Protecting New Plant Varieties through PVP: Practical Suggestions from a Plant Breeder for Plant Breeders

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ABSTRACT

A plant variety protection (PVP) certificate preserves a plant variety owner's exclusive rights to sell, reproduce, import, and export a plant variety and its seed. In addition, a PVP certificate prevents others from claiming PVP or utility patent rights. This chapter walks the reader through the process of applying for a PVP certificate and describes other ways to prevent the unauthorized use or sale of protected plant varieties.

1. INTRODUCTION

A plant variety protection (PVP) certificate preserves a plant variety owner's exclusive rights to sell, reproduce, import, and export the plant variety and its seed; In addition, a PVP certificate can also prevent others from claiming PVP or utility patent rights. The duration of a PVP certificate is 20 years (25 years for a tree or vine). A PVP certificate can, when combined with licensing, develop future funds for a breeding program. It also can preserve the financial and other interests of participants in a program, who may have provided upfront funds.

To be eligible for PVP, a variety must be:

- new and distinct from other varieties (novel)
- genetically uniform
- stable through successive generations

This chapter discusses the rules governing the U.S. PVP application procedure, which is administered by the U.S. Department of Agriculture (USDA).[1] The U.S. PVP Act is very similar to the provisions developed by the Convention of the International Union for the Protection of New Plant Varieties (UPOV), which have been, or are being, adopted in many nations around the world. Of course, anyone considering applying for a PVP certificate must thoroughly familiarize him- or herself with local laws and application procedures.

The U.S. PVP Office (PVPO) considers a variety to be new, and therefore eligible for PVP certification, only if propagating or harvested material of the variety has not been sold, or otherwise disposed of to other persons, for the purpose of exploiting the variety for more than one year, in the United States, or four years outside of the United States.

2. THE COUNTDOWN TO PVP CERTIFICATION

The breeder should be the person to complete the PVP certificate application because only he or she will possess the required information and be able to answer follow-up questions from the examiners. It is important to maintain good breeding records, because they are invaluable in case of an infringement challenge.

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2.1 *Two years in advance*

Obtain from the U.S. PVPO the instructions for application as well as the proper (species-specific) Exhibit C form (see Section 3.4 below for more details). Start conducting any tests that will be required to fill out Exhibit C (such as those for disease and pest resistance); such tests may take one or two years to complete.

2.2 *One year in advance*

Verify that the crop variety is worth protecting and that the potential returns on the sale of the crop justify the expense of the PVP certificate. The plant breeder should consult with his or her seed project leader (if he or she works for a national research center or a university) or his or her supervisor or sales manager (if he or she works in the private sector). The decision of whether or not to apply for a PVP certificate and subsequent commercialization must be driven by objective analysis, not emotion. It is easy to form an emotional attachment to a project that has required a great deal of time, effort, or money. Seek advice and suggestions from seed growers, advisory committees, company sales representatives, and, most critically, the farmers who will ultimately be growing the crops.

The following questions are important to consider:

- Is it likely that royalties or other returns on the variety will repay the cost of PVP certificate application?
- Does the variety have sufficient advantages over standard varieties? Is it likely to attract the interest of seed companies, seed growers, and (most importantly) farmers?
- How large are the new variety's seed volumes likely to become?
- How broad will the variety's geographical area of adaptation be?
- How large will the variety's potential market be?
- Do any seed companies or seed growers have a particular interest in the variety?

Depending on the answers to these questions, you will want to consider whether the variety is appropriate for general release (that is, release to all interested companies or growers) or exclusive/limited release (that is, to one or a limited group of companies and/or growers). PVP is most useful when the release is exclusive.

If there were several contributors to the breeding project, you would need to decide whether or not to pursue an application for a joint PVP certificate with them. Consider the following questions:

- What entities (companies, associations, and so on) contributed to the development of the new variety?
- Do these entities wish to seek a license for the new variety?
- Will these entities help to cover the application costs for a PVP certificate and certification?
- Do these entities have first refusal rights for licensing?

3. PREPARING THE PVP CERTIFICATE APPLICATION

The U.S. PVPO provides detailed instructions for how to fill out and submit application forms for PVP certification. All documents can be accessed online.[2]

3.1 *General application requirements and procedure*

A PVP application consists of:

1) A completed and signed Form S&T-470 (Application for Plant Variety Protection Certificate). The applicant must provide his or her name, address, and representative, and the variety's genus, species, and variety name (a temporary variety name will suffice until the PVP certificate is issued). The proposed variety name or experimental number must be cleared with the Seed Regulatory and Testing Branch of the USDA.[3]
2) the following "exhibits," all of which will be discussed in detail in the following sections:

- Exhibit A: Breeding History, consisting of the variety's genealogy, the methods used to develop the variety, a statement of the level of variability in any variety characteristics, a

statement of genetic stability, and the type and frequency of variants
- Exhibit B: Statement of Distinctness Guidelines, stating how the variety may be distinguished from all other varieties in the same crop
- Exhibit C: Objective Description of Variety, a crop-specific form
- Exhibit D: Optional Supporting Information
- Exhibit E: Statement of the Basis of Ownership, stating who owns the variety and verifying that the applicant is eligible to file for PVP in the United States
- Exhibit F: Declaration Regarding Deposit, stating that the applicant will submit a certain amount of propagation material to a seed depository

Included with the forms must be a check drawn on a U.S. bank (as of 6 October 2006, the fee for filing and examination was US$4,382), payable to "Treasury of the United States." Since fees are subject to change periodically, always check current schedules at the U.S. PVPO Web site.[4] Issue fees will also be charged when the certificate is issued.

The U.S. PVPO office maintains databases of known varieties of most U.S. crops (including those originating in the United States and in some foreign countries). The PVP examiner will compare the information given in the application with the database for that crop. The examiner may request additional data if he or she finds one or more varieties in the database with essentially similar descriptions (which often happens). Please note that if all other traits seem similar to another variety, then DNA profiling may be useful, at the discretion of the PVP examiner.

Remember, that the U.S. PVPO does not conduct actual field/greenhouse evaluation (so-called growing out) or other tests on varieties that are described in PVP applications. The applicant must provide all data. Diligence in this regard will be well worth the effort.

3.2 *Exhibit A: Breeding History*

3.2.1 *Parentage and breeding methods*

Exhibit A describes a number of different aspects of the variety's breeding history. First, it describes the pedigree of the new variety, including both the parents used in each cross and the source and pedigree of each parent. The PVP office specifies that:

Obtaining intellectual property rights requires disclosure. As part of this disclosure the applicant is to provide the public with information about his/her invention in exchange for protection of the variety. For Plant Variety Protection, this includes a full disclosure of the parentage and breeding methodology in the Exhibit A, Origin and Breeding History. This information would specify the plant material the applicant started from, i.e., the parentage. All material in the parentage must be traceable back to varieties, lines, or clones, etc. that are publicly known or a matter of common knowledge.[5]

Exhibit A also describes the breeding methods used in creating the new variety, including any specific selection criteria that were used. Keep it simple to avoid confusing the examiner. There is no need to say *why* certain selections were carried out, merely *what* was accomplished and *when* it took place.

3.2.2 *Uniformity and stability*

This statement declares that the variety has been observed to be uniform and stable for all characteristics over a certain number of generations. The words "uniform" and "stable" must be used in the statement.

The statement specifies the number of cycles of seed reproduction through which the variety has remained unchanged for all distinguishing characteristics. It is likely that stability dates from when you initiated increase of the line that became this variety. Remember that variation is acceptable, as long as it is predictable and the variants are describable and commercially acceptable. Many modern varieties include a low level of one or more variants.

A *variant* is a predictable phenotype that differs in one or more ways from the main phenotype of the variety. The applicant must identify the variant as typical of the variety and provide data on the percentage and frequency distribu-

tion of variant plants. It is permissible to have more than one variant, so long as each one is accounted for. However, the total frequency of all variants in the population cannot exceed 5%; a variety that is composed of more than 5% variants will be deemed a *mixture* (and thus not eligible for PVP).

An *off-type* is a phenotype that is not specified as an expected variant. If you find that you cannot remove a certain phenotype from your variety, consider describing it as a variant. If you do not describe it as a variant, the variant will be considered an off-type by certification inspectors or seed analysts.

3.3 *Exhibit B: Statement of Distinctness*

In order to demonstrate distinctiveness, the variety must be shown to be distinct in one or more traits from either:

(1) the variety that is most similar to it
(2) several similar varieties
(3) all other varieties of the species

When measuring quantitative traits, describe your statistical design and provide statistical references such as F values, least significant differences (LSD's), standard deviations (SD's), range, or other references, that may indicate the degree of variability in the tests; this provides an indication of just how distinct the variety really is, that is, if it can be distinguished from similar varieties. Include data taken from at least two locations (preferably from two different states) or over two years, but *do not pool data* across years or locations. The more data, the better. Sources of data may include trials at state agricultural colleges, cooperative tests performed by breeders in several states, or industry tests. However, be aware that the PVP office also has access to results from most of these tests and will likely use these to evaluate the distinctiveness of your variety. For many crops, the PVP office requests that several standard varieties be included in comparative tests against the variety submitted in the PVP application in order to provide a point of reference to evaluate distinctness.

The U.S. PVP application instructions indicate that:

- Differences in quantitative characters such as plant size, seed size, and maturity, that are not obvious and detectable without a direct comparison, must be supported by evidence provided by the applicant. The evidence must be given as numerical data obtained from at least two trials.
- Distinction based on differences in color needs to be referenced with a standard such as the Royal Horticultural Society Colour Chart or the Munsell Book of Color, unless dramatic (i.e., red versus green). Color chart measurements must be conducted in two or more localities or growing seasons.[6]

It is sometimes helpful to submit photos to demonstrate color differences.

Distinctions in disease reaction between the new variety and other varieties must be supported with data or results from at least two trials conducted in two or more localities or growing seasons, unless the distinction is dramatic (for example, other varieties are highly susceptible to disease, while the new variety is disease-resistant). Remember to include the following: the disease reaction to the causal agent or organism; the causal agent or source of the disease (if it has been demonstrated or identified); and the race, strain, or pathotype of the disease, where appropriate.

It is important to note that yield is not accepted by the PVP office as a basis for distinctness because it is not a sufficiently stable trait. Yields depend largely on environmental factors.

3.4 *Exhibit C: Objective Description of Variety*

As in Exhibit B, numerical data must be provided to support certain elements of the variety description: performance characteristics, pest resistance, quality, or other traits. Data should be gathered in at least two locations or over two years. Describe the statistical methods used, plus coefficient of variance (CV), SD, LSD, range, or other estimates of test variability.

3.4.1 *Essentially derived varieties*

An *essentially derived variety* is usually developed when one or a few genes or traits are added to a preexisting variety, resulting in a phenotypic change or changes. The change may be cosmetic (for example, a change in flower color) or economic (for example, the addition of a value-added, genetically engineered trait, such as an insect-resistance gene, into an existing variety).

The U.S. PVPO will approve an essentially derived variety if it shows one or more distinguishing characteristics *and* if the original variety has a PVP certificate issued after 1994. The U.S. PVPO will not protect an essentially derived variety if the original variety was not protected, or was protected only with pre-1994 criteria. PVP protection may not protect the owner of the variety from infringement liability if the original variety's germplasm comprises the majority of the essentially derived variety. For that reason, it is sensible to make arrangements to compensate the owner of the original variety for the use of the germplasm. At the time of this writing, there was no absolute rule regarding which varieties are essentially derived and which are not, though seed committees and organizations are working to develop criteria. Disagreements must be worked out between variety owners, or if this is not successful, by the courts.

3.5 *Exhibit D: Optional Supporting Information*

Exhibit D is required for wheat (milling and baking quality must be described), but it is optional for other crops. This exhibit describes quality factors of the crop and/or offers other information pertaining to variety uniqueness that is not included in the other exhibits.

3.6 *Exhibit E: Statement of Ownership*

Exhibit E is a statement of who developed the variety, who owns it, and who or what entity, if any, has rights to it. A single paragraph will suffice.

3.7 *Exhibit F: Declaration Regarding Deposit*

In Exhibit F, the applicant declares that he or she has included with the application a "voucher sample" of at least 3,000 untreated, viable seeds capable of propagating the application variety (minimum germination rate 85%). In the case of vegetative and clonal crops, the applicant declares that he or she will deposit a viable cell culture in a public depository, where it will be maintained for the duration of the certificate.

The U.S. PVPO may use a small subsample of the submitted seed (no more than 25 seeds) in the process of examining the application. The rest of the seed sample will be deposited by the U.S. PVPO in the National Seed Depository Laboratory (NSDL) at Fort Collins, Colorado. The NSDL keeps PVP seeds separate from their normal collections and only the applicant and the U.S. PVPO will have access to the seed for the duration of the certificate. These deposited seeds will be used in case of an identity challenge. The NSDL will return any remaining seed to the applicant after the PVP certificate has expired or is no longer in force.

4. OTHER CONSIDERATIONS

4.1 *Critical dates to keep in mind*

1. *Date of first sale*. You must apply for a PVP certificate within one year after the date of the first commercial sale of seed or planting stock of your variety. (Sales of experimental seed for further testing only are exempt.) You have four years from the date of the first commercial sale (six years for a tree or vine) to apply for a PVP certificate for foreign varieties. Keep evidence of the date of first sale in the form of an invoice or receipt.
2. *Date application is received in the U.S. PVPO*. The date the original application was received is considered to be the date of application, though requests for additional information may take months or years to satisfy. The variety can be sold while a PVP certificate is being sought for it.

4.2 *When to apply*

Apply for PVP certificate as soon as you decide to protect the variety and can assemble the necessary information (which should be before the date of

first sale). The amount of time it takes to get a PVP certificate application approved is highly variable. It depends on the current workload at the U.S. PVPO and can be lengthened by requests for additional information. Figure on at least a year or possibly two years.

4.3 *After filing*

Be prepared to respond to questions and requests from the PVP examiner; few applications are accepted as originally submitted. Some of these questions may be answerable with existing data; for others, more data may need to be collected.

5. FURTHER PROTECTION FOR PLANT VARIETIES

Although a PVP certificate gives you or your agent the sole right to sell the plant variety in question and protects the variety name from infringement, it is sensible to take additional precautions:

- Control all breeder seed that you or your organization grow, harvest, and maintain.
- Control all foundation seed production by producing it only within your organization or granting tight licenses or contracts to trusted seed producers.
- Control who gets foundation seed, through licenses or sales, with tight contracts.

5.1 *Enforce protection*

Stay alert for unauthorized sales of your PVP seed: such things as advertisements in local newspapers are giveaways of illegal activity. Tell any individuals, companies, or other organizations that sell or distribute your variety to be alert to illegal sales and to notify you immediately if they detect them.

It is important to realize that the unauthorized seller may very well not realize that the variety is protected. Notify the offender that he or she is selling a PVP-protected variety. A warning is often sufficient to stop the problem. If the offender persists in making illegal sales, threaten to cut him or her off from future releases. Sue only as a last resort, and consider whether a court battle is worth the cost in money and public relations.

5.2 *Bag-tag warning*

Before the PVP certificate is awarded, label all seed containers of the variety as follows:

> *Unauthorized Propagation Prohibited*
> *U.S. Variety Protection PVPA 1994*
> *Applied For*

After the PVP certificate is awarded, label seed containers as follows:

> *U.S. Protected Variety PVPA 1994*
> *Unauthorized Sales for Reproductive Purposes Prohibited*

5.3 *Brown-bag sales*

Under the *farmer exemption*, farmers are permitted to grow and save enough seed of a PVP variety to plant their own acreage.[7] If they decide not to plant the seed, they are allowed to sell it. However, some farmers produce and sell large volumes of seed, far more than they would be able to plant on their own farms. In the United States, this practice is unfortunately common in the Midwest and South, particularly with soybeans, cotton, and peanuts. Because the illegal seed is often sold in unmarked brown bags, this practice is popularly called "brown bagging." A recent Supreme Court decision that upholds the rights of PVP certificate owners may discourage, but will not stop, brown-bag sales.

Title V of the U.S. Federal Seed Act makes it unlawful to sell uncertified seed of a PVP variety by the variety name. Many state seed laws include similar provisos. On page one of the PVP application, you can state your intention to also apply for Title V protection. Of course, brown bagging can still occur even if Title V is in force. In such cases, you will need to seek help from the appropriate state, federal, or state seed-law enforcement agency. Seed-law enforcers can issue orders that prohibit offenders from further action, and may

issue a stop-sales order or fines to a persistent offender.

6. CONCLUSION

Assembling and submitting a PVP application for your variety can be either a nearly unbearable aggravation or a very easy task. It all depends on how organized, diligent, and proactive you are. The key elements are to plan well ahead, keep careful records, know what you need to do, know when you need to do it, and know what the PVP offices needs (not less and not more) to process your application. From a practical standpoint, this means keeping good breeding records, being familiar with the PVP Web site, knowing what the forms and exhibit schedules are, and keeping track of time. If you are organized, the application process will likely go smoothly. And remember, after your PVP certificate is issued, be diligent and watch for infringers. PVP can provide your variety, and your breeding program or business, with a foundation for realizing returns on your investments, which can then be used to develop the next round of improved varieties from your breeding program, for which you will then seek PVP. ■

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1 Pursuant to the PVP Act of 1970, 7 U.S.C. § 2321–2583.

2 www.ams.usda.gov/science/pvpo/apply.htm.

3 They may be contacted at: U.S. Department of Agriculture, Agricultural Marketing Service, Livestock and Seed Programs, Seed Regulatory and Testing Branch, 801 Summit Crossing, Place, Suite C, Gastonia, North Carolina, 28054-2193 (Phone: 704-810-8870). www.ams.usda.gov/lsg/seed.htm.

4 See *supra* note 2.

5 www.ams.usda.gov/science/PVPO/Forms/GuidelinesA.htm.

6 www.ams.usda.gov/Science/PVPO/Forms/GuidelinesB.htm.

7 McCarthy JT, RE Schechter and DJ Franklyn. 2004. *McCarthy's Desk Encyclopedia of Intellectual Property, Third Edition*. The Bureau of National Affairs, Inc.: Washington, DC.