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NEW VARIETIES OF PLANTS

**WIPO-UPOV SYMPOSIUM ON THE CO-EXISTENCE OF PATENTS
AND PLANT BREEDERS' RIGHTS IN THE PROMOTION OF
BIOTECHNOLOGICAL DEVELOPMENTS**

organized by
the World Intellectual Property Organization (WIPO)
and
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PLANT VARIETY RIGHTS —THE BREEDER'S EXEMPTION

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This paper deals with Plant Variety Rights (PVP), and more specifically with the Breeder's Exemption.

1. Why a special intellectual property system for plants?

Effective intellectual property rights (as mandated by the TRIPS Agreement¹, Article 27.3) are practically as well as legally essential. They recognise and encourage the work of plant innovators: and, most importantly, they allow the recovery of investments made in breeding. Plant breeding is slow, skilled and expensive work-producing a new variety may easily take ten years. Once produced, the variety (at least if it is open-pollinated) may be very easily copied. Without intellectual property (IP) rights, the breeder could charge a premium for new seed only in the first season. This would make the seed too expensive: few would buy it and the breeder would lose his investment and go out of business.

Without intellectual property rights, private breeding cannot be profitable. Breeding can then only be done by public bodies, publicly financed (universities or Governments, for example). Of course such bodies can do excellent work: indeed they are the only option available in some cases. But where a market exists, or can be developed, private initiative is to be preferred. Governments are fallible. Publicly sponsored work lacks the spurs of the profit motive (Adam Smith's invisible hand) and of competition; though more high-minded, it is less diverse, in approach and in resources.

Accepting that we need IP protection for breeding, why is it necessary to have a special system? Patents are the standard way of protecting technical developments. Though the system remains controversial (and is far from perfect), it is tried and tested. Why not use it for plant varieties? The English philosopher William of Occam laid down a vital principle: '*Entia non sunt multiplicanda sine ratione*²' (entities are not to be multiplied without a reason). We apply this principle in the natural sciences to select the simplest explanation that fits the facts. It applies equally to man-made laws and regulations.

Why then is a separate system required for plant varieties? There are various doubts and difficulties in applying the patent system to plant varieties. The patent system evolved to deal with mechanical inventions. Some have argued that it cannot be extended to cover 'life'; or if it can, it should not. 'Life' (it is said) cannot be invented, only discovered³. Patenting living organisms (it is claimed) is intrinsically immoral, or will have unacceptable results. These objections are strongly contested, but continue to cause anxieties.

Other objections are more specific. Patent rights require an invention, which the public can be taught to carry out by means of a written description. The process of breeding is rarely reproducible, depending on chance events: a variety may be reproducible (indeed must be, to qualify for protection) but the process by which it is first produced generally is not. Further, many new varieties are *prima facie* 'obvious'. They are obtained by crossing two parents

¹ The Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organisation.

² Also quote as: "*Entia non sunt multiplicanda praeter necessitatem*".

³ This objection carries much weight in Europe, where 'discoveries' are unpatentable (Art 52 European Patent Convention (EPC)), but little in USA, where 'inventions' are defined as including 'discoveries' (35 USC 100)

each with a different desirable property, and picking progeny that have both. This is, broadly, a predictable process, and thus, at least in some countries, may be considered lacking in 'inventive step' and not a proper subject for patent protection. The fact that to produce this 'obvious' product takes ten years of skilled work may count for nothing. Another concern is the right given to the patent owner. In some circumstances, the sole right to make use and sell a patented variety may be considered too broad, preventing re-planting of protected seeds - in others it may be considered too narrow, if selling the seeds gives the buyer the right to use them for their natural purpose, i.e. reproduction.

To get round these doubts and difficulties (all of which, individually, remain contentious and may have satisfactory answers), the UPOV Convention set up a new *sui generis* system-a new right specifically for plant varieties. This is not a patent. It has different requirements for protection. The variety need not be inventive or non-obvious, just 'distinct' from known varieties. It need not be reproducible from a written description - just 'stable,' so that it can (somehow) be reproduced in successive generations and retain all its properties. It must also be reasonably uniform. Rights over the variety are not so strong as a patent would give-initially they were limited to the right to reproduce propagating material of the variety for sale, though they have since been extended. Weaker rights reduce the problems of ethics associated with monopolies over organisms that may be important food sources.

UPOV began in the 1960's. Since then patent law has changed somewhat. The TRIPs Agreement (Article 27) has liberalised patenting requirements. Organisms clearly can be patented-though there is no obligation to patent plants (TRIPs Agreement, Article 27.3). The 'written description' requirement for inventions can be at least partially supplemented by a deposit of biological material. However, arguments about 'obviousness' and 'inventive step' remain: as do controversies about the strength of rights over important food crops. The UPOV system retains its importance. It is designed specifically to protect the work of breeders, while taking into account users' needs. In particular, and most importantly, it preserves public rights for further development.

2. The Breeder's Privilege under Plant Variety Protection

A fundamental purpose of intellectual property is to promote technical advance. In the United States of America, IP is only legal provided it serves: *"To promote the progress of science and useful arts ..."* (US Constitution, Art 1, s.6). For this reason, most patent laws have a "research exemption," to allow further development. This is particularly important for breeders, who traditionally work by incremental improvement of existing materials. If they do not have access to new materials, to make further improvements, their work is severely hindered. They need freedom to continue.

What then is the Research Exemption under plant variety rights? The 1991 Act of the UPOV Convention (UPOV 1991), Article 15(1) provides:

- (1) *(Compulsory exceptions) The breeder's right shall not extend to*
 - (i) *acts done privately and for non-commercial purposes,*
 - (ii) *acts done for experimental purposes and*

- (iii) *acts done for the purpose of breeding other varieties, and, ...[derived varieties aside], acts .. .[of commercial exploitation].. in respect of such other varieties.*

It follows from this that it is never an infringement of a plant variety right to use the variety for further breeding. This does not include, of course, use in commercial production: it is infringement to use a protected variety repeatedly, for example, as the parent of a hybrid. Equally, in general, it is not an infringement of a PVP to exploit or sell the new variety bred. However, under UPOV 1991 there is an exception to this latter proposition: the case of ‘essentially derived varieties.’

‘Essentially derived’ varieties

Varieties are by definition distinct from each other. Under the 1978 Act of the UPOV Convention (UPOV 1978), no registered variety could infringe another (leaving aside repeated use, of the kind discussed in the previous paragraph). As a result, very similar varieties could be, and were, registered. The coming of gene technology made this situation worse. In principle at least, an existing successful variety could have a new trait, based on a single gene, rapidly introduced. The resulting variety would be separately registrable, and would (it was felt) take unfair advantage of the work of the original breeder.

Such considerations led to the introduction, in UPOV 1991, of protection for ‘essentially derived varieties.’ Article 14(5)(b) of UPOV 1991 reads (in part:)

“... a variety shall be deemed to be essentially derived from another variety ("the initial variety") when

“(i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,

“(ii) it is clearly distinguishable from the initial variety and

“(iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.”

Sales of such derived varieties infringe the right in the initial variety. To help with the construction of this paragraph, Article 14(5)(c) of the Convention goes on to give examples. These include new varieties obtained from the originating variety by:

- selection of variants or mutants (naturally occurring or induced)
- selection of somaclonal variants (from tissue culture);

Genetically Modified (GM) technology;
‘back-crossing’⁴

⁴ It is not clear whether a single back-cross would necessarily give rise to essential derivation.

This list is not exhaustive. Other techniques may give rise to essentially derived varieties. One potentially controversial is marker-assisted crossing and subsequent selection.

What is the effect of this? A holder of rights in a successful protected variety can now challenge 'follow-up' varieties of competitors. If the new variety has a closely similar phenotype, and a closely similar genotype, there is a *prima facie* case of 'essential derivation.' This may be rebutted by proof that the new variety was not bred from the original variety, or by showing a different origin for at least some of the shared traits. A major problem with the concept is determining the 'essential characteristics' of the original variety, or, to put it more colloquially, how close is too close? To solve this, the breeding industry is trying to agree norms. These will vary by crop. Undoubtedly they will leave room for argument - and no doubt eventually litigation.

Note the following: 'Essential derivation' is a matter of fact-dependency is the (possible) legal consequence. These questions are for courts, not PVP offices, to decide. No question arises for decision until parties disagree. 'Essentially derived' varieties have themselves no protection against further derivation. This is because protection for derived varieties is granted to innovative breeders, and not to copyists. Therefore, it is a defense to the accusation of 'essential derivation' to prove that the claimant's variety was itself 'essentially derived.' Most importantly, the breeder's privilege is unaffected. A derived variety may be bred, and indeed registered: it is only commercial exploitation that requires permission. If, though derived, it has commercial merit, a deal with the owner of the original variety should be possible. The right to use protected varieties in breeding remains-it is only the development of close copies that is deterred.

Thus the plant variety protection system provides reasonably clear rights to use protected germplasm for further development. But is this enough to give breeders the freedom they may need? Several other rights can inhibit this freedom. These include:

- patents;
- national access rights (such as arise out of the CBD⁵);
- trade secrets;
- and contractual rights.

Of these, patents are so important as to require their own separate discussion. Access rights are increasingly important, but cannot be dealt with here: However, the FAO-sponsored International Treaty has made useful progress in tackling this problem. This leaves trade secrets and contractual rights to be briefly reviewed.

Trade Secrets

The patent system requires the inventor to teach the public how to operate the protected invention. This is not consistent with secrecy. The inventor's bargain with the public requires disclosure-in some countries, of the inventor's best method. The PVP system does not require the breeder to teach the public. It is sufficient to produce material of the new variety-which, in contrast, a patentee has no general obligation to do. However, material of

⁵ Convention on Biological Diversity, Rio: this came into force in December 1993.

the new variety may be exploited without being made available to the public. Varieties in the form of pure lines are naturally so made available when sold (and breeders of such lines are always at risk of having their materials illegally multiplied). Hybrid varieties are sold to the public, who however have no easy means of reproducing them. Parent lines are exploited by being used to make hybrids. Thus such parent lines are generally not made publicly available, and indeed considerable trouble is taken to keep them as in-house trade secrets. There is some dispute about whether this is proper, but the view of the industry is clear.

What constitutes a trade secret? Definitions vary, but the following is taken from the US Economic Espionage Act of 1996:

“All forms of information [embodied or not] ... if

“(A) the owner thereof has taken reasonable measures to keep such information secret; and

“(B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.”

I note in passing that this Act makes misuse of trade secrets in USA a criminal offence, potentially punishable by long terms of imprisonment.

The most difficult question about this definition is what constitutes ‘proper means’. Clearly stealing material of the variety from enclosed fields in which it was being grown would not be ‘proper means.’ However, suppose a farmer finds a protected pure line growing in his field (an unintended contaminant from the process)?

Contractual terms

This is another significant means whereby the access of breeders to protected varieties can be limited. One way in which this can happen is by developing agreements between breeders. One breeder will give another access to germplasm for the purpose of further breeding. Such access will typically be accompanied by restrictions on the use to which the germplasm is to be put, royalties to be paid, etc. In such agreements freely made between parties of generally equivalent status, the obligations undertaken will typically be balanced by the advantages obtained.

Contractual terms inhibiting exploitation may also be found in a quite different type of agreement—that for sales of seed. Since the genetic revolution, the analogies between the seed industry and the software industry grow apace—now the seed industry is starting to use shrink-wrap licences! Increasingly, bags of seed are found to bear labels limiting the rights of the purchaser: to replant seed, to use in breeding, and so on. In such cases, it seems that (as with computer software) the purchaser is not buying seed, but acquiring a temporary and limited license to use it. The terms may vary considerably. They may be directed simply to ensuring that the purchaser obtains no rights in unintended contaminants (parent lines)—such terms are perhaps no more than ‘reasonable measures’ to keep the lines secret. They may be much broader. Are they effective? This may require litigation to establish—and the answer may differ from country to country. If they are, they may largely nullify the effect of the breeder’s exemption.

To summarise: it is contended that the plant variety system makes an important exception to ensure that protected varieties are available for further development, so that the art can progress. However, the same exception is not available in other right systems. Such systems are increasingly prevalent, and may effectively smother the breeder's privilege. Is this what we want?

Slide 1

Plant variety rights - The Breeder's Exemption

Tim Roberts
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Slide 2

Topics for discussion

- Why a special IP system for plants?
- The Breeder's Privilege under PVP
- 'Essentially derived'
- Other restrictions on breeding

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Slide 3

We need IP for plants

- To recognise and encourage work of plant innovators
- To allow recovery of investment
 - breeding takes much time and money
 - products are easily copied

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Slide 4

Without IP

- Breeding must be done by public bodies (eg Governments)
- Governments fallible
- Lose benefits of
 - self-interest ()
 - competition
 - diversity

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Slide 5

Why PVP?

- **Patents** are the standard way of protecting technical developments
- **Do we need a separate system?**
- *‘Entia non sunt multiplicanda sine ratione’* - William of Occam
 - true of both natural and man-made laws

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Slide 6

Problems of patenting

- **Can (should?) organisms be patented?**
 - You **can’t** invent **‘life’**, only discover it
 - **It’s immoral** - intrinsically or in consequences
 - Breeding is **not reproducible**
- **Aren’t new varieties ‘obvious’?**
- **Are the rights of the patentee appropriate?**
 - **Too weak - or too strong?**

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Slide 10

Freedom to develop - PVP

- **Important purpose** of IP is to **promote technical advance**
 - “*To promote the progress of science and useful arts..*” (US Constitution, Art 1, s.6)
- **Most patent laws have “research exemption”**
- **Breeders traditionally work by incremental improvement of existing materials**
- **Must be free to continue**

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10

Slide 11

“Research Exemption” in PVP

- **“The Breeders’ Privilege” UPOV 91, Art 15(1)**
- (1) *(Compulsory exceptions) The breeder’s right shall not extend to*
 - (i) *acts done privately and for non-commercial purposes,*
 - (ii) *acts done for experimental purposes and*
 - (iii) *acts done for the purpose of breeding other varieties, and, ...[derived varieties aside], acts ...[of commercial exploitation].. in respect of such other varieties.*
- It is **never** an infringement of a PVP to use the variety for further breeding.
- It is **generally** not an infringement of a PVP to exploit or sell the new variety bred.
- **Exception for ‘essentially derived varieties’**

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11

Slide 12

‘Essentially derived’ varieties

- Varieties are by definition **distinct** from each other
- Under UPOV 1978, **no registered variety could infringe another** (repeated use aside)
- So **very similar** varieties were registered
- GM technology made this worse - single gene differences
- So UPOV 1991 extended protection to **‘essentially derived varieties’ (Art 14.5)**

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12

Slide 13

Essential derivation

- “a variety shall be deemed to be essentially derived from another variety (“the initial variety”) when
 - (i) it is **predominantly derived** from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,
 - (ii) it is **clearly distinguishable** from the initial variety and
 - (iii) except for the differences which result from the act of derivation, it **conforms to the initial variety in the expression of the essential characteristics** that result from the genotype or combination of genotypes of the initial variety.” [Article 14.5.b, UPOV 1991]

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Slide 14

Examples of Essential Derivation

- Article 14.5.c, UPOV 1991
- Varieties obtained by:
 - selection of mutants (naturally occurring or induced)
 - somaclonal variants (from tissue culture);
 - GM technology;
 - back-crossing (*repeatedly?*)
- List **not exhaustive** - may be others
 - *marker-assisted selection from crosses????*

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Slide 15

This means...?

- A PVP holder can now challenge a close copy of a successful protected variety
- If the new variety has a closely similar phenotype, and a closely similar genotype, there is a *prima facie* case of ‘essential derivation’
- This may be rebutted by proof that the new variety was not bred from the original variety
- **How close is too close?**
 - Industry is trying to develop schemes
 - room for argument - and eventually litigation

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Slide 16

Points to note

- Essential derivation is for **courts**, not PVP offices, **to decide**
- ‘Essentially derived’ varieties have themselves **no protection** against further derivation
 - so to prove that the claimant’s variety was itself ‘essentially derived’ is a defence
- **The breeder’s privilege is unaffected**
 - the derived variety may be registered, but not exploited
- Of course, there is some deterrence - but the right to use in breeding remains

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Slide 17

Freedom to develop - general

- Is freedom to develop under PVP enough?
- Other rights
 - **patents**
 - **CBD rights**
 - **trade secrets**
 - **contractual rights**

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Slide 18

Trade Secrets (1)

- The patent system requires the inventor to teach the public how to operate the invention
- **Not consistent with secrecy**
- The PVP system **does not** require public teaching
- So can (probably) combine with trade secrecy
 - not for seed sold to public
 - but for parent lines of hybrids

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Slide 19

Trade Secrets (2)

- “All forms of information.. if“
 - (A) “the owner thereof has taken reasonable measures to keep such information secret”; and
 - (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public
- Misuse now a criminal offence in USA
- ‘Proper means’ - means what?

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Slide 20

Contractual terms

- Development agreements between breeders
- Restrictions on seed sales - shrink-wrap licences!
 - sale for planting for consumption
 - no rights to breed
 - inbreds vs hybrids
- Enforceability?
 - may differ from country to country

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Slide 21

Conclusion

- PVP allows access for further development
 - Other rights may not
 - Should they?

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