The review is intended to examine “whether
some types of patents are inhibiting research and development in Australia, and determine
whether both Australian researchers and business would benefit from introducing an
experimental use exception provision into the Australian patent legislation.”\textsuperscript{48} These questions
will be answered by focusing on “whether an experimental use exemption would help
researchers more effectively use the patent system to commercialize their research and
development.”\textsuperscript{49} The ACIP has yet to issue a final report on this issue and is currently
considering various options to resolve the situation.\textsuperscript{50}

The Patents At 1990 contains no explicit experimental use exemption to infringement, and no
Australian court decision has definitively established an experimental use exemption as a part of
patent law.\textsuperscript{51} However, many Australian researchers have assumed that the exemption is an
intrinsic part of the patent contract, and accordingly, researchers are freely allowed to experiment
with patented subject matter.\textsuperscript{52} This dilemma creates an uncertainty affecting research and
development of which the ACIP is attempting to bring clarity as to whether the current law allows for an experimental use provision.  

Many Australian researchers have advocated for the allowance of experimentation on patented inventions on grounds that experimentation will spur further invention and will assist in verifying the particular invention’s compliance with the requirements of the Patents Act 1990. Others argue that incentives to innovate could decrease by the allowance of an experimental use exemption for three main reasons. First, experimental use is an exclusive right of the grantee, granted as a reward for acting as a pioneer in a given field. Secondly, the exemption will provide a loophole through which competitors could effectively reduce the economic value of patented inventions. Finally, “[i]t would also make it more difficult to determine infringements if the ‘bright line’ of no unauthorized use was diluted.”

The ACIP issued an options paper in December of 2004 which outlines various options through which the Australian government can provide researchers with a greater certainty as to what permissible actions they may take on patented subject matter to avoid infringement. The ACIP has focused on four of these options and requested submissions from interested parties.

The first option is maintain the current situation and allow the courts to decide whether experimental use of a patented invention will constitute infringement. One advantage of maintaining the current situation is that there is currently no empirical evidence of market failure, so the costs of the current uncertainty is outweighed by the potential harm of making significant changes to the law. In addition, this option will allow the law to be interpreted on a case-by-case basis, not through theory. Conversely, allowing the law to be interpreted through actual cases in the courts can prove extremely costly on losing parties, and patent monitoring and
licensing may become excessive due to narrow interpretations. Also, because of the uncertainty of the current law, researchers may begin to adopt risk adverse behavior. The second option is to introduce an amendment to the definition of exploitation to not include experimental use, “such as adding the phrase ‘other than experimental uses.’” Uncertainty will remain regarding the definition of ‘experimental uses.’ However, the ACIP believes that “the minimal changes required, clarifying that patent rights are inherently limited and allowing the law to evolve according to real world circumstances are major advantages.”

The third option is to provide an exemption in the Patents Act 1990 for acts that constitute fair experimentation on a patented invention, with a list of inclusive permissive uses. The exemption will focus on the act performed and provide factors for determining whether the experimentation is fair and a non-exclusive list of permissible acts. The exemption will provide clarity through the list of permissible acts while continuing to provide “courts with flexibility due to a key issues based approach.” Disadvantages to this option include the continued uncertainty due to this flexibility and the fact that the language may create a false comfort to the researchers because the ultimate interpretation will be determined by legal experts, not technologists.

The fourth option is to provide an exemption to patent law allowing experimentation on patented inventions exclusively “on the subject matter of the invention,” with a list of inclusive permitted uses of the invention. The exemption will only be available if the act is conducted either solely for or with the dominant purpose of experimentation, and will contain a non-exclusive list of permissible acts. The exemption will also grant the courts flexibility and will provide clarity through the list of permissible acts which are formulated in language which is easily understandable by the research community. However, this option may also create a
false comfort for researchers because the language will ultimately be determined by legal experts. 

**IV. Conclusion**

Australia has become a leader in the development of intellectual property law by developing the Australian innovation patent. Australia has provided guidance to foreign nations seeking to develop patent protection for inventions which do not quite qualify for a standard patent, by introducing this second-tier patent protection.

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4. Id.
5. ACIP Home, Supra note 2.
7. Id.
8. Id.
11. ACIP Report, pg. 6, supra note 3.
12. Id.
15. Id.
17. Id. (“In our view, ‘discovery’ in section 5 [of the Plant Breeder’s Rights Act of 1994] means merely the act of finding a physical specimen of a plant which was previously unknown to the general public. In our view it need not be unknown to everyone, but there should be an element of bringing to light something which was not common knowledge. So, for example, a person might ‘discover’ the theory of relativity through their own efforts and ingenuity, but because it is common knowledge they could not claim it as their ‘discovery’.”) Report of the Expert Panel on Breeding, Clarification of Plant Breeding Issues under the Plant Breeder’s Rights Act 1994, December 2002, Appendix 1, note 13, at [http://www.anbg.gov.au/breeders/appendices.html#link01](http://www.anbg.gov.au/breeders/appendices.html#link01).
18. Id.
19. Id.
20. Id.
Review Main Page, supra note 6.

ACIP Report, pg. 1, supra note 3.

ACIP Home, supra note 2. (The ACIP provided no estimated time-frame for when the final report will be issued on this issue.)


Id. at 2-3. (The options paper contains a specific list of benefits to allowing experimentation on patented inventions, including: “further knowledge not fully explained in the patent specification, determine the patent’s sufficiency or to compare it to prior art, test the validity of a patent, determine how the patented invention works, test whether a proposed product or process falls within the scope of a patent, reduce transaction costs for researchers (patent searches, legal advice, licensing etc), promote the development of new ideas and improvements of the patent and correspondingly reduce the likelihood of excessive monopolization, improve on the invention, “design around” the invention or develop a further patentable invention; determine whether the invention met the tester’s purposes in anticipation of requesting a license; and facilitate academic instructional experimentation with the invention.”)
Suggested factors include:
- “the purpose and character of the act; the subject matter of the invention; the availability of the invention in the marketplace; and the commercial effect of the act upon the patent holder.” 69

Permitted acts of fair experimentation include, but are not limited to:
- determining how an invention works;
- determining the scope of the claims;
- determining the validity of the claims;
- or developing an improvement to the invention.” 71

“…for example, to investigate its properties or improve upon it.” 75

See note 71.