

# Licensing Plant Varieties Developed at Universities

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## Observations Regarding Plant Variety Licensing in a University Context

Plant breeding research and the associated plant variety development has played a central role within research universities, especially those in countries or regions where agriculture is key to the regional economy. In the United States, land grant colleges were established in the mid-nineteenth century, in part, to support the local agricultural economy as the nation expanded its geography and population. The plant breeding and related research carried out at these universities helped establish the agriculture infrastructure in these newly developing regions.

In recent years, the support for plant breeding from traditional government funding sources has decreased. Several factors contribute to this change, including a shift in funding to support molecular biology and genomics as applied to agricultural research. Without a doubt, the genomic revolution of the 1990s will change the face of agriculture, but the path to direct benefit in all but the most major of crops is uncertain. Researchers are using these techniques to understand some of the fundamental aspects of plant biology in important agricultural crops, which may lead to traits that enhance disease resistance, abiotic stress tolerance, and even the nutritional or wellness-enhancing attributes of common crop plants. Such enhancements will surely create value, but the timeline to value creation is long.

With the decrease in government funding, universities have become more reliant on funding from grower or marketing-based organizations. Often these commodity groups or marketing order boards are state-sanctioned with a charter to levy their membership and use those funds to support, in part, research to develop new varieties or markets. Such local funding creates expectations of direct local benefit from the research that can

impact the commercialization strategy for those charged with variety rights management on behalf of the university.

The local benefit demanded can take the form of discounted royalty rates for the contributors, preferred access to new varieties (that is, access in advance of broader commercialization), or even requests to share royalties from broad-based licensing programs. In making any such decision on behalf of the university, the licensing office must weigh the impact on faculty research and be cognizant that a strong relationship with such local groups is essential to ensuring future support for the research program.

University plant breeding programs also need to understand and manage their relationship with private breeding organizations. In certain crops, the market is dominated by large specialized corporations, and the outlet for university technology, by necessity, flows through them. However, in other crops where the market may be small, the product of the university research is the finished variety licensed to propagators, seed houses, etc., that become the distribution channel to the grower.

With the advent of more sophisticated marketing of specialty fruit and vegetable crops, private breeding companies have been established to capture this value. Traditional university research programs are now direct competitors to these private breeding companies, leading to questions on how best to support the local agriculture community. One question to be considered is whether a university should license advanced germplasm to private breeding companies or retain it for internal use only. While any decision regarding the research program is rightly the purview of the academic research enterprise, the outcome has an impact on the role and nature of the plant variety licensing program.

Also, universities may enter into sponsored research agreements with individuals or companies to develop plant varieties just as they would do in other research areas. In return for funding the research, the sponsor may secure preferential access to the varieties. The terms and conditions of such preferential access or the nature of the license itself would be subject to the university's overarching policies relating to sponsored research.

Another somewhat unique element of plant variety licensing at universities is defining the exact nature of the customer and/or licensee. In the majority of nonplant licenses, the university's primary relationship is with the licensee, and the royalty paid under the license agreement is an invisible component of the price paid by the final customer. In vegetatively propagated crops, in particular, universities license to nurseries that propagate and sell plants to the grower. Nurseries often perceive their role as a service provider multiplying what has been created by the university. Often, licenses are nonexclusive, and so the nursery has very little incentive to promote the university's variety over others in its catalog.

Ultimately, demand for the variety is generated by the success of the variety based on grower experiences. The royalty paid to the university may be explicitly stated on the invoice such that the grower perceives the royalty as a university-imposed tax. Such perceptions can create ill will, especially when the growers believe that they have paid for the research leading to the variety through fees paid to their commodity organization or marketing order board.

These observations point to the fact that managing a plant variety licensing program has some fundamental differences as compared to managing other technologies created through university research. The remainder of this article will concern itself with some of the practical aspects of protecting and licensing plant varieties. The reader is also directed to a recent publication, *Intellectual Property Management in Health and Agricultural Innovation*,<sup>1</sup> which contains a number of chapters that expand on aspects of plant variety licensing applicable to university technology transfer offices.

## Types of Intellectual Property Protection Available

A range of options exist to protect the university's plant varieties. This section outlines the key options and highlights the context where they could apply. At no time should these comments be taken as a substitute for consultation with appropriately trained attorneys who specialize in the various forms of intellectual property protection.

## Bailments and Tangible Property Rights

Most university technology licenses relate to intellectual property and occasionally deal with the tangible property of the university. Such tangible property could include cell lines or mouse models for disease for use as research tools either by industry or public-sector scientists. For plant varieties, bailment agreements for the tangible property consisting of the finished variety or the parental germplasm are a key part of the normal process of testing and evaluating the commercial potential of a new variety.

For logistical and pragmatic reasons, most universities cannot develop a finished variety without the help of outside collaborators. These collaborators provide the land and crop-management infrastructure, as well as market-informed analysis of the commercial potential of the new variety. Because filing for intellectual property protection on advanced germplasm selections may be undesirable due, in part, to the cost of seeking protection, especially considering that many lines may need to be tested to determine if any are commercially useful and also because the invention may not be considered complete until commercial utility is proven, the preferred way to secure protection for the university's asset is to transfer possession (but not title) to plant material to the grower under a bailment.

The limitations imposed in the bailment agreement protects against the testing being considered a bar to further protection using plant patents or plant variety rights. Should the variety not prove useful, the university can terminate the bailment agreement and recover (or destroy) its property to prevent unwanted propagation.

Bailments can also play a role in a hybrid licensing strategy (described later in this article) whereby a licensor can maintain control over proprietary germplasm beyond the term of the plant patent or plant variety rights. Also, enforcement of the tangible property rights granted under the bailment may be less cumbersome than enforcement under intellectual property rights.

For example, in the United States, enforcement of tangible property rights generally takes place in state courts, whereas enforcement of plant patents and plant variety protection certificates requires action in federal courts. Also, in certain other countries,

while plant variety rights legislation may have been enacted, a judicial precedent for enforcing those rights may not have been established, whereas the enforcement of tangible property rights may be well-established. The use of bailments alone does come with certain risks, most notably the inability to limit use of plant material that escapes from the contractual control. As such, bailments should be used with caution.

### **United States Patents**

U.S. patents can be used to protect plant varieties. Unique to the U.S. is the ability to obtain a utility patent (as one would for any other invention), as well as a plant patent. The usual statutory requirements for patenting such as novelty, nonobviousness, and utility, as well as the requirement to correctly name the inventor(s), apply to plant patents. As such, it becomes important that any prerelease testing be carried out in such a way as to not create a statutory bar to issuance of the patent.

U.S. patent law allows for an experimental-use exception provided certain criteria are met. Included in these criteria is whether there was a secrecy obligation on the part of the testing party. Many of these criteria can be addressed by ensuring that the appropriate test agreement is in place prior to distribution of plant material to the testing party. Accurately naming inventors is also critical for any patent, but may be a more complicated issue for patenting plants, as will be discussed later in this article.

Filing and prosecution of a utility or a plant patent requires that the person have passed the patent bar and be registered to practice at the U.S. Patent and Trademark Office (USPTO), which means that universities generally retain outside counsel for this purpose.

#### *Utility Patents*

Utility patents are a useful option to consider when evaluating the appropriate intellectual property protection strategy for a new crop plant. Utility patents are available for all plants and are used quite extensively by the leading seed companies when protecting parental germplasm, including parental lines enhanced with biotechnology-derived traits. These utility patents are usually distinct from the patent that protects the technology underlying the particular trait (e.g., the mechanism of herbicide tolerance).

In most instances, the utility patent protects the parental line containing the enhanced trait and uses the claim structure of a utility patent to protect progeny of that line through conventional plant breeding. Utility patents are considerably more expensive to prepare and prosecute than plant patents, but the increased scope of the protection afforded by utility claims makes them a useful intellectual property management tool in high-value crops, especially those that employ a hybrid breeding strategy to achieve superior performance.

Utility patents do require the deposit of the claimed subject matter, which can create a challenge. Deposits of tissue-cultured plant material can suffice, but showing that the deposited material is sufficiently viable to meet the intent of the patent statute and finding a depository willing to accept and maintain the deposit for the duration of the patent can be a challenge. The American Type Culture Collection does provide depository services (<http://www.atcc.org>) for certain plant material claimed in utility patents.

### *Plant Patents*

The practice of plant variety licensing in the U.S. differs from that in most other places in the world due to the fact that plant variety rights are controlled by two different laws managed by two different branches of the government. U.S. plant patents cover *asexually reproduced plants* (that is, plants where the multiplication for commercial production is asexual) *other than tubers*. A plant patent holder has the right to exclude others from asexually reproducing the plant and from using, offering for sale, or selling the asexually reproduced plant or its parts or from importing that plant or its parts. Amendments to the statute in 1998 added the concept of plant parts and the ability to exclude imports as a response, in part, to importation of cut flowers covered by a U.S. plant patent.

A plant patent has a single claim to the plant described in the specification. The patent application must describe the plant in sufficient detail that the patent examiner can determine that it meets the novelty, nonobviousness, and utility criteria, but unlike U.S. plant variety protection certificates and analogous plant variety rights elsewhere in the world (both discussed below), the USPTO does not require the applicant to deposit the plant or subject the plant to physical evaluation of its described unique features. U.S.

plant patents do not contemplate the saved-seed concept present in other forms of plant variety rights (see below), presumably because the concept is not relevant to vegetatively propagated species.

### United States Plant Variety Protection Certificates

U.S. plant variety protection certificates (PVPCs) are issued by a division of the U.S. Department of Agriculture for a range of *sexually reproduced plants*. (For more information and a list of varieties for which PVPCs are issued, consult the Plant Variety Protection Office Web site at <http://www.ams.usda.gov/science/PVPO/CertificatesDB.htm>.)

The rights granted under PVPCs are equivalent to the rights granted under legislation that follows the Union for the Protection of New Plant Varieties (UPOV) treaty in other countries (see below). These rights include the right to control export, something not specifically granted under U.S. patent law. Regulating export is useful if one desires to manage the production and distribution of a variety globally. Absent specific restrictions in the form of a label or use license, a purchaser of a patented product can export that product, thus complicating a global marketing scheme. PVPCs also allow a farmer to save an amount of seed of a protected variety sufficient to replant the equivalent amount of that variety in subsequent years, but the farmer is not permitted to increase production nor transfer the seed to another individual.

Unlike patents, one does not need to be a registered patent attorney to submit an application for a PVPC, and universities can submit PVPC applications directly. Deposits of plant material are required for evaluation for distinctiveness, uniformity, and stability. As with U.S. patents, applicants must submit their application for a PVPC within one year of the first sale or offer for sale of a new variety in the United States.

### Foreign Plant Breeders and Variety Rights

Outside of the U.S., plant varieties are protected by the national laws of each country. Increasingly, these laws operate under the basic principles set out by the UPOV treaty, an international treaty administered in Switzerland. The United States is a party to this treaty and, as mentioned above, U.S. PVPCs follow UPOV guidelines even though U.S.

plant patents do not. While UPOV creates a framework, legislation in each country may vary in the way in which the basic principles are implemented, which requires those seeking international protection to understand the exact nature of the protection afforded by local plant variety rights laws.

Outside of the European Union, no mechanism exists to file for plant variety rights protection in multiple jurisdictions. In the EU, the Community Variety Protection Office offers protection in all EU member states; however, protection in individual member states is still available through national offices in that country. Most UPOV-compliant laws give variety developers in other countries four years (or six years for trees and vines) from the domestic sale to seek protection in the foreign jurisdiction.

Not every species is afforded protection in every country, necessitating a thorough analysis before embarking on an international licensing strategy. It is possible to work within a national system to add a particular species to the protected list, but such endeavors do require a strong internal advocate and usually a compelling economic reason (such as access to an important new variety that could create value for the agricultural economy). Even if protection is possible, it is important to consider whether the rights granted will be enforceable. In countries with well-developed judicial systems, litigation of plant variety rights occurs rarely, if at all. Predicting the course or outcome of an enforcement action in countries with less well-developed judicial systems is exceedingly difficult. The complexity and cost of broad protection, combined with the uncertainty of subsequent enforcement, requires that decisions to seek broad protection be well-thought-out.

## **Trademarks**

Trademarks provide another avenue to protect plant varieties that has application in certain circumstances. Trademarks identify the source of the good and protect the name or the brand, not the variety itself, and, except, in rare circumstances, should not be considered a substitute for plant variety rights protections. In the U.S., trademark rights can be created by use or by registration with the USPTO. In most other jurisdictions, trademarks must be registered with the appropriate authority.

A common misconception is that one can use the variety name as a trademark. In fact, the variety name can never be accorded the status of a trademark, no matter how well-recognized it becomes as that name is considered the generic name for that particular variety. Also, filing for plant variety protection in one jurisdiction using a particular name may preclude the use of that name as a trademark elsewhere in the world, irrespective of whether the variety is protected (or even protectable) in a particular country.

Trademarks are being increasingly used by commercial plant breeding organizations as a valuable part of a combined intellectual property rights management strategy, especially where the variety has some distinct consumer appeal. Like tangible property rights, trademark rights do not expire so long as they are used, and so afford a way to capture value beyond the traditional term of patent or plant variety rights protection.

However, the use of trademarks carries with it other responsibilities for the holder, such as ensuring that the trademark is used correctly by internal and third parties and that the goods bearing the mark meet quality standards specified by the holder. For a more comprehensive discussion of the use of trademarks in plant licensing, consult “Use of Trademarks in a Plant Licensing Program” in *Intellectual Property Management in Health and Agricultural Innovation*.<sup>2</sup>

### Commercial Registration

In many countries, before a variety can be sold, it must be registered with a governmental agency. As with plant variety rights, the process for commercial registration varies by jurisdiction, but the process lacks the consistency afforded to plant variety rights protection by the UPOV treaty. Understanding the nuances of commercial registration is usually far beyond the scope of any university licensing office and not within the purview of law firms or like agencies retained to file and prosecute plant variety rights applications. Often, it is preferable to require the licensee in the particular territory to seek and pay for any commercial registration needed to sell or license the technology to propagators or growers.

## Practical Aspects of Plant Variety Licensing

The following section discusses some practical aspects of protecting and licensing plant varieties.

### Managing Intellectual Property Rights Prior to Release of a Variety

As noted earlier, developing a new plant variety is a long process that begins with the initial breeding event and proceeds through multiple stages depending on the nature of the plant variety. In seeded crops, the steps could involve rounds of recurrent backcrossing to introgress the desired trait into a well-known and understood parental background or sequential inbreeding and selection to identify varieties with stable characteristics.

For vegetatively propagated species, the process may require extended observation of the performance of the selection on different rootstocks or in different environmental conditions. While such activities could be carried out within the somewhat regulated environment of the university, more commonly, plant breeders engage the support of third-party collaborators to propagate, multiply, grow, harvest, and evaluate potential new releases.

Under UPOV-compliant laws, such testing, and the incidental sale of the crop, may be permitted without compromising the ability to seek protection of the crop in a future filing. Similarly, under U.S. patent law, incidental use of the selection as part of the testing is permitted without loss of rights with respect to future patent filings. However, as mentioned earlier, to protect future intellectual property rights, it is important that all such third-party testing be carried out under agreements that ensure the testing does not trigger statutory bars to future protection domestically and internationally.

### Release of a New Variety

The decision to release a new variety from a university plant breeding program is complex. As the variety will be inextricably linked with the institution, it must meet a complex set of criteria and require institutional signoff. Who actually approves release will depend on the institution, but the technology transfer office may not be a required signatory to this process.

However, it does fall on such offices to manage intellectual property protection of released varieties, and some of the criteria addressed in the approval process have implications for patent and plant variety rights protection. Such criteria include the distinctiveness and stability as well as commercial utility of the variety and, often, the naming of the variety, which has implications if using trademarks is part of the overall intellectual property protection strategy. Ultimately, the decision on whether or not to seek intellectual property protection for the variety should be based on the best interest of the internal and external stakeholders.

For U.S. plant patents, a key requirement for protection is determining the inventorship for the patent. Because of the potentially long timeline between the initial cross and any final decision to release, identifying inventorship can be complex. One person may have initiated the process by deciding what parents to cross, another may have played a role in selecting particular progeny for further evaluation, and yet others may have perfected the invention by choosing the particular individual among the selected progeny for one that has the traits that make it useful in commercial agriculture. Depending on the circumstances, all such participants could rightfully be considered inventors. Because inaccurate inventorship can prejudice the validity of a patent, it is incumbent on a technology transfer office to accurately determine inventorship prior to filing a plant patent application.

For U.S. PVPCs and foreign plant variety rights, inventorship does not have the same legal significance, and so the driver for determining inventorship is ensuring internal equities with respect to royalty sharing. However, to maintain consistent treatment of contributors within the institution, inventorship determination for PVPCs should follow the same principles that apply to plant patents.

### **Postrelease Distribution of Plant Material**

Once a decision to release a variety has been made, a matter to be considered is the process for distributing what is likely to be a limited amount of the plant material. If a university does not have the physical resources to maintain the germplasm in suitable quantities (e.g., a foundation plant service), then some alternative arrangements are nec-

essary. If third parties are used to multiply or distribute initial plant material, it may or may not be appropriate to license them under intellectual property rights as their role in the commercialization may be transient.

When providing initial plant material of a new variety, it is important to ensure that all material supplied complies with all phytosanitary requirements and be verified as true to type. The university has to be concerned about the liability associated with the distribution of disease-carrying or off-type material. The future value of a new variety could be seriously compromised if a grower's initial experience with it is colored by a bad experience due to poor quality plant material distributed by or on behalf of the university.

Another issue that sometimes arises upon release of a new cultivar is what role a university should have in the allocation of a limited supply of plant material. Sometimes, marketing order boards or commodity groups ask to play a role in allocating plant material amongst their members to ensure that all that desire access have it and prevent market pressures from driving up the price. In any arrangement related to distribution of plant material, it is important to ensure that the rules that govern allocation are clear and understood and that the arrangement not be subject to allegations of favoritism of one party over another.

### **Licensing Strategies and the Relationship to the Local Industry**

Universities (land grant, or otherwise) may have a policy designed to give some form of preference to the local agricultural community. This preference may or may not arise due to direct funding of the plant breeding program by the industry. Local preference can take several forms, including preferential access (i.e., access ahead of a more widespread release) and differential financial terms in license agreements. The choice of whether or not to protect a variety may be influenced by the requirement of local preference, as the protection provides the legal basis for restricting access or differential pricing.

Beyond simple preferential treatment, the local industry may also demand input into broader national or international commercialization strategies where such commercialization is perceived to negatively impact the local industry. Simply delaying release or

charging a higher royalty may not be sufficient to allay such concerns. From the university's perspective, such industry concerns must be balanced against other drivers such as recouping the costs of intellectual property protection needed to support the local preference and meeting the overarching university mission of transferring its technology for the public benefit, both domestically and for humanitarian uses in developing countries.

### **Licensing terms**

Many factors contribute to determining the most appropriate terms in a plant variety license agreement. A key factor is the goal of the licensing strategy. Often this goal is to provide the broadest possible access to the variety, which leads to nonexclusive licensing to propagators, such that growers can purchase their plant material from a range of possible suppliers. Nonexclusive licensing can ensure that the variety is priced through a competitive market. However, nonexclusive arrangements do not create an incentive for licensees to promote the variety and may result in a new variety languishing for lack of a strong advocate. For a variety with a limited market potential, an exclusive license may provide the incentive to pursue the niche opportunity.

The royalty base for plant licenses, especially for vegetatively propagated crops, is often the propagation unit, with a set royalty per unit (e.g., per tree, per 1,000 seedlings, per bag of seed) rather than a percent of the sales price. Per-unit royalties do not allow the licensor to benefit from price increases due to inflation, so for agreements with a per-unit royalty, including a clause that allows royalties to adjust for inflation, is advantageous. A per-unit royalty model does have the advantage that royalty base is less subject to manipulation (for example, a licensed product may be discounted to drive sales of other related products) by the licensee.

Ideally, royalty rates should be related to the value created by the variety, but traditionally, royalties on tree sales range from \$1 to \$2 per tree. Considering the price of the average fruit or nut tree, this amounts to a royalty of 5 percent to 10 percent of the sales price. Also royalties on sales of seed crops are often in the 5 percent to 10 percent range. Such rates are justified because plant varieties are effectively finished products with no further development required.

For perennial crops, a disadvantage of a propagation unit-based (i.e., one-time) royalty is that this structure does not capture the value of the final consumed or used plant material. To capture this value, a production or box royalty may be appropriate. Extracting such production royalties from commodity items can be exceedingly difficult, because the grower is not receiving premium price for the product and, thus, has no added value to share with the licensor.

However, if the licensing strategy includes exclusive or restricted distribution terms (also known as *managed production*) and the grower receives a premium price for the product, then it is quite reasonable to expect that the licensor capture some portion of that premium through a production royalty. Such production royalties can be levied on the units of product shipped from the packhouse (i.e., per unit weight, carton, etc.) or as an annual fee based on production area (i.e., per acre, hectare, etc.)

Collecting royalties at the packhouse can pose difficulties due to the need to ensure accuracy in accounting for units shipped, especially where the product could be combined with similar products. Production area-based royalties can be easier to police as the planting area can be determined based on the number of units actually purchased at the outset and is not subject to season-to-season fluctuations in production. Production royalties vary based on price premium over commodity product received by the grower or packer for the variety. The royalty rate may also take into consideration other support (such as technical assistance and marketing materials) provided as part of the license agreement.

In certain instances, a university should consider the applicability of a hybrid licensing strategy for a new plant variety. Hybrid licenses can combine tangible property, patent or plant variety rights, and trademark rights in a single license and allow the licensor to leverage the unique attributes of each form of right. Through the bailment provisions, the licensor can limit access to the tangible property, and, if necessary, enforce destruction of the material should the licensee breach the terms of the agreement. The tangible property and trademark rights may run indefinitely, and, thus, the licensee can continue to extract value created in a particular variety past the term of patent or plant variety rights.

Such hybrid agreements are complex and should be drafted very carefully to ensure that each grant of rights is separate and separable from the others. Royalty terms must reflect the fact that the patent or plant variety rights will expire and, thus, should be structured with a specific royalty associated with each right granted.

For example, such structure enables a licensee to sell off-grade fruit without using the trademark at a lower royalty. Generally, hybrid licenses are only applicable to very high-value products, where the return to all the stakeholders warrants the additional costs associated with administering and enforcing the license agreement.

### **Licensing Internationally**

Varieties developed in one area are often well-adapted for similar climates and soils in other countries. Areas well-known for developing new varieties are regularly visited by growers from other countries looking for new varieties to enhance local agriculture.

Additionally, in the global production and marketing world of the twenty-first century, retail distributors are often searching for year-round supply of product in specific categories, so contraseasonal production opportunities exist for unique or valuable products to supply this year-round demand. For universities, this scenario provides an opportunity to explore international licensing in addition to licensing for domestic agriculture. For popular varieties, international licensing may surpass domestic licensing in terms of revenue.

For any university, licensing outside of its domestic market creates logistical challenges. For traditional utility inventions, international licensing is often the purview of the original exclusive licensee, and, thus, the university is not directly engaged in choosing the licensing partner or administering the license.

Because of the fragmented nature of agriculture, directly licensing a plant variety in another country can be logistically difficult. Undoubtedly one can license individual nurseries or producers directly, but postagreement management in such an environment is a challenge. An alternate approach is to select a master licensee for a particular country or region. The master licensee may be specific for the variety or crop type or may represent

a range of varieties. Effectively, this means the university has executed regional exclusive licenses with the right to sublicense.

In some countries, specialized plant variety management companies exist to manage university and private plant variety rights. In choosing a master licensee, one should take care to ensure that the master licensee can equitably represent the university's varieties. If the individual or company is representing competing varieties, the potential exists to favor one licensor over another based on the value the master licensee receives.

Another point to consider is whether the master licensee will use the university's variety as a way to sell other services for which the university receives no consideration.

Lastly, if the university's objective is broad distribution of a variety, choosing a nursery as the master licensee may be undesirable, as it would require the master licensee to enable competitors to meet the university's objectives.

These and other issues can be addressed by contract terms, but in general, it is preferable to choose the right partner at the outset than to be forced to terminate an agreement and find another partner down the road, especially in a foreign country where the laws and jurisprudence are different and potentially more favorable to the local party.

Often, testing a variety is the precursor to international licensing. Because of the costs of securing plant variety rights protection, such testing is often carried out under a bailment or test agreement. Determining when and where to test a variety does require careful consideration. Because of the long lead times between propagation and commercial production in certain varieties, testing may have to begin as soon as possible after domestic release to enable a reasonable determination of commercial utility prior to the end of the four- or six-year window to protect the variety.

If quarantine is required, it may even be necessary to start the process prior to the domestic release. Any delay in testing will mean that a decision to protect will be made without true knowledge of the commercial potential. Any prerelease testing should be

carried out under appropriate contractual terms that protect the ability to secure plant variety rights protection in the future.

Widespread testing without diligent controls can lead to uncontrolled propagation through unauthorized sharing (knowingly or through pilfering) of plant material. Once the plant material is widely distributed, it may be impossible to reassert control and this could lead to the loss of plant variety rights both within the test country and beyond. Where a master licensee is in place, all testing should be done under its auspices so it can determine whether the tester is a suitable business partner and the testing meets the broad goal of the licensing program.

When considering an international licensing strategy, one needs to determine where to protect the particular plant variety. Protection strategies may include both offensive and defensive protection. Protecting in the jurisdiction where the variety will be grown would be offensive, whereas protecting in jurisdictions where production is not anticipated but where, without protection, unregulated production could harm the market for the propagating material (due to import of propagating material from another country) or the crop would be defensive.

If the strategy relies on licensing propagation rather than production, protecting only in propagation regions may be sufficient. As protection in each jurisdiction requires a separate plant variety right application with its associated costs, the commercial opportunity must be carefully evaluated. Master licensees that are motivated primarily by commercial success and that understand the local market dynamics are often in a better position to determine the appropriate protection strategy. Once all such considerations are evaluated, the university may have to make the decision on whether or not to make the variety available internationally, and if so, whether or not royalty-bearing licenses are the best way to further the university mission.

If international licensing through a master licensee is determined to be appropriate and desirable, the next step is to determine how to equitably share royalties with that party. One solution is to simply share the royalty collected between the university and the mas-

ter licensee according to a predefined formula. The master licensee can be made responsible for the costs of any plant variety protection, commercial registration, or other steps associated with establishing the variety. If these costs are substantial, the agreement may have to consider some form of temporary relief or allow the master licensee to defer payment to induce participation.

A concern about a straight royalty split is that such a term does not prevent the master licensee from setting an unreasonably low royalty. One approach is to set a floor royalty to be paid to the university and share royalties over and above a predetermined amount. Alternatively, the university can set the amount it wishes to receive, and leave the local royalty structure to the master licensee's discretion.

As noted earlier, any international strategy must take into account the views of and impact on the domestic industry. If a strategy, for sound business reasons, appears to treat foreign producers more favorably, then the backlash from the domestic industry could create more damage to the university than the financial benefit from any royalty received from the licensing program.

Notwithstanding the potential for such negative reactions, international licensing may indeed serve the greater goals of a university by making valuable varieties available to farmers in developing countries to enhance the local food supply or support regional agricultural economies. Accordingly, all such elements should be evaluated before choosing this path.

## **Enforcement**

Enforcing plant variety rights, whether they be U.S. plant patents, U.S. PVPCs, or foreign plant variety rights, is an area with very little judicial precedent, and so any decision to pursue an infringement action must be carefully considered. Even in countries with well-established judicial systems such as the U.S., infringement suits are rare.

For both U.S. plant patents and U.S. PVPCs, as well as other UPOV-compliant rights, the basis for awarding the right is the physical description of the variety as provided in the

application. Thus, the decision as to whether the alleged plant infringes is based on comparing the physical characteristics, which by its very nature can be subjective and dependent on the conditions under which the plants were grown.

Despite the ability to characterize plants using DNA-based markers, and the widespread and accepted use of microsatellite markers for human identification in judicial processes, such markers are not the basis by which a court will determine infringement in plant cases. One reason for this is that human identification is made using a standard set of polymorphic alleles and the statistical probability inclusion/exclusion is very well-documented. In comparison, in plant species, no such standards or statistical information exists.

Notwithstanding the uncertainty of enforcement, plant variety licensing programs for universities can be very successful. The University of California strawberry variety program brings in annual royalties in the order of \$5 million from its global licensing program, so it is clear that the deterrent effect of litigation is sufficient to ensure acceptance and compliance with licensing agreements.

## Conclusion

University-developed plant varieties have played and will continue to play an important role in advancing agricultural production. Protecting and licensing these varieties effectively helps establish value for the university and its industry partners. The laws and practices in this area have some fundamental differences from those related to licensing other technologies created through university research, so understanding these differences is essential to capturing the value created.

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