



**CLARIFICATION OF PLANT BREEDING ISSUES
UNDER THE
*PLANT BREEDER'S RIGHTS ACT 1994***

**REPORT OF THE
EXPERT PANEL ON BREEDING**

December 2002





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ACKNOWLEDGEMENTS

The Panel wishes to thank all those who have provided comments that have assisted in development of this report, which seeks to clarify issues relating to eligible breeding methodologies and essential derivation under the *Plant Breeder's Rights Act 1994* (PBRA). This report is not a legal document. It is intended to reflect the views and opinions of the Panel for generic problem areas. Consequently it may not be applicable for every situation or particular purpose.

The Panel agreed that the draft report should be the subject of an extensive consultation process before finalisation. Comment has been invited from independent experts, a reference group with interests in 'traditional' and 'biotech' breeding, the Plant Breeder's Rights Advisory Committee (PBRAC) and, finally, publication seeking the views of the general community.

The consultation process encourages various and sometimes conflicting views that, in the final analysis, cannot always be reconciled. Such a process is, nevertheless, invaluable in assisting those responsible for the task at hand. The Panel acknowledges that its conclusions will not meet with unconditional approval from all sides. However, it is hopeful that its endeavours will promote greater clarity and understanding.

The Panel wishes to express its appreciation to a number of experts who offered comment on the report. These include Mr D Boreham, Dr P Brennan, Mr G Constable, Dr L Cook, Dr I Edwards, Dr M Ewing, Dr B Hare, Dr D Loch, Mr P Neilson, Ms C McCaffery, Mr D Moore, Mr H Roberts, Prof M Sedgley, and Ms A Sharpe.

The Panel would also like to thank the staff of the Plant Breeder's Rights Office (PBR Office) for providing the secretariat support for this report, in particular, the Deputy Registrar, Mr N Hulse, and Mr B Blazey.

TERMS OF REFERENCE

Following the 1999 review of Plant Breeder's Rights (PBR), the then Standing Committee on Agriculture and Resource Management (SCARM) recommended that:

- *the Registrar of Plant Breeder's Rights consult and communicate widely with the breeding community with the objective of providing a clearer explanation of breeding;*
- *the Registrar of Plant Breeder's Rights convene a panel of experts to provide examples of breeding methodologies that conform with the Plant Breeder's Rights Act 1994 and internationally accepted practice in accordance with the UPOV Convention;*
- *the Plant Breeder's Rights Office publish, through the Plant Varieties Journal and web page, a clearer explanation of breeding to respond to current uncertainties and guide applicants;*
- *the Plant Breeder's Rights Office work with the plant breeding and biotechnology industries to clarify essential derivation, develop practical solutions to intellectual property management of essentially derived varieties* and, through this process, examine ways in which changes might be made to the Plant Breeder's Rights Act 1994 to better protect the interests of the first breeder.*

[* Essentially derived variety (EDV) refers to the situation where the breeder of one variety (the 'first variety') claims that another breeder has developed another new variety (the 'second variety') that is distinct from, but closely resembles and is directly related to, the first variety in all important respects.]

MEMBERS OF THE EXPERT PANEL ON BREEDING

Mr Iain Dawson is Registrar of the Australian Cultivar Registration Authority, the internationally recognised registration authority for cultivars derived from Australian plant genera. He has over 20 years experience of horticultural and agricultural research specialising in the development of industries based on the exploitation of the native flora and is a regular contributor to cut flower and nursery industry conferences and forums. Mr Dawson is a manager at the Australian National Botanic Gardens in Canberra and an Accredited Consultant Qualified Person for Plant Breeder's Rights.

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Professor Marshall completed his studies in Agriculture at The University of Sydney in 1962 graduating with first class honours and The University Medal, and his Ph.D. studies in Genetics at The University of California, Davis in 1968. He subsequently worked at the Division of Plant Industry, CSIRO; the Grains Research Centre, Narrabri; and The University of Adelaide, principally in the areas of crop improvement and genetic resource conservation.

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Mr Doug Waterhouse is a quantitative geneticist and has worked for over 20 years as a researcher and plant breeder. He is currently Registrar of the Plant Breeder's Rights scheme in the Commonwealth Department of Agriculture, Fisheries and Forestry. He has led the Australian delegation at meetings of the *International Convention for the Protection of New Varieties of Plants 1991* (UPOV) since 1996 and is Vice Chairman of its Legal and Administrative Committee.

EXECUTIVE SUMMARY

This report focuses on clarifying issues relating to 'breeding' and 'essential derivation'¹ in the *Plant Breeder's Rights Act 1994* (PBRA), as proposed by the Standing Committee on Agriculture and Resource Management (SCARM).

The catalyst for the report was a perception that (i) applicants and objectors generally had a poor understanding of the threshold of eligible breeding required by the PBRA and (ii) the balance between first and subsequent breeder rights in relation to 'essentially derived varieties' (EDV) should be reviewed.

The report is set against the requirements of the PBRA and Australia's commitments under the Convention of *the International Union for the Protection of New Varieties of Plants 1991* (UPOV).

The Panel believes that, generally, breeders will welcome the report because it provides guidance, albeit at a general level, on how to satisfy the criteria for breeding required by the PBRA. The report concentrates on those situations where the eligibility of the breeding methodologies is most often questioned (for example bulk/pedigree selection within an existing population or the discovery of a natural variation/mutation).

The report provides guidance and clarification on 'breeding' by defining 'discovery', 'selective propagation', and 'eligible breeding' methodologies, as well as question and answer resolutions to common 'difficult' situations.

The Panel confirms that all varieties must meet the same minimum criteria regardless of the method of their origination. The Panel also notes that there are a number of misconceptions about what may automatically qualify or disqualify a variety from PBR registration.

The Panel acknowledges that in some exceptional cases the clarifications proposed might prove disadvantageous to the eligibility for protection of some varieties (for example, those varieties without information on their parents/origin).

The Panel confirms that Australia's current interpretation of breeding is consistent with international best practice and that no new, higher, or lower requirements for breeding are imposed.

EDV refers to the situation where the breeder of one variety (the 'first variety') claims that another breeder has developed another variety (the 'second variety') that is directly related to, and essentially the same, as the first variety.

The Panel agrees that breeding is an incremental process and the intent of the PBRA is to encourage the introduction of new varieties based on research and development.

¹ [* Essentially derived variety refers to the situation where the breeder of one variety (the 'first variety') claims that another breeder has developed another new variety (the 'second variety') that is distinct from, but closely resembles and is directly related to, the first variety in all important respects.]

The PBRA is not intended to facilitate or encourage 'copies'. In Australia, the second breeder's major defence against vexatious claims of EDV is to demonstrate 'important' difference otherwise the challenger's case will succeed, all else being equal. This is consistent with the intent of the PBRA, which is to produce new varieties and not copies. Therefore, in the opinion of the Panel, the current legislation encourages innovation, while providing protection for all breeders against plagiarism and vexatious challenge.

On a separate issue, occasionally seen as related, some see the development of new plant varieties through gene insertion as a 'quick and easy' process. The Panel believes that successful gene insertion is generally not quick and easy². Moreover, recognition is growing that 'traditional' and 'biotech' breeders share a mutual interest in working together. The Panel encourages the development of such mutually advantageous relationships.

Key Recommendations

The principal outcomes of this report are to:

- promote greater clarity as to what constitutes eligible 'breeding' for the purposes of the PBRA; and
- explain why, in respect of 'essentially derived varieties', the current balance between the first breeder and subsequent breeders is generally appropriate.

The Panel concludes that the provisions of the PBRA, and administrative approaches regarding breeding issues are soundly based. Accordingly, the only changes that the Panel recommends are in respect of EDV. Those changes are that PBR owner's ability to exercise their rights in respect of EDV should be extended to non-PBR varieties and that the responsibility to determine EDV is more appropriately a matter for the courts.

The Panel acknowledges that breeding methodologies continue to evolve and, therefore it would be inappropriate to limit eligibility for PBR to varieties developed by the application of existing methods.

The Panel also concludes that many of the criticisms relating to breeding arise through misunderstanding of the scope of the legislation. Accordingly the Panel also recommends that the PBR Office should make further efforts to improve overall understanding of the PBRA and of administration of the PBR scheme.

² Acknowledging that advanced technologies are being developed and refined to speed the process of gene insertion.

BACKGROUND

In July 1998, the then Standing Committee on Agriculture and Resource Management (SCARM) considered a report on Western Australian experience with the *Plant Breeder's Rights Act 1994* (PBRA) focussing on the relationship between the PBRA and End Point Royalties on grain. Subsequently, SCARM initiated research into more general experiences with the PBRA through a survey of government and private stakeholders. Twenty-seven organisations responded, including seven SCARM agencies, four Universities/Co-operative Research Centres, three Research and Development Corporations, three grain/seed industry organisations, three horticultural plant nurseries and two seed companies. Respondents were consistent in their support of the PBRA, recognising it as the most appropriate scheme for the granting of intellectual property rights on new plant varieties.

Nevertheless, a majority of respondents (i) felt that applicants and objectors generally had a poor understanding of the threshold of eligible breeding required by the PBRA and, (ii) questioned the balance between first and subsequent breeder rights in relation to 'essentially derived varieties'. Accordingly, SCARM recommended that the Registrar of the PBR Office establish an Expert Panel (the Panel) to clarify and explain what constitutes eligible breeding, and issues relating to EDV. The Plant Breeder's Rights Advisory Committee (PBRAC) considered the possible composition of such a panel and the Expert Panel on Breeding was formed, convening for the first time on 3 February 2001.

While the Panel acknowledges the PBRA has the potential to apply to all new varieties, it understands that about 1% of all applications are opposed on the basis that they have 'not been bred'. Considerable controversy often ensues with some opponents claiming, *inter alia*, that the threshold of eligible breeding is set too low.

Despite the small number of such disputes, decisions are not arrived at easily, involving delays and uncertainties, and consuming a disproportionate amount of resources.

The Panel aims, through this report, to provide guidance to minimise future dispute and conflicts and to assist in the understanding of the principles of 'patent-type' legislation, UPOV 1991 and of the PBRA.

CLARIFICATION OF BREEDING ISSUES

Breeding – A Mandatory Requirement for a Grant of PBR

To be a registrable plant variety, the variety must have a breeder, be distinct, uniform, and stable (see PBRA sections 34 and 43), and not have been exploited, or if so, only recently (see PBRA section 43(1)(5) and (6)).

The same requirement is reflected in UPOV 1991³ Article 1 *viz*: ‘breeder’s right means the right of the breeder provided for in this Convention’.

To be a breeder of a new variety, a person (or persons) must have bred that variety (see PBRA section 3(1) and UPOV 1991 Article 1).

Definition of Breeding

Section 5 of the PBRA broadly defines breeding as including ‘discovery’ and ‘selective propagation’. Neither ‘discovery’ nor ‘selective propagation’ is defined.

The Panel’s view, based on the advice of the Australian Government Solicitor⁴, regarding ‘discovery’ is that:

- (i) it has its normal meaning (as there is no relevant jurisprudence in the PBRA context);
- (ii) it can occur on more than one occasion;
- (iii) it does not occur if the variety is commonly known;
- (iv) in the absence of information to the contrary, the ‘discoverer’ is the first to file for PBR protection; and
- (v) a person cannot normally be considered the ‘discoverer’ of a plant if someone else provides the particulars of its existence to that person.

The Panel’s view regarding ‘selective propagation’ is that:

- (i) ‘selective propagation’ has its normal biological meaning; and
- (ii) the scientific basis for assessing whether ‘selective propagation’ has occurred is a comparison, between the candidate plant variety⁵ and the population/parents⁶ from which it was developed, that demonstrates a clear difference in at least one characteristic⁷.

Precedents

The Panel notes that the *Plant Variety Rights Act 1987* (PVRA) did not include a definition of breeding. ‘Originator’ was used as a threshold for eligibility to apply for

³ The Panel notes that Australia is a member of UPOV and is obliged to administer the PBRA in accordance with the Convention (see Articles 1 and 5).

⁴ See Appendix 1.

⁵ A plant variety is contained within a single botanical taxon of the lowest known rank (see PBRA section 3 (1) ‘plant variety’). As a corollary PBR protection is not available to a species *per se*.

⁶ A candidate variety can be compared to, and differentiated from: (i) its parents or, (ii) the original population/source material or any other generation between it and the original population/source.

⁷ ‘Characteristics’ means traits that result from the expression of a genotype or combination of genotypes.

protection. The Panel therefore concludes that references to the PVRA, or the precedents set during its operation, are not appropriate for deciding whether breeding has been satisfied for the purposes of the PBRA.

Proof of Breeding

The Panel acknowledges the wide range of methodologies used by breeders and notes that the level of complexity is usually directly related to the level of domestication of the species.

For example, the level of complexity is usually lower in the case of species that have not undergone extensive domestication, such as Australian wild flowers. Conversely, the level of complexity of breeding is usually far higher in respect of wheat, barley, and maize. Very sophisticated techniques may be applied to either highly domesticated or to undomesticated species.

The Panel's view of breeding is that, for the purposes of the PBRA, eligible breeding methodologies include the same three fundamental steps⁸:

1. *Amassing, or locating, plant material with sufficient variation (herein after referred to as the 'source population') to enable genetic variation to be identified. This variation could be: 'natural' variation (i.e. created without human interference such as spontaneous mutation); or could be 'man-made' variation (e.g. through genetic transformation, cross-pollination, induced mutations, etc).*
2. *Selection of a particular plant⁹, or group of plants, having a set of 'desirable' characteristics from within the source population.*
3. *Propagation of the particular plant form (in preference to other plant forms in the source population) must occur, resulting in a change in the expression¹⁰ of one or more characteristics between the source population and the new variety. For a registrable new variety to be produced, this propagation would have to result in a variety that also met the criteria of distinctness, uniformity and stability, and of non-exploitation.*

The Panel specifically notes that the finding/importation of a variety, by itself, does not meet the above criteria of breeding. Consequently, the test for eligibility for PBR protection is not satisfied.

The Panel also notes that the PBRA does not discriminate between varieties and, therefore, all varieties are assessed against the same criteria, regardless of the method of their origination. The Panel acknowledges that, because some applicants

⁸ Varieties maintained as hybrids, synthetics etc may not include the selective propagation component of step 3.

⁹ 'A plant' hereafter includes 'a group of plants' sharing the same characteristic(s).

¹⁰ Also includes a change in the frequency of expression.

will not be able to meet all of the criteria under the PBRA, not all new varieties will be eligible for PBR protection.

The Panel has endeavoured to give greater clarity to eligible breeding methodologies through the illustrative examples (see case scenarios) provided in this report.

Principles of Breeding and Administration of PBR Based on the PBRA

While the PBRA does not provide a comprehensive list of acceptable breeding methodologies, the aide-memoire to the UPOV Convention (on which the PBRA is based) lists, as methodologies usually accepted as breeding:

- (a) bulk or pedigree selection within an existing population;
- (b) discovery of a natural mutation;
- (c) the inducing of an artificial mutation;
- (d) chance cross-pollination;
- (e) deliberate cross-pollination;
- (f) any combination of the above.

Over time, a number of other more sophisticated methods have also come into common practice, including double haploids, somaclonal variation, etc.

The Panel believes that most of the misunderstandings related to breeding arise in the context of (a) and (b) above¹¹ and often focus on matters connected with the source population.

The Panel acknowledges that breeding methodologies continue to evolve and, therefore, it would be inappropriate to limit eligibility for PBR to varieties developed by the application of existing methods.

The Panel notes, and agrees with, the following administrative practice, which is consistent with UPOV 1991. It further notes that no new, higher, or lower requirements for breeding are imposed.

1. Development of new varieties by way of selection from within existing variation is a practice that has been used commonly for generations and constitutes breeding, which may lead to registrable varieties under the PBRA (see PBRA [section 43](#)).
2. Where a new variety has been developed by selective propagation from within an existing population:
 - (a) the applicant's claim that they discovered the plant from which the new variety was developed is accepted by the PBR Office on provision of a declaration to that effect in the Part 1 Application Form (see PBRA [section 26](#));

¹¹ These misconceptions often stem from (i) philosophical positions opposed to the granting of Intellectual Property (IP) rights in living materials, or (ii) expectations about the PBRA that bear little resemblance to the legislative requirements.

- (b) selective propagation is established where the population of the new variety is different from the population from which the discovered plant originated;
- (c) the applicant must supply either:
 - (i) evidence that the new variety has been selectively propagated by a direct comparison with the source population, or
 - (ii) a declaration specifying how the expression of a characteristic or characteristics in the new variety clearly differs from the expression of the same characteristic or characteristics in the source population.
- (d) a new variety must also meet the criteria demonstrating distinctness, uniformity and stability, (the so-called DUS criteria, see PBRA [sections 34 and 43](#));
- (e) where apparently conclusive evidence is produced challenging an applicant's claims of discovery and/or selective propagation, the applicant has the opportunity to address that evidence before PBR protection is withdrawn/revoked (see PBRA [sections 35 and 50](#)). The penalties for false statements are significant, including imprisonment (see PBRA [sections 75 and 76](#));
- (f) the legal test of whether an application for rights in a new variety must be granted, is that the Secretary of the Department is satisfied that requirements have been met (see PBRA [section 30, 31, 32 and 44](#)).

3. Proof of breeding, and of distinctness, are separate issues and can be tested and satisfied independently. Breeding relates to comparisons with the source population/parents, while distinctness relates to comparisons with all varieties of common knowledge¹².

In situations where the source population/parent is also the most similar variety of common knowledge, breeding and distinctiveness can be tested and satisfied simultaneously.

¹² See Appendix 2 on 'Variety of Common Knowledge'.

SOURCE POPULATION ISSUES – CASE SCENARIOS

1. Ownership of the Source Population
2. Location/Origin of the Source Population
3. Homogeneous Source Population
4. Parentage
5. Population Boundaries
6. Selection from a Variable Population

1. Ownership of the Source Population

Legal ownership of, or access to, the source population is not an eligibility requirement for PBR protection of a new variety.

- Q1. For PBR purposes, can a new variety be bred from a source population obtained from private or public land without permission of the owner, or from material held 'in trust' in a Genetic Resource Centre (GRC)?

YES. PBR does not require an applicant to prove authorisation to access resources/knowledge in the development of an invention.

The issue of legal ownership of the source population is outside the scope of UPOV 1991, the PBRA and other IP legislation. Therefore, a new variety's eligibility for PBR protection is not dependent on legal ownership, prior informed consent, or agreement to access the source population used to develop the new variety.

It must be understood that PBR requirements have a limited scope and that remedies for issues outside that scope must be pursued through appropriate channels. Issues of legal ownership of source population must be pursued and resolved separately in the relevant legal context. Protection will not automatically be invalidated on the basis of a Court decision relating to ownership of the source population (intellectual property rights exist independent of physical property rights).

The Panel's view is that it is inappropriate to seek to involve the PBR Office in matters that are outside its legally enforceable mandate. It is the responsibility of the interested party to be aware of, and to deal with, such matters in the appropriate fora.

2. Location/Origin of the Source Population

Eligibility for PBR protection of a new variety is not dependent on the location/origin of the source population, or whether the source population is cultivated or uncultivated (i.e. 'wild' or 'naturalised'¹³).

A previously unknown phenotype of *Grevillea* is identified as a mutant branch (a 'sport') on a single plant from a population of 10 plants in an uncultivated situation.

Q2.1 Can an applicant claim to be the breeder by discovering the sport and vegetatively propagating it in preference to other phenotypes¹⁴ on the plant, or in that population?

YES, provided that the variety is shown to be different from the plant on which it was discovered, and from the source population as a whole.

Q2.2 If an applicant discovered the same plant in a commercial nursery or on another's private property would this affect eligibility? (It is still the same new variety with the same characteristics).

NO. Location/origin is not a criterion for determining eligibility.

Neither UPOV 1991 nor current PBR Office practice limits the location/origin of the material in which a plant of a new variety may be discovered (however the location/origin must be known – see PBRA [section 26\(1\)\(g\)](#)). Accordingly, there are no special or different criteria applied to varieties arising from an uncultivated source population.

Q2.3 Several seed packets are received from a GRC. The seed from each packet is sown in individual rows. After evaluation one highly uniform row is 'selected' for further propagation. Can the person receiving the seed from the GRC seek protection successfully?

NO, generally speaking. Even if the applicant could show that the variety differs from the source population, the applicant could not normally claim to be the discoverer¹⁵. This is because the applicant would have been given the material rather than coming upon it independently.

¹³ 'Wild' refers to uncultivated species indigenous to the location while 'naturalised' refers to uncultivated species not indigenous to the location.

¹⁴ A plant's phenotype is the observable properties of the plant and is produced by the genotype in conjunction with the environment.

¹⁵ Unless either (i) the rights of the discoverer have been assigned to the applicants(s) (see PBRA [section 3\(1\)](#) 'breeder' or, (ii) the discoverer and the selective propagator jointly apply for PBR (see PBRA [section 5\(2\)](#)).

3. Homogeneous Source Population

PBR protection is not available for a variety arising from a selection in a homogeneous population.

On a collecting trip, a person obtains seeds from a number of plants that are scattered over a very wide area. The seeds from each plant are packeted separately and labelled. Subsequently, seed from each packet is sown as a single row and, after evaluation, one row is 'selected' for further propagation in preference to the other rows. Possible scenarios are as follows.

- Q3.1 The 'selected' row is uniform and all seed from the row is bulked to form the new variety.

NOT ELIGIBLE for protection unless the applicant can describe how the new variety differs from the source population in which the original plant was discovered.

- Q3.2 The selected row is not uniform and undergoes several cycles of single plant selection over successive generations. Further evaluation of the progeny of plants selected from the 'selected' row identifies one plant that is propagated in preference to the other plants in that generation. Progeny of that plant are highly uniform (including over generations) and no further selection is necessary.

ELIGIBLE for protection provided the applicant can describe how the variety differs from the source population, or any intermediate generation.

PBR protection is not available for a variety arising from a selection in a homogeneous population, because the plant variety is identical to its source population. In addition, where the source population is also a variety of common knowledge (VCK), the new variety would be ineligible through lack of distinctness.

The burden of proof to identify a difference or differences between the candidate variety and the source population rests with the breeder. Where a selection is demonstrated to be different from a supposedly homogeneous population, the selection may be eligible for protection.

Simply bringing an existing uniform variety into cultivation is not breeding.

4. Parentage

PBR protection is available when the breeding criteria (including that the variety is distinct from the parent and other varieties) are met through *prima facie* evidence, or a declaration.

Can the criteria for breeding be satisfied if the exact parentage of a new variety is unknown, or if nothing is known about the parents? Possible scenarios are as follows.

- Q4.1 A person discovers a desirable seedling by chance, but the parents are unknown. Although it may be possible to deduce the parents it cannot be done with any certainty. Is the variety potentially eligible for protection?

YES, based on current PBR Office practice where the applicant is required to declare how the variety differs from all potential parents. This may be done, for example, through direct/indirect comparisons of the candidate variety with existing varieties until the establishment of a difference or differences from all potential parents. Where the seedling is likely to have arisen from nearby plants, the applicant should provide argumentation in support of limiting the comparison process to those nearby plants.

- Q4.2 A breeding program, using recurrent selection, was initiated 15 years ago. Although the parentage is known, the source material has long since disappeared, and so has the person who initiated the work. Consequently, although the variety can be shown to be distinct from existing varieties, no information is available, and no claims are made, on how/why it differs from the source material. Does the variety potentially meet the requirements of 'breeding'?

NO. Without any prima facie evidence or declaration supporting breeding, the variety cannot be registered. (Also see Q4.3).

- Q4.3 A new variety is bred by recurrent selection following controlled pollination of two breeding lines. Although the breeding lines are no longer available, the applicant states, as evidence of breeding, that the new variety is different from the maternal parent as it is highly resistant to stem rot and the parent is not. Is the variety potentially eligible for protection?

YES. A prima facie case has been provided. It should be noted that the candidate variety could be compared to, and differentiated from, the original parent or parents or any intermediate generation.

- Q4.4 A new variety is bred by discovery and selective propagation from within what was thought to be an apomictic population. Although the source population is no longer available, the applicant states, as evidence of breeding, that the new variety is different from the source

population as it is highly resistant to stem rot and the source population is not. Is the variety potentially eligible for protection?

YES. A prima facie case has been provided to suggest that the variety is different from the source population.

Consistent with UPOV 1991 and current PBR Office practice, PBR protection is available when the applicant meets the breeding criteria through *prima facie* evidence, or a declaration to that effect. This includes demonstrating that the variety is distinct from the parent or other varieties (see PBRA sections 43 and 34). Inadequate evidence, including incomplete records, will not sustain a *prima facie* case that the criteria for breeding have been met.

Acceptable *prima facie* evidence can be provided in many forms. Where there is no possibility of comparing the variety with the source population (e.g. where the source population is extinct) a *prima facie* case for breeding may include a description of:

- the variability inherent in the breeding system of the variety (e.g. selfed vs outcrossed);
- why the source population or the progeny of the source population was likely to be variable (e.g. through observation, etc);
- the methods used to isolate and purify one phenotype from that variability;
- details of test growing that took place outside Australia in the case of varieties bred overseas (see PBRA section 34).

5. Population Boundaries

To prove that breeding has occurred, the applicant may have to define the population boundary of the source population before demonstrating the difference between the source population and the new variety. Proof of breeding is a different proof than that required to demonstrate distinctness, uniformity and stability (DUS).

A number of plants are collected from uncultivated areas throughout a State. After evaluation one plant is 'selected'. It is clearly different from the other collected plants, as is expected, due to the wide-ranging conditions under which the species has evolved. Other plants in 'the area' where the selected plant was collected are likely to be less different. Sometimes 'the area' is quite small, e.g. 10m², sometimes it is much larger, e.g. 10km².

Q5.1 Can the applicant use the entire State collection as the source population?

NO, generally speaking. It is the responsibility of the breeder to define and to justify what constitutes the area of the source population¹⁶. Generally, the larger the area, the more difficult it becomes for the breeder to justify their claim.

Examples may be encountered of seeds obtained from a GRC where the parentage is not known and the seeds may be variable or highly uniform. This part of the report should be read in conjunction with 2.1 Location/Origin of the Source Population, Question 2.3 and with 6.1 Selection from a Variable Population, Question 6.4.

To meet the criteria of selective propagation, a new variety must be different from plants growing in the immediate breeding population in which it was discovered.

Generally, the source population are plants growing in the 'immediate vicinity' in which the selection was made. When population boundaries are unclear, the source population is taken to include plants growing in the area of the breeding population in which the new plant was discovered. Generally, this area will be quite limited. However, it is recognised that in exceptional circumstances the area could be quite large, depending on the species, its environment and mode of reproduction. **It is the responsibility of the breeder to define and to justify what constitutes the boundary of the source population.**

Note that while the criteria for breeding may be satisfied, a new variety may not be distinguishable from other known populations, in which case the application for protection would fail through lack of distinctiveness.

¹⁶ For further information see *FloraBank* Guidelines 10 at www.florabank.org.au

6. Selection from a Variable Population

Eligibility for PBR protection is dependent on the new variety meeting all the criteria, including breeding and distinctness from all other varieties of common knowledge. Eligibility of breeding is affected by the frequency of plants indistinguishable from the variety that occur in the source population¹⁷.

Many populations of plants exhibit a wide range of phenotypes. For example, a population of *Banksias* may exhibit a range of flower colours from red to violet. When a plant is selected from within the known range of a variable population there may be other plants in that same population (or other populations) that are the same as, or very similar to, the selected plant. Does the existence (real or notional) of 'similar' plants, not occurring as known varieties/forms, make protection unavailable?

A 'preferred' plant is discovered in an uncultivated population. Possible scenarios are as follows.

- Q6.1 No other plant in the source population possesses the same combination of characteristics. The plant is propagated vegetatively in preference to the other plants in the uncultivated population. Is the variety arising from the preferred plant potentially eligible for protection?

YES.

- Q6.2 The plant is propagated vegetatively in preference to the other plants and can be shown to be different from the population as a whole, but not from every individual plant in the population (around 1% of plants in the source population possess the same combination of characteristics). Is the potential new variety arising from the preferred plant likely to qualify for protection?

YES. *This is because the potential new variety has been compared with the source population and shown to be distinct within the 1% allowable statistical limit.*

- Q6.3 Does the decision on breeding eligibility change according to the frequency of plants identical to the desirable plant (e.g. when the desirable plant constitutes 5%, 10%, 50%, or 90% of the source population)?

YES. *At some point, the variety is no longer eligible for PBR when it becomes statistically indistinguishable from the source population.*

¹⁷ The UPOV test for comparing two (or more) phenotypes/populations to determine distinctiveness is more stringent than that normal for scientific testing. For example, the probability that two populations are different is usually accepted in most scientific tests when the P value is ≤ 0.05 (i.e. 5%) while the UPOV level is set at only 1%.

Q.6.4 A person receives a packet of seed from a GRC. When grown, the seed produces a population of highly variable plants. One plant was 'selected' and shown to be different from that variable population. Is the variety potentially eligible for protection?

YES.

Consistent with UPOV 1991 and current PBR Office practice, if a variety meets the criteria for breeding of 'discovery' and 'selective propagation', it is then also assessed against the DUS criteria before determining eligibility for protection.

The Panel noted that there may be statistical occurrences of plants in the source population (or other populations) that are indistinguishable from that which the breeder has discovered; selectively propagated; met the distinctness/uniformity/stability test; and registered. The breeder's right is not normally infringed by commercialisation of populations that include indistinguishable plants provided that:

- the indistinguishable plants have not been sourced from the registered variety; and
- the population as a whole is distinguishable from the registered variety.

ESSENTIALLY DERIVED VARIETY (EDV)

Terms of Reference and the Panel's Approach

The terms of reference established by SCARM regarding EDV are:

- *the Plant Breeder's Rights Office work with the plant breeding and biotechnology industries to clarify essential derivation, develop practical solutions to intellectual property management of essentially derived varieties* and, through this process, examine ways in which changes might be made to the Plant Breeder's Rights Act 1994 to better protect the interests of the first breeder.*

[* Essentially derived variety refers to the situation where the breeder of one variety (the 'first variety') claims that another breeder has developed another new variety (the 'second variety') that is distinct from, but closely resembles and is directly related to, the first variety in all important respects.]

The Panel's deliberations have not been assisted by:

- minimal argumentation presented as to why there is a need to change the PBRA to 'better protect the interests of the first breeder' in respect of clarification of essentially derived varieties and associated intellectual property management.
Although some concerns seem to be focused on the 'threat' that genetic modification (including patented gene modification) of conventionally bred varieties may pose for 'traditional' breeding programs;
- minimal empirical experience with EDV challenges under the PBRA to date, and no body of EDV experience globally to draw upon;
- a lack of public understanding of the function of the EDV concept, which is to protect against 'copycat' activity while not restricting the breeding of new varieties.

Fundamentally, EDV, as currently defined under the PBRA, potentially only encompasses a minor subset of all incrementally bred varieties. The minimal experience with EDV, even after 8 years operation, testifies perhaps to how small this potential subset really is. To this extent, possible changes to the scope/definition of EDV may have much less impact than some seem to envisage. Even then, such changes may have more impact on 'traditional' breeders than on 'biotech' breeders.

The Panel emphasises the difficulty of examining a provision as yet untested in Australia and tested minimally overseas. The provision is also the subject of debate that sometimes goes to issues that are only indirectly related to the prime function of EDV. Given the 'frontier' nature of EDV the Panel acknowledges that future events may necessitate reconsideration of the views expressed in this report.

Background : Incremental Breeding and Essential Derivation

Real progress in plant innovation—which must be the goal of intellectual property rights—relies on access to the latest improvements and new variation. As a general rule, the easier the access, the more incremental breeding is promoted.

Incremental breeding refers to the breeding of an unlimited series of new varieties with each subsequent variety being bred from, and relying heavily on, the characteristics of the previous varieties. The differences between the previous and subsequent variety can be large, small or very small, with the latter being the most common. They are, in fact, derived varieties that are different and new, but they are not copies (EDVs).

Any proposition to strengthen the first breeder's power by extending EDV to all incrementally bred varieties (and not just copies) would go to the fundamentals of the PBR system, with profound implications for the community of breeders, for consumers and for Australia's national interests. The view of the Panel is that examination of such a proposition goes beyond its terms of reference.

Freedom to Operate

- In the context of PBR, incremental breeding¹⁸ is associated with 'freedom to operate' (more formally known as the 'breeder's exemption', or the 'research exemption'), which prescribes free access to PBR varieties (see PBRA [section 16](#)) for the purpose of research or breeding a new variety and, in virtually all (non EDV) cases, the commercialisation of that new variety.

Along with other criteria, the PBR Office examines each new candidate variety for distinctness, uniformity and stability (the DUS test). The PBRA provides for a challenge to the candidate variety up to, and after, the grant of rights on the grounds, *inter alia*, that the criteria of DUS have not been met. While at least one clear difference is required to qualify for protection, economic/aesthetic/performance/values are not, *per se*, relevant for PBR protection. PBR is primarily a registration scheme based on perceived 'physical difference(s)' (eg a morphological, phenological or physiological difference) that distinguishes the candidate variety from all others. The difference may result in characteristics that have no agronomic value relevant to the registration process. Accordingly, a PBR registration of a plant sold through a garden centre is not a guarantee of performance/value, it simply warns against infringement of the innovator's rights.

There is a deliberate limited tension between the protection of the new variety and the unfettered commercialisation of varieties developed from it. PBRA [section 16](#) specifically allows free access to a PBR variety to breed other varieties (freedom to operate). With regard to commercialisation of such an incrementally bred variety that is registered under the PBR scheme, where the change on the first variety is large, the breeder of the second variety can exercise PBR in that variety without reference to the breeder of the first variety.

¹⁸ The term 'incrementally bred' is applicable to all varieties that share the majority of their characteristics with direct ancestors, irrespective of the breeding methodology used.

However, where a relatively minor change between two varieties occurs, the PBRA recognizes the rights of the first breeder through the possibility of a 'declaration of essential derivation'. Basically, the EDV concept is directed towards protection against 'copycat' activity, not against incremental breeding and the innovation that springs from that endeavour. Genetic modification, whether done by 'traditional' or 'biotech' methods, is not necessarily 'copying'.

The first breeder must apply for a declaration of EDV in terms of the criteria established under the PBRA, and, if successful, has equal rights with the second breeder in the essentially derived variety of the second breeder as is described below:

[Section 11](#) of the PBRA states:

Subject to sections 16, 17, 18, 19 and 23, PBR in a plant variety is the exclusive right, subject to this Act, to do, or to license another person to do, the following acts in relation to propagating material of the variety:

- (a) produce or reproduce the material;
- (b) condition the material for the purpose of propagation;
- (c) offer the material for sale;
- (d) sell the material;
- (e) import the material;
- (f) export the material;
- (g) stock the material for the purposes described in paragraph (a), (b), (c), (d), (e) or (f).

Despite the seemingly positive tone of section 11, the plant breeder's right is one of exclusion, as are rights granted by other forms of patent legislation. So that, currently, if EDV were declared, the first breeder could exclude the second breeder from doing the acts established under section 11 and *vice versa*, meaning that neither breeder would be able to do the acts. Both breeders would be able to exercise the full extent of their rights, but effectively the new essentially derived variety could not be commercialised.

EDV does not hinder access to the existing variety for research and development, *per se*. What it does is provide protection for the first breeder if their variety is copied by providing a mechanism that enables the first breeder to effectively veto commercialisation of the EDV, or extract a rent for the use of their intellectual property.

The Basis for a Declaration of EDV

Currently an EDV challenge in Australia can be made at the time of the PBR application for the second variety but can only be declared after the grant of PBR is made.

The test of whether the second variety is essentially derived from the first variety rests on the three criteria specified in the PBRA (see PBRA [section 4](#)), *viz*:

- it is predominantly derived from the first variety; and

- it retains the essential characteristics that result from the genotype or combination of genotypes of the first variety; and
- it does not exhibit any 'important' (as distinct from cosmetic) features that differentiate it from the first variety.

Interpreting these criteria consistently may be problematic as:

1. There are no definitions for the terms 'predominantly derived from', 'retaining the essential features of' etc, [an issue for all UPOV countries]
2. There is no definition for the term 'important, more than cosmetic, features' [an issue unique to the Australian PBRA]
 - however, 'important' would probably be taken to denote significant changes that affect performance, value or place in the market. For example, purple anthers in wheat, which do not affect performance or value of the crop, might fall into the category of a cosmetic feature.

It is not within the Panel's Terms of Reference to define these terms. Such definitions should be determined by the membership of UPOV, or by a court.

Membership of UPOV obliges Australia to meet minimum requirements but does not set upper limits, provided there is consistency with the minimum standards. The current provisions of the PBRA regarding essential derivation go further than the relevant UPOV 1991 provisions by:

1. Defining 'essential characteristics' as 'heritable traits . . . that contribute to the principal features, performance or value of the variety' (see PBRA section 3(1));
2. Requiring that important differences (more than cosmetic) must be demonstrated if the second variety is not to be regarded as an EDV; and
3. Stipulating that the PBR Office should make decisions in relation to a declaration that a variety is essentially derived.

Current Limitations of EDV and the Scope for Change

Non-PBR 'Copycats'

As the intent of PBR is to promote innovation, 'widening' of EDV in a way that threatens the development of innovation or restricts the breeder's exemption would, in the view of the Panel, be a negative step. This does not necessarily mean that there are no measures that could further protect the first breeder and stimulate innovation.

The Panel found that an EDV challenge is limited currently to applications (although the declaration can only be made in respect of a granted variety) for a grant of PBR in a new variety, or to grants already made. This means that those who breed from PBR varieties but do not enter their new variety into the PBR scheme cannot be challenged under the EDV provision of the PBRA.

Theoretically, the removal of the limitation of a declaration of EDV to only PBR varieties would give the first breeder a wider range of potential situations in which to exercise their exclusive right within Australia. The Panel believes that the current limitation is inconsistent with the intent of the legislation, which is to provide protection for the innovator. (Such a change would not necessarily hinder genetic modifiers of PBR varieties because new, genetically modified varieties might fall outside the other EDV criteria.)

The Panel recommends that the PBRA be amended to extend the capacity for an application for a declaration of EDV to varieties that are not the subject of PBR application or grant.

'More than Cosmetic' Differences

The Panel also considered removing the limitation that provides for an exemption from EDV declaration for those new varieties that can claim the 'more than cosmetic' defence. Removal of the exemption would increase the scope of the first breeder to exercise their negative right. It would also increase the level of uncertainty in plant innovation as subsequent breeders would be less sure that their new varieties would be outside the ambit of an EDV declaration.

The view of the Panel is that the aim of plant innovation is furthered if a breeder can meet the initial DUS criteria and then demonstrate that their incrementally bred variety has 'more than cosmetic' differences. The Panel therefore does not recommend change to this provision.

The EDV Adjudication Process

Currently the PBRA stipulates that the PBR Office must take decisions in relation to declarations of EDV. Hypothetically, (because there is no experience with EDV declarations to date), the two key areas of EDV examination would be:

- (i) The important (non-cosmetic) differences; and
- (ii) The scientific (genetic) evidence related to parentage.

The Important 'Non Cosmetic' Differences

As indicated above, PBR is primarily a registration scheme based on perceived 'physical difference or differences' (eg morphological, phenological or physiological difference) that distinguishes the candidate variety from all others. The difference may result in characteristics that have no agronomic or aesthetic value relevant to the registration process. Accordingly, PBR registration of a plant is not a guarantee of performance/value, it simply warns against infringement of the innovator's rights.

The expertise of the PBR Office does not extend to balancing the evidence of competing claims involving issues of economic impairment and/or aesthetic consideration. This has never been the role of the Office since the scheme is based on identifying 'physical' differences between plants, not assessing performance/value/merit of those differences.

Any EDV challenge would involve costs that, under current regulations, would be distributed across all applicants, irrespective of their involvement in the specific EDV

action. Moreover, any appeals under the current system would likely list the PBR Office as first defendant, inevitably magnifying the costs of running the scheme.

The scheme does not currently have the funds to provide such judicial capacity. A contingency fund, established from an increase in fees for all PBR users could provide such capacity. However, the Panel believes it would be impractical and inappropriate for the PBR Office to attempt to acquire and maintain such a specialised judicial capacity when it already exists elsewhere.

The Panel also believes that the scope to initiate a declaration of EDV through the PBR Office would result in action being taken more lightly, involve judgments that are very different from those traditionally made by PBR Offices, lead, in all likelihood, to further appeals to higher authorities, and impose unwarranted additional costs on the running of the scheme.

The Panel sees no compelling reason for all PBR users to bear the cost of EDV actions by individuals seeking to protect their own interests. Allegations of intellectual property impairment are routinely dealt with in the courts. Moreover, under other PBR systems, e.g. in Europe, allegations of EDV impairment is the responsibility of the judicial system. Courts are already equipped to deal with such disputes and action through the courts is a course that requires a serious cost/benefit analysis by both parties. Given the expense of maintaining structural capability to make judgments that would remain appealable, and accepted international practice that EDV challenges are a matter for the courts to decide, the Panel believes that the PBRA should be amended to bring it into line with such international practice.

The Panel observes that such a change would be more consistent with other aspects of the PBRA (e.g. infringement of rights) for a court of competent jurisdiction to decide whether a declaration in respect of EDV should be made. Moreover, if EDV is extended to non-PBR varieties it will not be possible for the PBR Office to have jurisdiction over such disputes.

The Scientific (Genetic) Evidence Related to Parentage

The PBR Office is not equipped for these examinations nor does it have specialist facilities to undertake DNA testing. In any event, DNA testing is normally commissioned by the applicant/breeder through a specialist independent organization.

The Panel strongly recommends that the PBRA be amended to remove the PBR Office from the adjudication process in respect of claims for EDV.

If the above recommendation is not adopted, the Panel strongly recommends that the current legislation should be reviewed with the aim of ensuring full cost recovery associated with claims for EDV.

GENERAL OBSERVATIONS

Incremental Breeding, Benefit Sharing, Gene Patenting

The following observations are extrinsic to the focus of this report.

The view of the Panel is that the attitudes of 'traditional' breeders towards the alleged threat posed by 'biotech' breeders are in a state of flux. Some take the view that by working co-operatively there are mutual benefits to be gained by all parties and that failure to work together will see many opportunities slip irretrievably away. Others have difficulty with this concept.

There is a view that favours extending the rights of the first breeder to cover the development and commercialisation of all incrementally bred varieties (as opposed to essentially derived varieties as defined under the Act), whether or not those varieties exhibit important differences. The Panel notes that this view, while bringing PBR more into line with patents, is fundamentally inconsistent with UPOV principles¹⁹.

The Panel understands that this push for benefit sharing across varieties derives from the perceived threat that 'biotech' breeding springs easily off 'traditional breeding' without recognising the true contribution of 'traditional', or first, breeders. It is also held that bio-technicians gain an unfair advantage when they insert patented genes into 'traditional' varieties. This is because the new gene inserted PBR registered variety may not be accessible for further research/development/commercialisation (because of patent considerations) while all other registered varieties without patent complications are available for further research/development/commercialisation. This situation is said to highlight the 'imbalance' of rights between PBR and patents. The real effects of this imbalance need to be verified before changes to the 'core' of the PBR system could be considered.

The view of the Panel is that changes to EDV cannot resolve the fundamental differences between patent and PBR principles. Patents give the capacity for almost total lockup of the invention while PBR gives free access. The wisdom of recreating those elements of the patent system that PBR was specifically designed to address, is questionable.

While broad empowerment of the individual breeder, in terms of exclusive right over incrementally bred varieties, has the potential to bring patents and PBR more into line, it would not resolve the underlying fundamental differences, and

- such a move would be a major shift negating the checks and balances envisaged by Parliament in introducing the PBR system by moving the balance of power more in favour of the individual, and away from public-good interests,
- such a proposition would require extensive consultation that this Panel is not in a position to conduct.

¹⁹ UPOV 1991 Article 15 (1) (iii) – the 'breeder's exemption'.

Patented Genes in PBR Varieties

UPOV envisages the registration of new varieties arising from all potential breeding methodologies, including genetic engineering, as does the Australian PBR system. The insertion of a patented gene into a PBR variety to create a new variety could prevent automatic access to that variety, while automatic access for further breeding is, in normal circumstances, guaranteed under PBR.

The new 'patented gene inserted variety' would not have to be PBR-protected because it would already have a deal of protection arising from the patent²⁰, would not be automatically accessible, would probably fall inside the set of varieties susceptible for a declaration of EDV (other countries) but outside the set of varieties than can be declared EDV in Australia.

Moreover, the patentee can choose whether to use a PBR/non-PBR variety as a 'host variety', and whether or not to apply for PBR in the second variety in order to avoid any possibility of EDV challenge.

Biotech Gene Insertion -- The "First Breeder's Nightmare"

In dealing with the notion that it is simple to insert a gene to create a new market-ready variety, the Panel has posed the following *ad hoc* propositions for discussion.

The Propositions

The first breeder is at the mercy of those with a gene gun.

Putting a gene into a variety to create a new variety is a disincentive for the first breeder to maintain/increase baseline varieties.

Those who seek to insert genes in baseline varieties have no interest in the maintenance of such varieties, or in benefit sharing.

Putting a gene into a variety is not creating a new variety. It is plagiarism.

Putting a gene into a variety to create a new, market ready variety is quick and getting easy.

Once these gene-inserted varieties are created they can be locked up by patent from further incremental breeding.

Once a breakthrough transformative technology has been achieved, its application over a range of adapted varieties is straightforward.

Better protection for the first breeder will promote plant innovation and benefit Australia.

Discussion

Mixing and recombining genes to form new varieties is the essence of plant breeding and has been carried on for generations. There is nothing

²⁰ Subject to the normal assumptions regarding claims made in patent applications

new in this concept. Plagiarism (copying), in plant breeding terms, only occurs when the new variety is virtually identical to the parent variety. Plagiarism can be dealt with under the current definition of EDV in the PBRA.

There are some common misconceptions about gene technology. It is not simply a matter of choosing a gene and putting it into a plant. Considerable effort and resources and risk are involved. Firstly, the relevant gene needs to be identified, isolated and the process for insertion established. Secondly, it may take many, perhaps hundreds of attempts to insert a gene successfully without deleterious side effects. A screening process is required to identify which plant(s) have been transformed in the desired manner. Thirdly, a transformed plant is often less than adequate and needs to be backcrossed with a well-adapted variety (although, this is less the case in relation to a number of field crops). Fourthly, rigorous testing and scrutiny by the Office of the Gene Technology Regulator is required to ensure that the transformed variety has no detrimental consequences to environment or public health.

Gene technologists rely on well-adapted varieties into which to insert their genetic sequences. Where do they get these well-adapted varieties from? They either use public varieties (which will presumably either run out or become outdated) or they use PBR varieties. It may be possible for them to use PBR varieties without recognising the efforts of the first breeder but they run the risk of EDV claims and/or ultimately a decline in baseline varieties. If the first breeder does not get their financial return there will be no funding for the breeding of future varieties. The logical process is for gene technologists to negotiate with 'conventional' breeders to produce the base material (i.e. well adapted varieties) into which genes can be inserted. Moreover, conventional breeders are usually required to make the transformed variety market ready.

Experience in the US to date, admittedly a relatively short timeline, shows that there has been no demonstrated decrease in the breeding of baseline varieties as a result of gene technology. Gene technologists generally recognise that they share a mutual interest in having a wide choice of baseline varieties on which to work and there are numerous alliances with conventional breeders that demonstrate this. Further, organisations are competing to gain access to baseline varieties (provided legal title is clear) creating the circumstances for parties to negotiate mutually beneficial arrangements. The development of co-operative arrangements is recommended.

More than ninety per cent of biotechnological and genetic resources for food and agriculture arise overseas. Creating barriers to the introduction of such technology into Australia can only lead to Australia becoming a less desirable investment destination and, ultimately, will ensure its decline as a vanguard plant breeding nation. Biotech companies may simply remove Australia from their investment maps if 'freedom to operate/access to varieties' is harder here than elsewhere.

This would mean that investment and technology imports into Australia would decrease and that breeding would go offshore.

Problems perceived in the patents system (e.g. the potential power of patents to 'lock up' material for future breeding through broad patent claims) are matters of current debate. Plant Breeder's Rights' regimes have been developed specifically to meet the particular needs of intellectual property in plants. Accordingly there are some differences between the two systems. Consequently, it is not possible to apply all of the concepts associated with industrial patents to plants. Moreover, since the PBRA policy intent is to promote the development of new varieties of plants, any proposals that may hinder that intent would need to be examined carefully.

Plant breeding has become a technically sophisticated science. It is no longer necessary to utilise the descendants of a long breeding line to achieve a new variety that is all but identical to current varieties, save for one or more distinct characteristics. For example, this can be done in the major field crops by accessing and crossing unprotected germplasm before applying the appropriate selection methods to isolate the desired individuals. This would avoid the necessity to recognise/work with the 'traditional' or first breeder (and all but circumvents EDV issues). The effect of the PBRA should be to encourage breeders and biotechnologists to work cooperatively to mutual benefit, and should not alienate the parties by polarising their efforts.

Level of Understanding of PBR

The Panel notes that there is considerable scope for improvement in the general level of understanding of the PBR scheme and that the PBR Office should continue to make efforts to improve such understanding.

Intellectual Property Rights

Ownership of intellectual property in plants is a long established, legitimate system. Such rights form the basis of an international multilateral agreement (the *International Convention for the Protection of New Varieties of Plants 1991* (UPOV)) supported by 51 member countries under the aegis of the United Nations. Participation in this international system, on which the PBRA is based, enhances Australia's competitiveness in agriculture and benefits our overall economy due to the pervasive usage of plants in industry. The PBRA includes specific provisions to protect the public interest, while the rights accorded are of limited scope and duration.

A 'Perfect' System

Perfect regulatory systems are a rarity. Most systems are in a continual state of adjustment to reflect all kinds of changes, technological, market, ethical, etc.

The Panel believes that PBR is a good system and, like most systems, is a work in progress. Indeed, the Panel's current consideration of how 'breeding' might be clarified has itself been stimulated by an overwhelmingly positive response to a review of the worth of the PBR scheme through the SCARM process.

Variety of Common Knowledge

The Panel acknowledges the absence of a comprehensive definition of 'variety of common knowledge' (VCK).

Historically, UPOV has approached the issue by way of an inclusive list of activities that may bring a variety into common knowledge. The Panel notes recent discussions in UPOV have been unable to develop a definition of VCK that is acceptable to all and supports continuing discussions on this matter in the UPOV forum.

The Panel notes that the test for VCK is not limited only to Australia, but is addressed in a worldwide context. Accessing the requisite information may be problematic. However, [section 50](#) of the PBRA provides a means to revoke a grant of rights if new information comes to light.

PBR and Other Legislation

There is a general lack of understanding that the PBR system (like others) co-exists with other legally enforceable rights, and of the various possible implications of this reality.

For example, dispute over the physical ownership of plants is an issue for common law proceedings in the courts. Intellectual property ownership is the basis of the UPOV and the derived PBR system. Physical ownership is not an issue under UPOV, or under the PBRA. Some parties are not familiar with this reality, or choose not to accept it. There is scope for commercial agreement in relation to such matters outside the PBR.

It is feasible for a new variety to be registered under the PBRA but for the exercise of the breeder's right to be restricted by other legislation, for example, prohibition against the use of a variety in food, or against the growing of a variety as a noxious weed.

Opposition to Grant of Rights

The Panel is critical of uninformed/unsupported opposition to applications for protection, emphasizing that clear and convincing evidence is the only foundation of valid objection. Assertions, or unsubstantiated claims, are invalid and unacceptable. The Panel also recognizes that it is not the responsibility of the PBR Office to provide legal advice to an objector, or to act on behalf of any party.

The Panel further recognises that:

- UPOV (and the derived PBR system) operates on the presumption that, if nothing is proved to the contrary, a breeder's *prima facie* claim to have produced a new variety is valid;
- UPOV's premise is that the benefit of doubt lies with the breeder;
- the legal test of eligibility for protection under the PBRA is when the Secretary (or delegate) of the Department of Agriculture, Fisheries and Forestry is satisfied that the relevant criteria have been, and continue to be, met;

- lack of comprehensive supporting information or the presence of inconclusive contradictory information is not a bar to the Secretary being satisfied that a grant of rights should be made, while conclusive proof would be;
- if all requirements of the PBRA are met, and the truthfulness, accuracy and correctness of the breeder's claims are not disproved, a grant of rights must be made; and
- the penalties for false statements in relation to PBR are significant, including imprisonment.

PBR and the Convention on Biodiversity (CBD)

The Panel perceives a lack of understanding of the interaction between PBR and the Convention of Biodiversity (CBD). While acknowledging that the linkages between PBR and the CBD are not seamless, scope for conflict is more imagined than real. The two are not so much in conflict as having different emphases.

APPENDIX **1**
DEPARTMENT OF ATTORNEY GENERAL'S ADVICE ON 'DISCOVERY'

AUSTRALIAN GOVERNMENT SOLICITOR

7 November 2000

Mr Doug Waterhouse
Agriculture, Fisheries and Forestry - Australia
Plant Breeders' Rights Australia
Edmund Barton Building
Broughton Street
BARTON ACT 2600

Dear Mr Waterhouse

Plant Breeder's Rights Act 1994 - 'Discovery'

1. I refer to our previous discussions in relation to the above matter, and to your request for advice on the meaning of the expression "discovery" in section 5 of the *Plant Breeder's Rights Act 1994* (the Act), which provides as follows:

(1) A reference in this Act to breeding, in relation to a new plant variety, includes a reference to the discovery of a plant together with its use in selective propagation so as to enable the development of the new plant variety.

(2) If a plant is discovered by one person but used in selective propagation by another so as to enable the development of a new plant variety, those persons are together taken to be the joint breeders of the new plant variety.

2. You have asked that in providing the advice we work through a series of "primers", and these are addressed below.

Primer 1 - What is "discovery"?

3. The word "discovery" in everyday usage has a number of different meanings. The word is not defined in the Act itself, nor has it been judicially interpreted in the context of the Act. The two rules of statutory interpretation of particular relevance are, firstly, that words should where possible be given their ordinary meaning, and secondly, that any part of an Act should be read in the context of the Act as a whole.

4. The Shorter Oxford English Dictionary (3rd edition) relevantly defines "discovery" as "the finding out or bringing to light that which was previously unknown". The words "bringing to light" may

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suggest that discovery involves drawing attention to the thing discovered. This is also consistent with the Dictionary's other definitions of "discovery" as the uncovering or disclosure of something not generally known.

5. The Macquarie Dictionary (3rd edition) relevantly defines "discovery" as "something discovered", and defines "discover" as "to get knowledge of, learn of, to find out; gain sight or knowledge of (something previously unseen or unknown)." The words "learn of" suggest that the thing discovered may only be new to the discoverer, and not to everyone. Also cited is the "archaic" usage of discover to mean "make known".

6. Efforts to define the word "discovery" in tax legislation, where it generally refers to the "discovery" of error or omissions in calculations, have favoured the natural or everyday meaning of the word, per Cohen LJ in *Commercial Structures Ltd v Briggs (Inspector of Taxes)* [1948] 2 All ER 1041 at 1049:

"If some other meaning is to be given to "discover" than the natural meaning "to find out", I should like to learn what it is."

7. A similar approach has been taken in Australia, in *Francis v Commissioner of Stamp Duties* (1953) 53 SR (NSW) 257, where Street CJ said at 263:

"To "discover" means to obtain knowledge or to become aware of some fact or circumstances for the first time, in other words, as has been said in the English decisions, "to find out".

8. However, the word must also be looked at the context of the Act as a whole, and in the context of a regime involving competing applications for intellectual property rights. This arguably imports some sense of novelty to the word; that the "discovery" should not be new only to the discoverer. Support for this may be found in the requirement in sub-section 43(2) of the Act that a variety must be distinct from any other variety which is "common knowledge".

9. From the wording of section 5, it is clear that discovery alone is not sufficient to found an application for PBR. It must be accompanied by selective propagation. This suggests that the bar for "discovery" need not be set very high, and that, for instance, it need not of itself satisfy the requirements for an "invention" in accordance with section 10 of the Act and paragraph 51(xviii) of the Constitution.

10. This is consistent with the case law in relation to patents, which clearly distinguishes between a "discovery" and an invention. So, for example, in the case of *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 at 264 the Court acknowledged that mere discoveries are not patentable unless they are acted on in a way which produces something new and practical (as was the situation in that case):

"There may indeed be discovery without invention - either because the discovery is of some piece of abstract information without any suggestion of a practical application of it to a useful end, or because its application lies outside the realm of "manufacture".

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11. Discovery of an abstract piece of information without any suggestion of practical application may be equated with discovery of a plant without any suggestion that steps be taken to develop or propagate it.

12. We have also considered whether "discovery" might be said to refer to the particular properties of the plant, instead of the physical plant itself. However, given the distinct definitions of "plant" and "plant variety" in section 3 of the Act, we do not think that this is a viable interpretation.

13. In our view, "discovery" in section 5 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".

Primer 2 - How can a person claim to have discovered a plant?

14. Under sub-paragraph 44(1)(b)(iii) of the Act, the Secretary must be satisfied that the applicant is entitled to make the application. Under sub-section 24(1), only a breeder of a plant variety may apply for a grant of PBR (or their assignee, under section 25). Breeding, in accordance with section 5 of the Act, includes (but is not limited to) the discovery of a plant together with its selective propagation.

15. It is therefore incumbent upon the applicant to provide sufficient information in their application to satisfy the Secretary that they are the breeder of the plant variety. We note in this regard that section 26 of the Act requires the applicant to provide particulars, including at paragraph 26(1)(c) a statement that they are the "breeder" of the plant, and at paragraph 26(1)(e) a description and photograph of a plant of the variety sufficient to distinguish it *prima facie* from plant varieties which are of common knowledge. Paragraph 26(1)(i) provides that the applicant must also supply details of an "approved person" who can verify the particulars in the application.

16. If the applicant is required to establish their "discovery" of a plant, in order to show they are the breeder of a plant variety, then the Secretary needs to determine firstly, that the applicant found the plant, and secondly, that the plant is not generally known or of a variety already registered. The first premise should be able to be established from the applicant's own statement, noting that section 75(1) makes it an offence to make, knowingly or recklessly, a false statement in an application. The second premise will presumably be within the Secretary's own knowledge, on the basis that the plant will either be on the register or will be common knowledge.

17. Either premise may be overturned by further evidence which the Secretary considers more compelling - for instance, information provided by an objector. However, on the basis that it is an offence under section 75(1) to make a false statement in support of an application, we do not consider that the Secretary need look behind the particulars supplied under section 26 unless he or she is given good reason to do so.

Primer 3 - Can discovery occur more than once?

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18. Your position is that discovery may occur more than once, and we agree. So long as the plant is not a matter of common knowledge, it is possible for more than one person to discover it. If, however, the plant becomes generally known, or is made known to a person, that person could not claim to have "discovered" it. This is supported by the definition of "breeder" in sub-section 3(1) of the Act, which anticipates in paragraph (b) that two persons may breed a plant independently.

Primer 4 - What can disqualify a person as a discoverer of a plant?

19. Whether a person has discovered a plant is ultimately a question of fact. If the plant is of a variety which is already registered, or there is satisfactory evidence that the plant is common knowledge, then the person cannot claim to have discovered it. If the plant is not otherwise registered or known, and the applicant claims to have discovered it and provides adequate details of the discovery, this should be adequate to establish their right to make an application.

20. Of course, if another person, such as an objector, provided evidence that the applicant had been informed of the plant or been provided with a cutting, or something similar, and could not be said to have "discovered" it, the Secretary would have to weigh that information on its merits. In such a circumstance both parties should be made aware of sub-section 75(1) and the relevant penalty.

Primer 5 - Can discovery be disallowed simply by a claim that another person discovered the plant and informed the second person?

21. Where one person has discovered the plant and informed a second, who conducted selective propagation, a joint application is appropriate under sub-section 24(3). The wording of sub-section 5(2) suggests that this will be a collaboration, an interpretation supported by the Explanatory Memorandum, which refers to "the joint process of discovery and development of a new plant variety".

22. However, in the absence of a collaboration our view is that a mere claim that another person had discovered the plant and informed the applicant, who then used that information to obtain and propagate the plant, would not be sufficient without convincing evidence. Again, the provisions of section 75(1) mean that great care should be taken in assessing whether a person has deliberately provided false information under the Act, and an applicant's statements should not be lightly disregarded.

23. Ultimately, if the evidence suggests that the allegation is true, then the applicant may fail to qualify as a "breeder" and not be entitled to apply for PBR. However an unsupported assertion would in our view be insufficient to establish this.

Primer 6 - Is there a difference between discovering the plant and discovering characteristics hitherto unknown about the plant?

24. In our view there is a difference, and the discovery of new characteristics in a plant variety does not amount to discovery of a plant under section 5. As discussed above, section 3 of the Act clearly defines "plant" in terms of the broad types of botanical specimen which the word includes, whereas the expression "plant variety" concerns the detailed characteristics of a botanical

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specimen. Discovering a plant merely means finding a physical example of a plant, and not discovering its particular characteristics.

25. This view is consistent with section 45 of the Act, which provides that only one grant of PBR may be made in relation to a plant variety. Even if new characteristics of the plant were found, once the plant variety is registered it cannot be registered again. While the variety's characteristics are important in determining whether it is distinct, stable and uniform, as required by section 43, what those characteristics actually are is not relevant.

26. This is supported by the interpretation of the word "discovery" in the case of *Beatty (Earl) v Inland Revenue Commissioners* [1953] 2 All ER 758 at 761-2, per Vaisey J (although this case concerned the "discovery" by the tax Office of a fault in a tax return), which suggests that discovery of a thing does not rest upon all understanding of its characteristics:

"It seems to me that this is a true analogy: - A man finds or discovers in his land a diamond. He thinks it is only a piece of glass, but, though he did not at first find out it was a diamond, he had in the true sense discovered it on the day that he found it. I think that the discovery need not be a complete and detailed or accurate discovery ... it is not necessary for them to have probed the matter to its depths or to define precisely the ground on which they have made the assessments ... [T]he commissioners, to revert for a moment to my analogy, thought that the diamond which they had found was only a piece of glass, but it was none the less a discovery."

27. If, however, the newly discovered characteristic means that the variety is not uniform or stable as was previously thought, there could be grounds for revoking the grant of PBR under section 50, as had the Secretary been aware of those facts at the time of making the grant he or she would have refused to make it.

Primer 7 - Can discovery be made of a plant that is owned by another person or which is on Crown land?

28. In terms of the Act, there does not appear to be anything which would prevent discovery of a plant taking place on property which does not belong to the applicant, or which would prevent "discovery" being made of a plant which physically belongs to someone else. These may raise other legal issues between the applicant and the "owner", but the Act does not provide the avenues to deal with them. As we have discussed elsewhere, ownership of a physical specimen of a plant is quite distinct from ownership of the intellectual property rights in the plant variety, in the same way that a person may own a book without owning the copyright in the book.

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Primer 8 - What should the PBR Office do to confirm discovery?

29. In our view the PBR Office (acting for the Secretary) does not need to do anything to "confirm" discovery except satisfy itself that the information provided by the applicant is sufficient to establish the discovery, and that it is appropriately verified by the person nominated under paragraph 26(2)(i) of the Act.

30. On the basis that sub-section 75(1), already referred to, provides that to make, recklessly or knowingly, a false statement in an application, or otherwise under the Act, is an offence punishable by six months' imprisonment, we consider the Secretary should be able to assume the information provided by the applicant, and verified by the nominated "approved person", is correct in the absence of evidence to the contrary.

31. The Secretary is not required to look further than the application unless the Secretary finds the information provided to be insufficient, or unless some inconsistency or flaw gives rise to suspicion. In such a case the Secretary should seek further evidence from the applicant or the approved person.

32. In the event that an objection is made, it is for the objector to provide the Secretary with evidence in support of the objection. If the objection does not include evidence, but only assertions, or evidence which is not convincing, then the Secretary may ask the objector for better evidence, but if the objector is unable to provide it then the Secretary is not required to establish the objector's case for them.

Primer 9 - Is discovery independent of the DUS criteria?

33. Under section 43 of the Act, and under Article 5 of the UPOV Convention, in order for a plant variety to be registrable it must be distinct, uniform, and stable (the DUS criteria). "Distinct" means that it must be clearly distinguishable from other known plant varieties, "uniform" means its characteristics remain uniform upon propagation, and "stable" means its characteristics remain stable after repeated propagation.

34. We do not think that the DUS criteria have any bearing on the issue of "discovery". The DUS criteria relate to plant varieties, whereas discovery is merely of a plant. The DUS criteria would presumably be applied to the characteristics revealed or developed in the course of the selective propagation which must accompany discovery in order to amount to "breeding" as defined in section 5.

Primer 10 - Can the discovery of a plant in the wild constitute a discovery under section 5?

35. There appears to be no reason why the discovery of a plant in the wild would not constitute "discovery" under the Act. Indeed, this seems like the type of circumstance where discovery of a hitherto unknown plant would be most likely to occur.

Summary

36. In summary, we are of the view that "discovery" merely means the finding of a physical plant which is not common knowledge. Where the

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plant is found does not impact on whether it has been "discovered" under section 5.

Yours sincerely

Sarah Byrne
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Australian Government Solicitor

APPENDIX 2 VARIETY OF COMMON KNOWLEDGE

A 'variety of common knowledge' (VCK) is not defined in the *International Convention for the Protection of New Varieties of Plants 1991* (UPOV 1991). The 1961/72/78 revisions of the UPOV Convention, under Article 6, Conditions Required for Protection, state that 'the variety must be clearly distinguishable . . . from any other variety whose existence is a matter of common knowledge at the time protection is applied for'. It then goes on to indicate how Common Knowledge may be established: '*. . . by reference to various factors such as: cultivation or marketing already in progress, entry in an official register of varieties already made or in the course of being made, inclusion in a reference collection, or precise description in a publication*'.

The Convention as revised in 1991 says at Article 7, Distinctness, 'The variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application'. It then goes on to add the single comment that: '*In particular, the filing of an application for the granting of a breeder's right or for the entering of another variety in an official register of varieties, in any country, shall be deemed to render that other variety a matter of common knowledge from the date of the application, provided that the application leads to a granting of a breeder's right or to the entering of the said other variety in the official register of varieties, as the case may be*'.

The records of the discussions that took place at the UPOV 1991 Diplomatic Conference make it clear that the intention of this sentence was to clarify a particular situation that might exist in the case of two 'competing' PBR applications in different countries. It was not intended to be an exhaustive definition of what constitutes Common Knowledge, and the potential need for a much fuller set of examples was in fact raised.

This suggestion was not followed up, and, until recently, Article 7 was being taken as a complete definition, which gave rise to a number of misconceptions as to what constitutes a variety of Common Knowledge. Clearly Common Knowledge is always a legal matter upon which a national authority will rule.

UPOV Revisits Variety of Common Knowledge

Arising from very lengthy discussions, the UPOV Technical Committee is considering the following:

Varieties of Common Knowledge

Key aspects for determining whether a variety is a variety and moreover whether its existence is a matter of common knowledge are set out below. These considerations apply equally to all types of variety, whether protected or not, and include plant material such as ecotypes and land-races. Further developments and a more detailed explanation of the issues related to varieties of common knowledge are to be found in document TGP/3, "Varieties of Common Knowledge". (*The Panel notes that at the time of this report TGP/3 was not drafted*)

Criteria for a Variety

A variety whose existence is a matter of common knowledge must satisfy the definition of a variety set out in Article 1(vi) of the 1991 Act of the UPOV Convention, but this does not necessarily require fulfillment of the DUS criteria required for grant of a breeder's right under the UPOV Convention.

Existence of a Variety

Living plant material must be in existence for a variety to be taken into account for distinctness.²¹

Common Knowledge

Specific aspects that should be considered to establish common knowledge include:

- (a) Commercialization of propagating or harvested material of the variety or publishing a detailed description;
- (b) The filing of an application for the grant of a breeder's right or for the entering of a variety in an official register of varieties, in any country, which is deemed to render that variety a matter of common knowledge from the date of the application, provided that the application leads to the grant of a breeder's right or to the entering of the variety in the official register of varieties, as the case may be;

²¹ The Panel notes that debate on the existence of living material, as a qualifier for variety of common knowledge is ongoing.

- (c) existence of living plant material in publicly accessible plant collections.

Common knowledge is not restricted to national or geographical borders.

In applying the notion of common knowledge in cases of dispute and particularly applications for a declaration of nullity, UPOV Contracting Parties are recommended to be prepared to take into account not only knowledge that exists in documented form, but also the knowledge of relevant communities around the world provided that this knowledge can be credibly substantiated so as to satisfy the standard of proof of the civil law courts.

The definition of “variety” introduced in Article 1(vi) of the 1991 Act plays an important role in this context. The words ‘irrespective of whether the conditions for the grant of a breeder’s right are fully met’ make it clear that commonly known varieties which are not protectable may, however, still be varieties which meet the criteria of Article 1(vi), from which a candidate variety must be clearly distinguished. This means, for example, that land races which are capable of satisfying the definition of “variety,” and which can in consequence be defined and propagated unchanged should be regarded as varieties of common knowledge for distinctness purposes.

APPENDIX 3 ABBREVIATIONS AND ACRONYMS

CBD	Convention on Biodiversity
DUS	Distinctness, Uniformity, Stability
EDV	Essentially Derived Variety/ies
GRC	Genetic Resource Centre
IP	Intellectual Property
PBR	Plant Breeder's Rights
PBRA	<i>Plant Breeder's Rights Act 1994</i> as amended
PBRAC	The Plant Breeder's Rights Advisory Committee
PBR Office	Plant Breeder's Rights Office
PVRA	<i>Plant Variety Rights Act 1987</i> as amended
SCARM	Standing Committee on Agriculture and Resource Management
UPOV 1991	Convention of the International Union for the Protection of New Variety of Plants as revised in 1991
VCK	Variety of Common Knowledge