



Grains Research and
Development Corporation

Professor Emeritus J V Lovett
MANAGING DIRECTOR

24 September, 2002

Mr J Roberts
The Secretary
Advisory Council on Intellectual Property
PO Box 200
WODEN ACT 2606

Dear Mr Roberts

Exclusion of plant subject matter from innovation patents

I refer to the ACIP Chairman's letter of 2 July 2002, seeking the GRDC's views about the exclusion of plant and animal subject matter from the recently introduced innovation patent.

Thank you for the opportunity to provide the GRDC's comments on this issue. We are pleased to respond, as this issue has the potential to significantly affect the GRDC and its stakeholders. Our response is attached.

We note that many other organisations have been asked to provide comment. We have, therefore, restricted our comments to the exclusion of plant subject matter from innovation patents.

I understand that the ACIP intends to hold consultative meetings to allow stakeholders a chance to discuss the matter in more detail. The GRDC looks forward to taking part in those consultations.

Yours sincerely

A handwritten signature in black ink, appearing to be 'John Lovett', written in a cursive style. The signature is positioned above the printed name of the sender.

JOHN LOVETT
Managing Director

Grains Research and Development Corporation

Comments to Advisory Council on Intellectual Property in
relation to exclusion of plant matter from innovation patents

23 September 2002

1. Introduction

On 2 July 2002 the Advisory Council on Intellectual Property (ACIP) wrote to the Grains Research and Development Corporation (GRDC), seeking the GRDC's views about the exclusion of plant and animal subject matter from the recently introduced innovation patent. This paper provides the GRDC's comments.

2. Summary of GRDC's view

The GRDC's view is that, on balance:

- (a) the scope of protection provided to plant varieties under the Plant Breeders Rights Act 1994 (PBR Act) and Patents Act 1990 (Patent Act) should not be changed. Innovation patents should not be available to protect plant varieties in place of PBR; and
- (b) innovation patent protection would be appropriate for germplasm and biological processes for the generation of plants. This is because there is a "gap" in intellectual property coverage of germplasm and biological processes for the generation of plants, which can currently be protected by standard patents, but only if they meet the criteria for grant of a standard patent.

The GRDC does not deal with animal subject matter, so does have any comments in relation to exclusion of animal subject matter from innovation patents.

3. Background

3.1 The GRDC's role

The GRDC is a statutory corporation established by regulations under the *Primary Industries and Energy Research and Development Act 1989*. It is funded by Australian graingrowers through a levy, with matching funding from the Commonwealth Government.

The GRDC's role is to invest in research, development and related activities to benefit Australian graingrowers, within the context of the wider grains industry and community. The GRDC does not itself carry out research.

The GRDC aims for the delivery of new technologies, products (including plant varieties) and services to meet national, regional, commodity and multi-commodity challenges. In the majority of cases, the GRDC's research partners also invest in the activity.

The GRDC, therefore, has a broad perspective on this matter, needing to taking into account the interests of the GRDC's direct stakeholders (grain growers and the Commonwealth Government) and its research partners.

3.2 The GRDC's use of patents and plant breeders rights protection

The GRDC, together with its research partners, often protects the intellectual property developed using the GRDC's investments:

- for plant varieties, by registration under the PBR Act; and
- for other technologies (such as a biological process for generation of plants), by using standard patents under the Patents Act.

However, a substantial part of the research in which GRDC invests cannot be protected by either PBR or standard patent. Germplasm is a key example. The GRDC, together with research partners such as:

- Queensland Department of Primary Industry (QDPI);
- Department of Natural Resources and Energy (DNRE); and
- Value Added Wheat Co-operative Research Centre (VAWCRC),

invest significant resources into developing germplasm. This can only be protected by contract. This makes transactions overly complex and slow, and gives the GRDC and its research partners only limited protection.

4. Key issues

Two key issues, in the GRDC's view, need to be addressed in any system of intellectual property protection of plants and biological processes for the generation of plants. They are:

- to maximise the amount of effective research into plants and related biological processes; and
- to allow growers to retain seed for planting future crops.

5. Ensuring a maximum amount of effective research

The GRDC believes that Australia's grain growers (and the wider community) will benefit if the amount of research carried out into plant technologies is maximised. That requires ensuring that information remains available for future research, whilst providing incentive for research to be carried out.

Granting intellectual property rights provides an appropriate incentive, enabling intellectual property owners to make a return on their investment, possibly to invest in further research. For plant varieties this balance is best achieved by retaining the current combination of standard patent and PBR protection, for the reasons below. Allowing innovation patents in relation to plant varieties may, in the long term, tip the

balance too far in favour of the intellectual property rights owner. These reasons are set out below.

However, for biological processes leading to new plant genotypes, which do not satisfy the requirements for a standard patent, innovation patents would be a useful form of protection.

5.1 The Patents Act and PBR Act currently provide appropriate thresholds for protection of plant varieties, but not biological processes

The Patents Act allows an invention relating to plant technology to be registered under a standard patent, but sets a high threshold. Key elements in section 18(1) of the Patents Act include that:

- there must be an invention, and not just a discovery; and
- it must involve an inventive step.

A plant variety or biological process for the generation of plants, which meets this threshold, can be protected under a standard patent. There is therefore no need to discuss this situation further.

The issue arises where a plant variety or biological process does not meet this threshold. Most plant varieties would not fulfil the threshold criteria for a standard patent. However, a plant variety can be registered under the PBR Act, if it is (among other things, under section 43):

- distinct;
- uniform; and
- stable.

Crucially, the PBR Act provides protection to plant varieties that is not available to other technologies that do not meet the threshold requirements for a standard patent. For those technologies, an innovation patent is the only available form of registration. Many of the justifications for innovation patents (outlined in the ACIP Background Paper) are fulfilled by the PBR Act.

We note the comment in the ACIP Background Paper that:

“While the innovation patent addresses the gap [in protection] for most industries, the exclusion [of plants from innovation patents] means that this “gap” remains for industries where R&D associated with plants and animals is carried out.” [square brackets are GRDC text]

In our view, the “gap” only exists for biological processes for the generation of plants, which do not meet the threshold for standard patents. For those

biological processes, innovation patents may be appropriate in the absence of any other alternatives.

5.2 *The threshold for innovation patent protection is unclear*

In order to be protected, an invention must have an “innovative step” – that is, when compared to the prior art base, does it make a substantial contribution to the working of the invention? The “innovative step” requirement has not yet been judicially tested, so the GRDC is not clear about what plants, or biological processes relating to plants, could be protected by an innovation patent. The GRDC therefore does not know what level of improvement would be required in a plant variety over its predecessors for the contribution to be “substantial” (and an invention as opposed to a discovery).

A new plant variety is built on decades, if not centuries of work in developing previous varieties. Almost all new plant varieties represent very small incremental improvements over their predecessors. In Australia, wheat and barley are the two most heavily-researched grain crops, yet improvements in yield average only 1% per year.

Is it intended that such small incremental improvements be protectable under innovation patents? If so, for the reasons given below we believe an innovation patent is not appropriate for plant varieties. If not, innovation patents would only be available for a plant variety making a very large improvement. We would then question what added protection innovation patents would add for plant varieties.

On 5 August 2002, DataDot Technology claimed it was about to initiate Federal Court action against Alpha Microtech for infringement of an innovation patent.¹ If the case proceeds, it may provide useful guidance on the contents of the “innovative step” requirement.

For biological processes relating to the generation of plants, the scope of the “innovative step” requirement may be crucial in determining whether an innovation patent system would be available in practice.

5.3 *PBR specifically provides for further research and commercialisation by third parties*

The PBR Act grants a breeder a bundle of exclusive rights over the registered plant variety. However, section 16 allows a variety covered by PBR to be used by third parties for experimental purposes or to breed other plant varieties. A breeder must lodge a reference sample, which can be accessed and exploited by others through further breeding.

¹ Australian Financial Review, 5 August 2002, p. 5.

By contrast, the Patents Act gives the patentee the exclusive rights to “exploit” the invention during the term of the patent. “Exploit” means, among other things, to make, see or otherwise dispose of the patented product. This allows a third party to use the intellectual property for further research – but they cannot sell a product using the patented intellectual property unless they obtain the patentee’s permission. The Patents Act therefore gives much stronger protection of intellectual property than does the PBR Act.

This key difference means that, where either a standard or innovation patent is in place:

- a breeder would need to obtain licences, and in many cases, pay royalties to use the patented intellectual property in a product or process; and
- the patent holder can block the commercial release of a product incorporating its patented intellectual property. A patent holder is under little obligation to give approval to or allow a licence on reasonable terms, as long as it is itself meeting the reasonable requirements of the public by supplying the patented product or process. The Patents Act does provide for a court to order compulsory licences (Chapter 12). However, the requirement that it be court-ordered means it would be slow and expensive to obtain a compulsory licence. The compulsory licence scheme has rarely been used in Australia.²

These requirements will generally only be a disincentive where there is a lack of experience and resources in negotiating suitable terms of access, rather than the fact that the technology itself is protected. However, in the GRDC’s experience, there is a widespread lack of experience and resources available for negotiation of licences in agricultural research in Australia. This has meant that research is often significantly delayed or does not occur at all.

The ability to prevent further commercialisation seems unreasonable in the case of plant varieties. As stated above, a new plant variety is built on decades, if not centuries of work in developing previous varieties, and usually represents only a very small incremental improvement over its predecessors.

It is, therefore, appropriate to allow a breeder to protect the exact variety he or she has developed, but it is not appropriate to allow the breeder to prevent or impose conditions on it being further bred and the results commercialised. The latter may be possible under an innovation patent regime, depending on how the requirement for an “innovative step” is interpreted – see below.

² Lawson, C. “Patenting genes and gene sequences and competition: patenting at the expense of competition” *Federal Law Review*, 2002, Vol. 30, p. 97 at 113-114.

Nicol, D. and Nielsen, J. “The Australian medical biotechnology industry and access to intellectual property: issues for patent law development” *Sydney Law Review*, 2001, Vol. 23(3), p. 347 at 371.

For biological processes relating to the generation of plants, the incentive provided by an innovation patent may outweigh the costs described above – but this depends on how big the “gap” really is. Also, it is still possible to use other methods, such as contract, to protect intellectual property in many cases.

5.4 *PBR does give adequate reward to breeders of plant varieties*

A key reason for allowing protection of intellectual property is to provide the developer of the intellectual property with sufficient incentive to invest in developing the property.

The ACIP Background Paper states that a major difference between patents and PBR is that under PBR, “the grower does not have to pay a royalty on the crop produced”. This is misleading.

Under Section 11 of the PBR Act, one of the exclusive rights in relation to a registered plant variety is the right to produce or reproduce the material, or to license another to do so. Over the last three or four years it has become increasingly common for breeders to require, as a condition of the licence to growers to grow the registered variety, that the grower pay an end point royalty (EPR) to the breeder. The EPR is collected at the point of harvest, and is usually set at a rate of \$x per tonne of harvested material.

Section 18 of the PBR Act provides an exception to the exclusive rights under section 11. There has been concern that section 18 could be interpreted in a way that allowed unauthorised commercialisation of propagating material, any by doing so denying the breeder any reward. The *Plant Breeder Rights Amendment Bill 2002* proposes to replace section 18, with a new section 18 which removes this possible interpretation.⁴

EPRs have only recently been introduced, but indicate that the PBR Act can provide sufficient return on investment to encourage breeders to make further investments in breeding plant varieties.

5.5 *Innovation patents can give unwarranted advantage*

Both a standard patent and PBR are examined before grant. There is, therefore, a reasonable degree of certainty that they would be upheld if challenged, although not absolute. This gives a standard patent or PBR significant commercial value. It also provides a check that the grant of a standard patent or PBR is warranted.

An innovation patent is not examined before grant – only a formalities check is carried out. An innovation patent thus creates a great deal of uncertainty, both for the patentee and for third parties who are not sure whether the patent would survive challenge.

⁴ See Explanatory Memorandum for detailed discussion of new section 18.

However, an innovation patent potentially still has commercial value, because it can be extremely expensive to challenge the validity of a patent (see above). This applies even if it would probably be held invalid on examination. Breeders in Europe have previously expressed concern about the possibility of competitors building a wall of patents around germplasm.⁵ This concern would be magnified for innovation patents, because they are cheap to obtain and there is no examination.

Thus the mere existence of an (unexamined) innovation patent can act as a considerable deterrent to other researchers in the field. The GRDC is concerned that this may have an unwarranted “chilling” effect on research in the area of plant breeding. This is another reason not to extend innovation patents to plant varieties.

Despite the above concerns, for biological processes leading to plants, innovation patents appear to provide at least some useful protection in the absence of other intellectual property protection.

6. Farm saved seed

The PBR Act specifically excludes farm saved seed from infringement of the PBR. There is no such exception in the Patents Act.

In Australia, wheat and barley are the most significant grain crops. Approximately 90% of each year’s crop is planted using farm saved seed. For other crops, such as canola, sorghum and sunflowers, which are hybrids, growers tend to buy seed annually because the seed performance deteriorates.

Farm saved seed is crucially important to Australian growers for the major crops, for both economic and technical reasons:

- yields in Australia are typically about two tonnes per hectare, which is only one-third of yields obtained by Australia’s competitors;
- Australia’s highly variable climate means that Australian growers face a much higher risk of crop failure than do their competitors;
- Australian growers do not receive subsidies, in contrast with their competitors;
- in southern Australia, warm and dry conditions at the time of harvest make it practical to save seed. By contrast, overseas there is often rain at harvest time making it less practical to save seed; and

⁵ Adcock, M., Llewelyn, M. & Sayegh, A., “The attitude and concerns of European plant breeders to plant intellectual property”, conference paper presented at International Conference on Plant Intellectual Property Rights within Europe and the Global Community, Angers, France, 10-11 January 2001.

- Australia's infrastructure relies on farm saved seed. Requiring growers to buy new seed each year cannot take place until appropriate identity preservation, quality assurance systems and infrastructure are put in place. This would take time.

It is crucial that growers be able to minimise costs as much as possible, to remain internationally competitive. Farm saved seed, in combination with an appropriate EPR system, allows growers to minimise costs while providing breeders with an incentive, and enabling appropriate sharing of risk between growers and breeders. For plant varieties, this balance is best achieved by retaining the current PBR system.

7. Response to specific questions

The ACIP Background Paper asked four questions. We respond as follows.

1. *Is the current "gap" in IP protection for inventions with a lower level of threshold, that involve plant and animal subject matter, seen as an existing or potential problem?*

The GRDC only has comments in relation to plant subject matter, not animals.

The GRDC does not view the "gap" in IP protection as an existing or potential problem for plant varieties. Plant varieties are adequately protected by PBR. However, the "gap" is an existing problem for biological processes including germplasm. Contract is the only existing way of protecting the (often valuable) results of research in this area. Relying solely on contracts is both unwieldy and risky, because third parties will often not be bound by the contract. Innovation patents have significant weaknesses, but in the absence of anything better may be a useful way of protecting biological processes.

2. *Given the existence of the standard patent system and the PBR system, is there a need for those involved with plant and animal subject matter R&D in Australia to be able to protect their research with the innovation patent?*

See answer to Question 1.

3. *What, if any, are the national benefits of excluding plant and animal subject matter from the innovation patent?*

In relation to plant varieties, the PBR Act offers more appropriate protection than innovation patents. Over the long term it is likely to encourage more and better research, for the reasons outlined above. This benefits growers, researchers, and the wider Australian community.

The PBR Act also allows growers to save seed, which is important to maintaining Australian growers' competitiveness against their overseas rivals. That would be unlikely under innovation patents, as the patent holder would wish to prevent the loss of control over seed that farm saved seed entails.

Excluding biological processes from innovation patents would increase certainty for researchers, because of the uncertain status of (unexamined) innovation patents discussed above. However, in the absence of any other form of intellectual property protection, the incentive to invest that innovation patents provide would probably outweigh the costs, despite the flaws in the innovation patent system.

4. *What impact would the innovation patent have on non IP right holders were it to include plant and animal subject matter?*

See answer to Question 3.