Plants, Germplasm, Genebanks, and Intellectual Property: Principles, Options, and Management

JOHN DODDS, *Founder, Dodds & Associates, U.S.A.*
ANATOLE KRATTIGER, *Research Professor, the Biodesign Institute at Arizona State University, Chair, bioDevelopments-International Institute; and Adjunct Professor, Cornell University, U.S.A.*
STANLEY P. KOWALSKI, *Visiting Scholar, The Franklin Pierce Law Center, U.S.A.*

ABSTRACT

In ever-increasing numbers, institutions are establishing technology transfer offices (TTOs). These offices serve a variety of functions, all of which must be integrated to cost effectively transfer technologies and to benefit the institutions. A critical function of the TTO is to proactively manage intellectual property (IP) issues pertinent to crops. Crops can be covered by more than one form of IP rights protection, often simultaneously. These rights protections include trademarks, trade secrets, plant and utility patents, and plant variety protection (PVP). Closely related is the importance of careful and organized genebank management, a critical component of an overall IP and tangible property management system. PVP provides one type of protection that allows TTOs to responsively serve clients and generate revenue. PVP is a form of IP rights protection for crops with potentially global applications, and either a PVP office, or a PVP subsection in the TTO, would be wisely established by an institution. In addition, this chapter provides important information to assist in establishing a national PVP office and in the selection and implementation of various types of IP rights protection for crops and germplasm.

1. INTRODUCTION

Plants affect people's everyday lives in terms of quality and cost—the cost of food, feed, fiber, fuel, and other necessities. Plants provide raw materials for industry, such as vegetable oils, rubber, and drugs and other health care items. By 2020 the Earth's population is likely to reach 9 billion. To meet the increasing demand, annual global food production will have to increase to more than 3,000 million metric tons from the current 1,800 million metric tons. At the same time, productive farmland is, and will continue to be, diverted at an increasing rate to nonfarm uses, and access to water will continue to be a major limiting factor for agricultural productivity.

To address the challenge of meeting the needs of the world's growing population, plant breeders are developing improved plants that can produce more, while using less land and less water. As trained professionals whose endeavor is developing plants that are genetically equipped to produce higher yields of quality products, plant breeders will contribute significantly to meeting these challenges. While producing higher yields, these improved plants will also be more resistant to pests and diseases, so they can potentially reduce the need for large (and expensive) applications of fertilizers and crop protection chemicals. Finally, these plants reduce the need for additional irrigation from precious water resources, thereby contributing to further conservation.

The breeding of new plant varieties is thus an economically important activity that contributes in many different ways to the social and economic well-being of societies. In many cases, new plant varieties are absolutely essential for human survival. However, there are many

Dodds J, A Krattiger and SP Kowalski. 2007. Plants, Germplasm, Genebanks, and Intellectual Property: Principles, Options, and Management. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

© 2007. J Dodds, A Krattiger and SP Kowalski. *Sharing the Art of IP Management:* Photocopying and distribution through the Internet for noncommercial purposes is permitted and encouraged.

challenges associated with crop breeding. For example, experience has shown that a breeder has difficulty recovering his financial investment when he sells his initial supplies in the first years of a new variety's life. The breeder's competitors can secure supplies of propagating material and, in a short time, be in a position to compete with the breeder, thus profiting from the many years of effort invested by the breeder. In this way, the rewards of the plant breeder's innovative efforts can be rapidly lost to himself or herself. The initial phase of protection is therefore critical, because developing new varieties in most plant species may take between ten and 20 years.

These new varieties are crucial to the needs of modern society. They contribute to a varied diet and provide for a wide choice of ornamental and amenity plants. Generating sufficient variety, however, requires substantial investment in crop breeding programs. Accordingly, many countries, while continuing to invest in public sector plant breeding research, have established open free-market systems in which exclusive rights of exploitation (patent-like protections) are granted to the breeders of new varieties of plants.

This chapter presents a general overview of the types of IP protections that are available for plants. It then focuses on plant variety protection (PVP) as one key example of plant IP rights protection, an option that can be broadly applied to the needs of developing countries.

2. DEFINITIONS

Before discussing some specific issues in relation to crops, germplasm, and genebanks, it is important to have a common understanding of what is meant by certain words:

- *breed.* To develop new or improved strains of organisms, chiefly through controlled mating or pollination and the selection of offspring for desirable traits.
- *breeding line*. Genetic group that has been selected and bred for special combinations of traits.
- *enhancement*. The process of improving germplasm accessions by breeding, while retaining the important genetic contributions of the accessions. This process may entail simple selection.
- *gene.* The fundamental physical and functional unit of heredity. A gene is an ordered sequence of nucleotides in a particular position, on a particular chromosome, encoding a specific functional product.
- *genebank*. A genebank is a special facility that stores living samples of the diversity of crop varieties and their wild relatives. These samples are usually in the form of seeds or other plant parts. Some of the plants that genebanks hold are extinct in the wild. The value of the genetic resources conserved in genebanks encompasses not only their current use value and expected future use value, but also the option value associated with the flexibility to respond to some unknown future events.
- *genetic resource.* Often used as a synonym to germplasm, this is a seed, plant, or plant part that is useful in crop breeding, research, or conservation because of its genetic attributes. Genetic resources are maintained for the purposes of studying, managing, or using the genetic information they possess.
- *improved material.* An elite breeding line.
- *landrace.* A population of plants, typically genetically heterogeneous, commonly developed in traditional agriculture from many years of farmer-directed selection and specifically adapted to local conditions.
- *public domain.* Public ownership status of information not protected by patents or copyrights.
- *wild species.* A species that has not been subject to breeding with intent to alter them from their wild state.

3. IP ISSUES THAT AFFECT GENETIC RESOURCE MANAGEMENT

It is useful to recall that plant breeding is a knowledge-based activity. Consequently, it is a nonexhaustive activity. In other words, the results of applying the knowledge are not decreased if shared with others. What is lost in sharing, however, is *market value*. In other words, a plant breeder who

has invested millions of dollars over many years cannot extract value if others appropriate the new variety and sell it at the mere cost of seed production. The free distribution of varieties provides the breeder with no incentive to invest. IP systems remedy this situation by providing a level of protection to breeders.

IP rights is a broad term for the various rights that the law provides for the protection of economic investment in creative effort. The principal categories of IP protections relevant to agricultural research are patents, plant variety rights, trade secrets, copyrights, and trademarks.

3.1 *Patents*

Patents are a statutory form of protection that allows an inventor rights of exclusivity on the sale or use of his or her invention for a limited period of time, in a particular territory, in exchange for a full public disclosure of the invention.

In the case of plants, there are two forms of patenting. The first is called a plant patent. It applies only to materials that are asexually propagated, such as pineapples and bananas. The second is called a "utility patent." This does not protect the plant per se, but rather the invention that is embodied in the plant (for example, a method for conferring insect resistance through the incorporation of resistant genes into the plant).

3.2 *Plant variety protection*

Plant variety protection (PVP) is another form of IP protection for plants. PVP gives the breeder exclusive rights to a new and distinct plant variety so that the breeder can exploit it.

The breeder is defined by the 1991 UPOV (International Union for the Protection of New Varieties of Plants) Convention as the person who bred, or discovered, and developed a variety. Therefore, protection is not limited to breeders who produce a variety as a result of crossing parent plants and selecting from the progeny. The term *breeder* also includes a person who discovers a mutation and converts that discovery into a cultivated variety by a process of selective propagation. Discovery itself, however, does not constitute breeding.

The PVP Act (PVPA), enacted in December of 1970 and amended in 1994, provides legal IP rights protection to developers of new varieties of plants that are sexually reproduced (by seed) or are tuber propagated. Bacteria and fungi are excluded. The PVPA is administered by the U.S. Department of Agriculture.

A Certificate of Protection is awarded to an owner of a variety after an examination shows that the variety is new and distinct from other varieties and is genetically uniform and stable though successive generations. The term of protection is 20 years, for most crops, and 25 years for trees, shrubs, and vines. The owner of a U.S.-protected variety has exclusive rights to multiply and market the seed of that variety.

The characteristics of the PVP systems are summarized in Table 1 and are compared both to plant patents and utility patents. A detailed discussion of PVP and its global applicability is published by Blakeney and colleagues.[1]

3.3 *Trade secrets*

U.S. trade secret laws have been used to protect in-house breeding materials, such as the inbred lines of maize used as parents of hybrids. These laws do not, however, protect against independent discovery or reverse engineering of products by the purchasers.

It should be remembered, moreover, that genetic resources have a *dual property* nature: they are physical material (tangible property) that may be associated with human-made improvements (IP). This dual nature is the reason for genetic resources to be, on the one hand, physical property in the form of germplasm and, on the other hand, IP in the form of modified genetic information constituting inventions, trade secrets, and new plant varieties.

3.4 *Copyrights*

Copyrights are becoming more important for protecting IP in the field of plant breeding because the databases that hold information about plant genes can often be copyrighted. Such copyrights

Table 1: Comparison of Plant Variety Protection Systems

Action or stipulation	UPOV 78	UPOV 91	TRIPS Compatible Patent Law[2]	Utility Patents (since 1985; United States)	Plant Patent Act (since 1930; United States)	PVP Act[3] (since 1970; United States)
Protects	Varieties of selected genera and species as listed	Varieties of all genera and species	All plant species and enabling technologies	Plant genotypes not normally found in nature	Asexually reproduced plants, including cultivated, mutant, and hybrid	Sexually reproduced plants
Excludes					Uncultivated and tuber-propagated plants	First-generation hybrids, uncultivated plants
Requires	Novelty, distinctness, uniformity, stability	Novelty, distinctness, uniformity, stability	Novelty, inventiveness, enablement	Novelty, utility, nonobviousness, enablement	Novelty, distinctness, stability	Distinctness, uniformity, stability
Disclosure			Description of novel characteristics and genealogy, enabling disclosure, deposit of novel material	Enabling disclosure, best mode disclosure, deposit of novel material	As complete as possible photographs or drawings	Description of novel characteristics and genealogy, seed deposit
Claims			Not determined	Varietal claim, generic claims, claims to plant genes, gene transfer vectors, processes for producing plants, and so on	Single varietal claim	Single varietal claim
Rights	Prevents others from producing for commercial purpose, offering for sale, marketing	Prevents others from producing or reproducing, conditioning for the purpose of propagation, offering for sale, selling or other marketing, importing, exporting, stocking for any purposes detailed above	Prevents others from making the patented product, using the patented process, or using, offering for sale, selling or importing for those purposes the patented product or the product obtained by the patented process (extends to harvested material)	Prevents others from making, using, or selling claimed invention, or from selling a component of the claimed invention	Prevents others from asexually reproducing, selling, or using claimed plant	Prevents others from importing or selling, sexually or asexually reproducing, distributing without proper notice, producing a hybrid or new variety, using the claimed plant
Exemptions	Exemptions for breeding and for farmers to save own seed mandatory	Exemptions for breeding except where new variety is essentially derived; optional farmers' exemption and only for use on same farm and subject to a license and/or fee; private use and research	Breeders' rights and farmers' rights, in principle compatible with TRIPS but not yet tested		Does not protect sexual reproduction of claimed plant; does not protect plant products	Exemptions for developing a new hybrid or variety and for farmers' saving and sale of seed; compulsory license provision
Duration of protection	15 years for most crops (20 years for grapevines and trees)	20 years for most crops (25 years for grapevines and trees)	20 years from date of filing	20 years from effective filing date (after 8 June 1995); 17 years from issue date (prior to 8 June 1995)	20 years from effective filing date (after 8 June 1995); 17 years from issue date (prior to 8 June 1995)	Protected while application is pending, plus 20 years from issuance date for most crops (25 years for vines and trees)
Priority				First to invent in the United States	First to invent in the United States	First to file in the United States or another UPOV member country
Double protection	Protection by both patent and PVP not allowed	Protection allowed by both patents and PVP				

Source: Modified from Krattiger and Potter.[4]

do not, however, affect trade in products developed using the protected information.

3.5 *Trademarks*

Trademarks can be used to protect brand names, such as Monsanto's Roundup Ready®. But trademarks protect only the names and other symbols denoting products or technologies, not the technologies themselves. Still, trademarks may give customers a proof of quality, and so they may be as important as variety protection.

4. "NON-IP" MATTERS AFFECTING GENETIC RESOURCES MANAGEMENT

As indicated above, there are tangible property rights that have a bearing on the ownership of genetic resources. The Convention on Biological Diversity (see below) affirmed the sovereign rights of nations over their genetic resources. Such ownership is a tangible property right on the ownership of the actual material.

There exist, however, a number of other non-IP matters that affect the day-to-day lives of genetic resource specialists working in the field. These most typically include indigenous knowledge issues and access to and transfer of materials.

4.1 *Indigenous knowledge*

The formal IP system of patents, PVP, copyrights, and so on is based on a set of statutory (legislative) rules. The current system allows so-called *prior art* to be used as a way of determining whether novelty exists with regard to an invention. The current formal system does not adequately allow for indigenous knowledge to form the basis of prior art or allow indigenous people to be the inventors or breeders. This has led to significant controversy in the international community. Both WIPO (World Intellectual Property Organization) and UPOV are actively reviewing and debating this topic to try to develop a mechanism that would prescribe a role for such knowledge within the formal system. One noteworthy example within a national program is the PVP Office of the Philippines' mechanism for allowing the registration of descriptors for indigenous materials. These descriptors are reviewed as part of the examination process for awarding a PVP certificate.

4.2 *Material transfer agreements*

When genetic resources are transferred, it is increasingly common for them to be accompanied by an MTA. Such a document forms a contractual relationship between the shipper and the recipient. It is common for MTA agreements to attach terms and conditions regarding both the approved use of genetic resources and the rights to ownership of such materials or their derivatives.

MTA agreements can appear in a number of forms. While the most common is a conventional sheet of paper, it is also possible for the material to come with language included on the bag. The use of so-called bag-tag language is becoming increasingly common. At issue, however, is whether the "shipper" who applies the MTA language actually owns title to the materials and has the right to allocate ownership rights.

5. INTERNATIONAL TREATIES

Generally, plant genetic resources are governed by national, regional and international laws, which regulate ownership, access, and benefit sharing. Internationally, these concerns are regulated by treaties such as the CBD, the International Union for the Protection of New Varieties of Plants (UPOV) Convention, the International Treaty of Plant Genetic Resources, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

5.1 *The Convention on Biological Diversity (CBD)*

The CBD is the central instrument related to international biodiversity. It broadly delimits the rights of states and other relevant actors over biological resources and affirms the sovereign rights of states to exploit their own resources pursuant to their own environmental policies. The sovereign rights of states over their own biological resources are limited by the recognition that these resources are a common concern of humankind.

The Convention also provides a broad framework for member states' policies concerning access, development and the transfer of technologies. It also acknowledges the necessity for all parties to recognize and protect IP rights in this field. The Convention further recognizes both the dependence of local communities on biological resources and the roles that these communities play in the conservation and sustainable use of these resources. Finally, it points to the need for equitably sharing the benefits that arise from the use of traditional knowledge, innovations, and practices.

5.2 *UPOV*

The UPOV Covention is the only international treaty focusing on PVP. It recognizes not only the rights of individual plant breeders who have developed or discovered plant varieties that are new, distinct, uniform, and stable, but also accords certain rights to farmers. Under the 1978 version of the Convention, farmers are permitted to reuse propagating material from the previous year's harvest, and they can freely exchange the seeds of protected varieties with other farmers. Plant breeders are also allowed to use protected varieties to breed and commercialize other new varieties.

The latest revision of the Convention, adopted in 1991, has further strengthened the rights of commercial plant breeders. These revisions include the obligation for member states to provide protection to all plant genera and species. Furthermore, it extends breeders' rights to all seed production of a protected variety, even though countries can decide on their own internal laws regarding this issue. In some cases, the revision grants to commercial breeders the rights to the harvested material of the variety and extends protection to varieties that are "essentially derived" from a protected variety.

5.3 *The International Treaty on Plant Genetic Resources for Food and Agriculture*

The International Treaty on Plant Genetic Resources for Food and Agriculture was adopted by consensus of the member states of the United Nations Food and Agriculture Organization (FAO) in November 2001. The Treaty envisions a multilateral system to facilitate access to key genetic resources, with minimal procedural and administrative costs. Initially, the treaty applies to 35 crops and some 80 forages that are under the control of member governments and that are not subject to IP rights. Thus, the treaty includes practically all the crops that humanity depends on for its food supply. The treaty invites all holders of listed plant genetic resources to join the multilateral system. The list itself can be changed with the consensus of the parties to the treaty.

The multilateral system is intended to be efficient, effective, and transparent. It aims to ease access, not only to plant genetic resources for food and agriculture, but also to information about those resources, so that any benefits that may arise from their use can be shared fairly and equitably.

In this context, it is worth dwelling briefly on the difference between *farmers' rights* and *farmers' exemption/privilege*. Because the terms are often used interchangeably, there has been significant confusion regarding their use. *Farmers' rights* is a term developed by FAO under the Revised Undertaking for Plant Genetic Resources. Resolution 5/89 of the treaty states, "*…rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources.*" Resolution 3/91 states that these rights are to be "*implemented through an international fund on plant genetic resources that will support plant genetic conservation and utilisation programmes, particularly, but not exclusively, in the developing countries….*"

The difference is further elaborated in the FAO Treaty. However, no specific future action is targeted here; instead, the treaty gives voice to a general equity objective. These areas are still the subject of much debate, and the mechanism with which to ensure both participation and benefit sharing has not yet been elucidated.

The concept of farmers' exemption or farmers' privilege in PVP legislation, on the other hand, hinges on the notion that a farmer has a right to "fair use" of his or her own produced seed. Most national legislations embrace this notion of fair use, as do UPOV's model laws, and allow farmers to use seed produced on their own

farms for further sowing. Only if the farmer sells or trades the seeds is an infringement of the PVP holder's rights committed. Article 15 of UPOV 1991 states that:

a) [Compulsory exception] The breeder's right shall not extend to:
   (i) Acts done privately and for non-commercial purposes;
   (ii) Acts done for experimental purposes; […]

b) [Optional exception] Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest that they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)(a)(i) or (ii).

5.4 *The TRIPS Agreement*

TRIPS was the result of an initiative by developed countries to introduce more stringent IP rights trade rules. The agreement sought to extend the security of IP rights internationally. Article 27.1 of the TRIPS Agreement implies that patents may be available in biotechnology fields, a position that Article 27.3 consolidates with regard to granting IP rights in biotechnology, particularly as it relates to plants.

6. SPECIFIC ISSUES RELATED TO GENEBANK MANAGEMENT

A genebank manager addresses both the many technical aspects relevant to the use of genetic resources and issues related to the ownership of genetic resources. As outlined below, these issues usually come in different phases of the work.

In accordance with the CBD, incoming material must be acquired with the consent of the nation that "owns" these resources. This is achieved through a germplasm acquisition agreement (GAA) or an MTA that clearly indicates the rights that the owner is giving to the genebank in terms of using and distributing such materials.

In-house materials may include those acquired prior to the CBD. These may be in the form of genebanks, botanic gardens, and so on. While the ownership of in-house materials is still contentious, the law is clear that such materials may be used freely without prior permissions. It is very important here to distinguish between "genetic resources" collected in nature and "improved materials." IP rights will attach only to the latter. Indeed, a sound knowledge of the biology of the materials and the ownership and legal rights associated with them is essential.

Outgoing materials are those materials the genebank manager distributes to others, either for research, direct use, or for use in improvement programs. This is often when problems arise. Carefully using appropriate MTAs is the most effective way to deal with these issues. The MTA should reflect a range of matters: international law, policy of the organization, nature of the material, nature of the recipient, nature of the acquisition of the material, and conditions relating to incoming MTA on the material (see examples included in this *Handbook*).

Genebank management has recently become a very sensitive issue. An organized, stepwise approach is vital for effectively managing a genebank and for avoiding difficulties. Potential ownership issues about genetic resources must be clearly analyzed, and documentation procedures for the acquisition and distribution of such materials must be effective and thorough.

The legal issues surrounding genebanks have changed dramatically over the last decade. Such changes will continue, and genebank managers must be alert to the effects of these changes. When appropriate, managers should seek professional advice about how these changes affect their respective institutions. Genebank managers must not, however, lose sight of their crucial social role: they guard and preserve the basic building blocks upon which human survival and food security depend. They work not only for this generation but for generations to come.

7. PVP: IP PROTECTION FOR CROP VARIETIES

PVP addresses a specific need that applies broadly across the globe, in both developed and developing countries. So-called PVP regimes are implemented in order to:

- provide breeders (both public and private sectors) with an opportunity to receive a reasonable return on past investments
- provide an incentive for continued or increased investment in future breeding research
- recognize the legal right of the innovator to be recognized as such
- acknowledge his or her economic right to remuneration for his or her efforts

In order to foster these laws and agreements within the global economy, UPOV was formed through a union of states. These states agreed to grant exclusive exploitation rights to the breeders of new plant varieties on an internationally harmonized basis. UPOV developed a set of model laws that provided a general legislative framework for PVP. Indeed, some provisions of TRIPS refer to the use of UPOV standards as an effective mechanism for complying with WTO standards. One very effective aspect of this arrangement is the provision for mutuality, which allows cross protection between jurisdictions for states that are members of the UPOV system. Countries often use the model law produced by UPOV as a framework for developing their own legislative standards. This is not to say that the system is wrinkle free. For example, the differences between protected varieties and other forms of plant genetic material (including genetic resources and landraces) has yet to be established.

The U.S. system is a useful model and because of the UPOV system's efforts toward harmonization, most of the provisions in the U.S. PVP system are consistent with those in other jurisdictions. It should be noted that many jurisdictions have patent laws allowing for the protection of plants. This is complementary to the PVP legislation. It is possible, and increasingly common in the United States, for protection to be taken on the variety, and, in addition, for a patent on the inventive nature of the product and/or process to be filed. Finally, the new variety name is usually trademarked. (For more information about the U.S. PVP system, see section 3.2.)

The model law of UPOV, and effectively of all national legislatures, also allows a government to issue a compulsory use license. In effect, if a country has a compelling need to multiply a protected variety, then the government can issue a license for its use. The PVP holder would, however, still have the legal right to be given a reasonable royalty payment.

To qualify as a protected variety, the plant variety coming out of a breeding program must be able to demonstrate:

- distinctness
- uniformity
- stability

The way in which these criteria are met is described in more detail in section 7.3 below.

7.1 *PVP application process*

PVP application forms and the supporting documentation, such as the UPOV crop guides, will guide the applicant (and examiner) through the steps of describing the history, breeding origin, and variety, making seed deposits, paying fees, and, if all is as required, obtaining a PVP certificate. If application materials exist, the relevant ministry of agriculture will have them; if application materials are not available, this chapter provides information to help develop them.

Anyone who is the owner, breeder, developer, or discoverer of a unique cultivar of a sexually reproduced or tuber-propagated plant may apply for PVP. This applies to any citizen in any UPOV member country. The applicant may be an individual, a public institution, or a corporation.

The protection works by prohibiting a person from selling, marketing, offering, delivering, consigning, exchanging, or exposing the variety for sale without explicit consent of the owner. In addition, a person is prohibited from soliciting an offer to buy the variety, or transfer or possess it in any manner. It is also illegal to import or export the variety, sexually multiply it, propagate it

by tuber, use the variety in producing (as distinguished from developing) a hybrid, or condition the variety for the purpose of propagation. It is worth adding here that plant parts (flowers, pollen, and so on) are also protected. This is critical in reviewing infringement actions to determine where the material has been used.

7.2 *Exemptions*

In general, there are two exemptions to the protection provided: 1) a research exemption and 2) a farmer's exemption (also called farmer's privilege).[5]

A *research exemption* allows for breeding to develop a new variety; a *farmer's exemption* allows for the saving of seed for the sole use of replanting the farmer's land. However, if the farmer sells or trades the seeds, he infringes on the rights of the PVP holder. The controversies surrounding this provision turn largely on the definition of terms. It should be noted that neither plant patents nor utility patents provide these exemptions.

7.3 *Examination standards*

The owner must prove the distinctness, uniformity, and stability of the new variety. The burden is entirely on the applicant.

For distinctness, the applicant may:

- list the single variety he or she believes is most similar to the new variety and describe how the new variety differs from it
- list a group of varieties that are similar to the new variety and describe how it differs from varieties within that group
- describe how the variety differs from all other known varieties in the crop kind

The PVP office maintains databases of both public and private varieties of crops. The examiner uses these and other sources to determine which, if any, varieties are indistinguishable from the new one. If the examiner finds varieties that appear to be indistinguishable from the application variety, the applicant will be notified that supplemental data is necessary. To obtain additional data, applicants may perform additional field or greenhouse replications and may use DNA profiling and other analyses to substantiate distinctness. In the United States, the PVP office does not perform tests to confirm the distinctness of a variety. That responsibility rests with the applicant.

For uniformity, a statement must report the level of variability in any characteristic of the variety. Variation, which is predictable, describable, and commercially acceptable, may be allowed.

For stability, a statement of genetic stability is required, showing the number of cycles of seed reproduction for which the variety has remained unchanged in all distinguishing characteristics.

Special mention should be made of essentially derived materials. Good examples are so called "sports." If PVP protection has been obtained on a potato variety that has a red skin after decades of breeding, and then someone selects a field sport with a white skin, the new white skin material is determined to be essentially derived from the original variety and will be protected under the 1991 UPOV act.

7.4 *Enforcement*

The owner of a protected variety may bring civil action against persons infringing on his or her rights, and the owner may ask a court to issue an injunction to prevent others from further violations. The owner of the protected variety must bring suit in such cases—the USDA will not take that action. In the United States, IP protection for plants is provided through plant patents, PVP, and utility patents. Plant patents provide protection for asexually reproduced (by vegetation) varieties excluding tubers. PVP provides protection for sexually (by seed) reproduced varieties including tubers, F_1 hybrids, and essentially derived varieties. Utility patents currently offer protection for any plant type or plant parts. A plant variety can also receive double protection under a utility patent and PVP.

7.5 *Contents of a complete application and exhibit forms*

A PVP application consists of a completed and signed form that includes Exhibits A, B, C, and E (Exhibit D is optional):

A) Exhibit A (Breeding History)

B) Exhibit B (Statement of Distinctness, previously called "Novelty Statement")
C) Exhibit C (Objective Description)
D) Exhibit D (Additional descriptive Information)
E) Exhibit E (Statement of Ownership)

Also required is a sample of at least 2,500 untreated viable seeds, capable of propagating the application variety, and, for a tuber-propagated variety, verification that a viable cell culture will be deposited. A check for the filing fee is also required.

7.5.1 *Exhibit A: Breeding History*

The applicant is required to provide the following:

- full disclosure of the genealogy back to publicly known varieties, lines, or clones, including the breeding method
- details of subsequent stages of selection and multiplication used to develop the variety
- statement of uniformity reporting the level of variability in any characteristics of the variety (commercially acceptable variability is allowed)
- statement of genetic stability showing the number of cycles of seed reproduction for which the variety has remained unchanged in all distinguishing characteristics
- information about the type and frequency of variants observed during reproduction and multiplication
- information about the frequency of off-types (in other words, impure lines) observed or known to occur

7.5.2 *Exhibit B: Statement of Distinctness*

The applicant is required to give a summary of the variety's distinctness, stating clearly how the application variety may be distinguished from all other varieties in the same crop. If the variety is most similar to one variety or group of varieties, the applicant must (1) identify these varieties and state all differences objectively, (2) attach statistical data for characters expressed numerically and demonstrate that these are clear differences and (3) submit, if helpful, seed and plant specimens or photographs (prints) of seed and plant comparisons that clearly indicate distinctness.

7.5.3 *Exhibit C: Objective Description of Variety*

The PVP office has prepared forms for the applicant to provide a botanical description of the variety for most crops. These forms list the botanical characteristics for a kind of crop and the degree of expression of each characteristic. These forms also provide a list of recommended varieties that the applicant should compare to the application variety. The applicant needs to complete the form for his or her variety as thoroughly as possible.

7.5.4 *Exhibit D: Optional Supporting Information*

The applicant may provide additional information, specimens, and/or materials in support of the claims of the application.

7.5.5 *Exhibit E: Statement of Ownership*

The applicant is required to furnish a statement for the basis of the applicant's ownership. The PVP office has prepared a form to simplify this requirement. The form also includes a statement to verify that the applicant is eligible to file for PVP in the United States.

7.6 *Steps needed to start and operate a national PVP office*

You may be reading this chapter because you are in the process of setting up a PVP office. If that is the case, then the topics below will help you effectively and efficiently establish the office.

The basic operation of this office and its actions can be translated into the following steps:

1. **Setting up the office.** The initial setting up of the office will have a physical component (obtaining the necessary space, equipment, and other physical resources) and a legislative component (setting up the laws and regulations, and examining guidelines).
2. **Appointing the staff.** A registrar for the PVP office, a number of examiners, and support staff, both clerical and technical, will need to be appointed.
3. **Training the staff.** The PVP office staff needs to be trained in both the technical

processes related to the examination and the legal and clerical matters related to issuing and registering the certificate.

4. **Establishing the formal procedure.** The office must set up formal procedures, such as law enactment, rule approval, and examination standards.
5. **Notifying the public that the office is functional.** Once the PVP office is functional, staff must inform the public that they may avail themselves of the services the office provides.
6. **Distributing information and application material.** As part of the public awareness campaign, staff should make information and forms publicly available. In an increasing number of jurisdictions, application forms are available online at the PVP office Web site.
7. **Informing and educating the public about how to apply.** Attorneys and agents may need to be educated about the actual mechanics of preparing and submitting applications.
8. **Receiving application.** The filing date is a critical component of the application process, and detailed rules should inform applicants about the application filing date.
9. **Reviewing the applications.** This is the heart of the process. Applications are reviewed (1) for compliance with general applications standards and (2) for technical content.
10. **Examinations standards and their application.** The 1991 UPOV act, the rules, and possibly the examiner's manual provide an objective set of standards that can be applied to particular applications. The importance of such objectivity for the credibility of the system cannot be overstated.
11. **Communicating with the client.** Effective communication with the applicant is absolutely essential. All correspondence must be consistently dated, numbered, and sent by registered or certified mail.
12. **Communicating with policy-makers.** When establishing the office, it will be crucial to keep in very close communication with senior policy-makers. The act and regulations will need legislative action, and they must also be consistent with other domestic laws. Regulations will also often need to comply with WTO requirements.
13. **Storing deposits.** Facilities must be arranged for storing exhibits of the materials.
14. **Preparing certificates.** A format and style must be established for the production and registration of PVP certificates.
15. **Dealing with disputes.** The legislation and regulations will usually contain provisions allowing for applicants who are refused a PVP certificate to appeal the decision either through the PVP office and/or through the judicial system.
16. **Sample deposits.** An appropriate, adequate system must be in place for applicants to deposit seed or plant materials. This facility may belong to the ministry of agriculture in most countries or may be managed by a related organization. The facility should meet appropriate international seed storage guidelines and have adequate mechanisms for safekeeping/security of the seed samples.

8. CONCLUSIONS

It is clear that a PVP regime effectively harmonized across different countries would significantly lower the costs for users, and hence increase returns on plant-breeding investments. This would undoubtedly lead to more varieties and more choices for farmers. A costly regime, on the other hand, discourages smaller national companies from filing for PVP protection and increases the cost of participating in foreign markets that, in turn, favors large multinational companies with the resources and infrastructure to operate across multiple national regimes.

All of the IP protection mechanisms discussed in this chapter depend upon enforcement by national governments. If a law is only as good as its enforcement, then a regulatory body such as a PVP office is only as good as the people who

implement the regulations. In order to reinforce national policy initiatives in many countries, a comprehensive, in-depth training program is recommended to equip personnel with the information and experience required to establish the long-term health of a PVP system. This training could be combined with a coordinated effort to regionalize the PVP system through jointly training administrators from a number of countries, which would increase cooperation and harmonization within the region.

Of course, different people within the system require different training. As a starting point, all participants, whether officers, management, or even individuals in breeding companies, need to be brought to a certain minimum level of competence in the application of the regulations. A general program, such as a Web-based training course or other distance-learning approaches, could help to achieve this goal. For management staff, tailored workshops could be used to expose staff members to areas of conflict and to increase their knowledge of the importance of PVP in the development of plant breeding businesses. These courses and workshops could be augmented by an internship program, in which selected individuals would be given more intensive training through collaboration with public and private institutions from countries with well-established PVP systems. These highly trained individuals could form a core group that would then further develop staff expertise. ■

JOHN DODDS, *Founder, Dodds and Associates, 1707 N Street NW, Washington., D.C., 20036, U.S.A. j.dodds@doddsassociates.com*

ANATOLE KRATTIGER, *Research Professor, the Biodesign Institute at Arizona State University; Chair, bioDevelopments-International Institute; and Adjunct Professor, Cornell University. PO Box 26, Interlaken, NY, 14847, U.S.A. afk3@cornell.edu*

STANLEY P. KOWALSKI, *Visiting Scholar, The Franklin Pierce Law Center, 2 White Street, Concord, NH, 03301, U.S.A. spk3@cornell.edu or skowalski@piercelaw.edu*

1 Blakeney M, JI Cohen and S Crespi. 1999. Intellectual Property Rights and Agricultural Biotechnology. In *Managing Agricultural Biotechnology. Addressing Research Program Needs and Policy Implications* (ed. JI Cohen). pp. 209-227. CAB International Press; Blakeney M. 1999. Agricultural Research and the Management of Intellectual Property. In *Managing Agricultural Biotechnology. Addressing Research Program Needs and Policy Implications* (ed. JI Cohen). pp. 228-40. CAB International Press.

2 Modified from Helfer LR. 2002. Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments FAO Legal Papers Online, No. 31. www.fao.org/Legal/Prs-OL/lp031.pdf.

3 The initial PVP Act of the United States was not UPOV compliant, but in 1980 the United States acceded to UPOV 1978 and later to UPOV 1991. A further jump in investment was seen after 1986 when the U.S. Patent and Trademark Office established that plant varieties were patentable subject matter.

4 Krattiger AF and RH Potter. 2002. The Status of Plant Variety Protection Issues in the Asia-Pacific Region: An Overview. *Asian Seed* 9(5): 17–20.

5 Farmer's exemption or farmer's privilege should not be confused with "Farmer's Rights". Farmer's rights is a concept that became popular during the 1980s through the FAO Revised Undertaking for Plant Genetic Resources (Resolution 5/89) in an attempt to recognize and reward the *"...rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources..."* (see www.fao.org/docrep/X0255E/x0255e03.htm for a detailed history). The term now constitutes a central element in the International Treaty on Plant Genetic Resources for Food and Agriculture where it is called "Farmers' Rights." ftp://ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf.æ