Intellectual Property Rights and Public Plant Breeding

Recommendations, and proceedings of a conference on best practices for intellectual property protection of publically developed plant germplasm

Raleigh, NC
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Compiled and edited by

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Executive Summary

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Intellectual Property Rights and Public Breeding: Facilitating Public-Private Partnerships

Background: Intellectual Property Rights (IPRs) can play a critical role in protecting the genetic integrity of a variety and generating revenue to support continued breeding work.

While the private and public seed sector share the same goal of developing improved varieties, there are important differences that must be considered when developing appropriate IPR for cultivars developed in the public sector. Public breeding often focuses on crops with high social returns to investment but low private returns, such as small grains, perennials, cover and soil building crops, root and tuber crops, and tree crops. Public breeders often focus on long arc research, that is, research in which the payoff may require many years of work, often by many individuals. After development and proof of concept by the public sector, the new products are commercialized by the private sector with little return of funding to the public side. In many cases the public breeding sector collaborates with the private sector to commercialize public cultivars, and considerations must be made to facilitate this technology transfer.

Current germplasm exchange policies are inconsistent across public-sector institutions, and in many cases restrict plant breeders' freedom to operate. Institutions have different royalty-sharing agreements that may or may not direct royalty money to the breeding program that generated it. These inconsistencies create confusion and inefficiencies for potential private sector partners wishing to commercialize public cultivars and for those paying royalties to support continued breeding efforts.

The two-day conference, held just prior to the National Association of Plant Breeders' annual meeting in Raleigh, NC, convened stakeholders from the public and private sectors with the goal of developing a consensus document addressing the following specific objectives:

- 1) Develop a statement of best practices for the use of IPR and licensing agreements for public cultivars and germplasm
- 2) Provide examples of effective strategies for utilizing royalty money or other funding sources to support public cultivar development
- 3) Explore existing technology transfer mechanisms to ensure that useful germplasm from public programs moves out of breeding plots and into farmers' fields

Summit Findings and Recommendations

Intellectual property rights for the public sector

- Publicly developed cultivars should be immediately available for breeding.
- Farmers must be allowed to save seed of cultivars developed by the public sector.

Recommendation 1: Develop a professional standard similar to the wheat workers code of ethics for exchanging and releasing germplasm from public sector breeding programs. This professional standard would serve both for pre-release MTAs and to guide IPR protection on release of a public cultivar.

Funding public plant breeding programs at the institutional level

- Public sector breeding programs require a fair return of incoming revenue to maintain the breeding program.
- Revenue generation through royalties will not always fund a full plant breeding program, however, crops with large royalty income may be able to generate revenue to support other crops.

Recommendation 2: Develop best practices for dispersing royalty revenue to plant breeding programs and for joint release of cultivars from collaborative plant breeding projects

Capacity funding

- Cultivar development can be a public good, particularly when the public sector addresses
 environmental concerns or crops that have little private sector investment despite their importance to
 farmers.
- If the public sector is serving a public good it is likely that royalties will not be adequate to fully support cultivar development efforts and so capacity funding is needed.

Recommendation 3: Increase Farm Bill authorization and appropriations to support cultivar development capacity at public institutions. This includes increased base funding for programs and better targeting and availability of competitive grants.

Recommendation 1:

Professional standard of ethics for sharing germplasm

Slightly modified from the Wheat Workers Code of Ethics for Distribution of Germplasm as written in 1976 and 1994.

1. The originating breeder, institution, or company has certain rights to the unreleased material. These rights are not waived with the distribution of seeds or plant material but remain with the originator.

- 2. The recipient of unreleased seeds or plant material shall make no secondary distributions of the germplasm without the permission of the owner/breeder.
- 3. The owner/breeder distributing unreleased seeds or other propagating material grants permission for use (1) in tests under the recipient's control, and (2) as a parent for making crosses from which selections will be made. All other uses, including those below, require the written approval of the owner/breeder.
 - Testing in regional or international nurseries;
 - Increase and release as a cultivar;
 - Reselection from within the stock;
 - Use as a parent of a commercial F1 hybrid, synthetic, or multiline cultivar;
 - Use as a recurrent parent in backcrossing;
 - Mutation breeding; selection of somaclonal variants; or use as a recipient parent for asexual gene transfer, including gene transfer using molecular genetic techniques; and
 - Genotyping with molecular markers.
- 4. Plant materials of this nature entered in crop cultivar trials shall not be used for seed increase. Reasonable precautions to ensure retention or recovery of plant materials at harvest shall be taken.
- 5. Under exceptional circumstances, the distributor of germplasm stocks may impose additional restrictions on use or may waive any of the above.

Professional standard of ethics for releasing germplasm and finished cultivars

Publicly developed cultivars should be immediately available for breeding

Plant Variety Protection under the terms of the Plant Variety Protection Act, Plant Patents under the Plant Patent Act, and licenses that permit breeding under terms such as the code of ethics for sharing germplasm are all supported forms of intellectual property protection. Sometimes the utility patent may be the best choice to ensure that a cultivar is commercialized, but when used, utility patents and licensing agreements with terms restricting the availability of cultivars developed with public funds for breeding must be avoided.

Farmers must be allowed to save seed of cultivars developed by the public sector

Under the Plant Variety Protection Act, farmers are permitted to save seed in the quantities needed for their own planting. Farmers' rights to save seed are a key component of the US international treaty on plant genetic resources obligations, and must be included in any release of cultivars developed with public funding.

Public sector breeders deserve a fair return for their efforts

Royalty arrangements should follow best practices for university technology transfer offices as described next.

Recommendation 2:

Best practices for university technology transfer offices handling plant germplasm and cultivar release

Cultivars and germplasm developed with public funding will be released using mechanisms that permit the continued use of their genetics for breeding. This includes Plant Patents, Plant Variety Protection Certificates (Plant Variety Protection Act) and licenses that permit cultivars to be used for breeding as described in the professional standard of ethics for germplasm exchange. Utility patents or licenses on plant cultivars that restrict their use in breeding or restrict farmers' rights to save seed must be avoided.

The release of cultivars under mechanisms that allow for continued breeding and seed saving does not preclude the generation of revenue for breeding programs. Many cultivars generate revenue under licensing agreements, without any federal form of intellectual property protection. Because of the unique nature of cultivar development and commercialization, cultivar release has historically been handled by *sui generis* systems at public universities. However, the revenue generated from licenses of public cultivars at most universities have now been rolled into a standard intellectual property protection and royalty distribution system in recent years, to the detriment of cultivar innovation.

It is important to understand that innovation in cultivars is fundamentally different than other inventions in two ways that impact how intellectual property rights and revenue generation may influence continued innovation. First, in order to improve on a cultivar, it is necessary to be able to cross that cultivar with other lines and continue selection. For inanimate inventions, a utility patent requires the inventor to disclose how the invention was created, to allow "any person skilled in the art... to make and use the same (35 U.S. Code §112)." For plants, this is not possible unless the seed is available for continued experimentation and breeding. In this way, the Plant Variety Protection Act (7 U.S. Code §57) is more in keeping with the original intent of utility patents. PVP protects the cultivar itself (a unique combination of genes) but allows for continued innovation (use of the genes in other combinations).

Second, cultivar innovation depends on a pipeline for incremental, yearly improvements. Many inventions in more basic sciences and engineering come out of a good idea that is then reduced to practice. In the development of cultivars, turning a good idea into a cultivar depends on an active, continuing program of selection. Once a robust pipeline is developed, it can consistently release cultivars each year, but the pipeline cannot stop and start with any hope of success. This continuing program is required for an active research program, but is difficult to impossible to fund on short-term research grants. In this respect, it is less like a research program and more like a small business whose success depends on reliable delivery of product improvements every year. Without a consistent revenue stream, the system that produces cultivar innovation fails. Licensing fees for cultivars developed in the public sector are therefore more properly thought of as revenue that is generated to recover the costs of developing a cultivar rather than royalties. Royalties would only be generated after the costs of creating the cultivar that was licensed had been covered.

It may be helpful to think of cultivar development and release as a similar activity to that of a university-sponsored start-up. Many universities are now supporting faculty entrepreneurial activity by allowing faculty-led start-up companies to use a portion of the revenue generated from their activities to build and maintain the company. Since university-owned intellectual property is the primary asset of such start-

ups, if the university collected all the revenue from inventions and did not allow the start-up to re-invest it in their business, they would quickly cease to exist. This can partly explain the decline in public cultivar development programs as the historic revenue stream from licenses that supported continued innovation and maintenance of breeding programs has been diverted to other university uses.

Two examples can provide a starting point for discussion on best practices in terms of returning revenue to breeding programs so that cultivar innovation will continue.

1. Paraphrased from Barry Tillman's paper: At the University of Florida, the Office of Technology Licensing (OTL) is responsible for the commercialization of university research that is protected by Utility Patent. New discoveries, which are protected by Utility Patent, often require the creation of a new company, or they are potential new products licensed to a large corporation. Although OTL is dedicated to developing research discoveries into marketable products, plant cultivars do not generally fit their technology transfer model. A large part of the OTL "currency" is the number and success of the startup companies which are enabled by university discoveries and inventions. Moving plant cultivars into the marketplace is a different process with different metrics. The potential for rapid change in cultivars coupled with established industries prohibits starting a new company for every new cultivar. A unified mechanism was needed which would allow legal protection and licensing of cultivars to qualified seed or nursery producers. This required a different business model than most university technology transfer offices utilize. University of Florida plant breeders, working with OTL representatives have developed a system for cultivar release that is generating more revenue for both the breeding programs and the university than under the previous model. In addition, the University of Florida has hired new plant breeders in part because of their potential to generate revenue to fund research and breeding programs.

Most commonly, cultivars are protected by either PVP or Plant Patent and are released by the University of Florida directly to a separate entity, the Florida Foundation Seed Producers (FFSP), rather than to OTL. FFSP applies for intellectual property protection, develops licenses and disburses royalties. This dual system for cultivars used to be the norm and is now unique. Table 1 presents the royalty distribution policies administered by both OTL and FFSP. Royalty disbursement through the OTL is weighted toward the inventor and the University of Florida Research Foundation, under which OTL operates. In contrast, the royalty distribution through FFSP is weighted toward the inventor's program when total royalty amounts are lower and divides them more equitably across units and the Florida Agricultural Experiment Station when royalties increase. The vast majority of UF-IFAS cultivars earn less than \$50,000 in annual royalties. In the FFSP system, 70% of the royalties will return to the inventor's program. Over the past twenty years, these modest sums have allowed University of Florida plant breeding programs to grow and thrive.

Table 1. Example from the University of Florida

Royalty distribution based on percentage of Net Adjusted Income (NAI)

Recipient	Office of Tech Licensing standard policy		Florida Foundation Seed Producers cultivar-specific policy		
	<\$500,000	≥ \$500,000	≤ \$71,428	\$71,429- \$214,285	> \$214,285
Inventor(s)	40%	25%	20%	20%	20%
UFRF***	35%	45%	_	_	_
FFSP**	_	_	10%	10%	10%
			70% [†]		
Inventor's Program(s)	10%	10%	100% of first \$50,000 plus	50% of next \$100,000 and	33.3% of all over \$150,000
Inventor's Department	7.5%	10%	_	25% of all over \$50,000	33.3% of all over \$150,000
Inventor's College	7.5%	10%	_	25% of all over \$50,000	33.3% of all over \$150,000

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2. At the University of Wisconsin, cultivars were historically released through the Wisconsin Crop Improvement Association (WCIA), which also maintains seed inspection and quality programs. Currently, all intellectual property created by faculty, including new cultivars, is handled by the Wisconsin Alumni Research Foundation with a standard distribution system for royalties. Because this standard distribution system returns no revenue to the program that created the invention, crop breeders worked to develop an alternative with WARF and WCIA. In Wisconsin, the Wisconsin Alumni Research Foundation (WARF) routinely encourages entrepreneurial activity by faculty. When WARF helps faculty members start small companies to commercialize a product, the main asset of that start-up

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is the intellectual property developed by the faculty member. If all royalty revenue then went to WARF to be redistributed to the university, the start-up would fail. In these cases, WARF allows these businesses to keep some of the revenue, and WARF distributes the remainder as royalties under their standard distribution system. Recently, plant breeders at UW Madison were able to negotiate an arrangement with WARF where the Wisconsin Crop Improvement Association receives the same benefits as a WARF sanctioned faculty start-up. The WCIA receives 50% of revenue from licensed crop germplasm and WARF receives the other half. This is then distributed as outlined in Table 2, resulting in 42.5% of total revenue going to the breeding program that generated it.

Table 2: Example from UW Madison

Royalty distribution based on percentage of revenue

	Totals under WARF* WARF	Totals under WCIA** model	Breakdown under WCIA model [†]	
		WCIA/WARF	WCIA	WARF
Recipient Total	100%	100%	50%	50%
Inventor(s)	20%	8.5%		17%
Inventor's Program(s)	_	42.5%	85%	_
Inventor's Department	15%	6.375%	_	12.75%
Inventor's College	_	_		_
WARF (to UW Madison)	65%	27.65%	_	55.25%
WCIA	_	15%	15%	15%

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These two models show that it is possible to return a substantial percentage of revenue created through cultivar innovation to the breeding program that generated the cultivar, supporting the program infrastructure that is critical to continued innovation. Whether through re-creating a *sui generis* system like the University of Florida or adapting the current system to more accurately reflect the realities of

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creating new cultivars, breeding programs can at least partially fund themselves through revenue from the licensing and sales of their cultivars.

However, it is not reasonable to expect public plant breeding programs to serve farmers in their states and the broader public good while generating all of their own operating expenses. Plant breeding and cultivar development in the public interest often includes target traits that are not being developed in the private sector because it is difficult to financially recover the investment through seed sales or licensing fees. Examples include the development of perennial crops for conservation, developing crops for regional and state needs that do not represent large national seed markets and developing crops with consumer benefits such as increased nutritional content. As Land Grant Universities exist to serve the public interest, other methods of public funding of cultivar development must also be explored, as described next.

Recommendation 3. Capacity Funding

Increase Farm Bill authorization, appropriations and administrative support for cultivar development capacity at public institutions. This includes increased base funding for programs and better targeting and availability of competitive grants.

2018 Farm Bill:

- Require a minimum of \$50 million per year in total NIFA research funding with explicit support for public cultivar development research.
- Reauthorize the National Genetic Resources Program with the explicit charge of establishing a national strategic germplasm assessment and utilization plan.
- Expand duties of the National Genetic Resources Advisory Council (NGRAC) to provide guidance to the Secretary on USDA funding for public cultivar development, the state of our "in-field" crop genetic diversity, and resources needed to sustain the next generation of public cultivar developers.
- Ensure that all cultivars developed with public funds protect the rights of farmers to save seeds and the rights of breeders to share and improve such germplasm and breeds.

Agricultural Appropriations:

- Increase Hatch, Evans-Allen and all other such Land Grant University capacity funds by 10% with the explicit charge of supporting public cultivar development and the training and ongoing retention of the next generation of public cultivar developers.
- Increase funding for the National Genetic Resources Program by 20% to address significant backlog of existing accessions deemed critical to preserve viability and public access.
- Increase AFRI starting with the FY 2018 budget with the goal of reaching the full level of authorized funding of \$700 million by the end of the upcoming term.

USDA and Administrative:

- Develop a distinct program for public plant breeding research within the AFRI Foundation Program with a clear requirement for the development and release of publically bred cultivars.
- Expand support for graduate student-led public plant breeding research through AFRI, OREI, SCRI
 and other funding mechanisms for graduate and post-doctoral research, with a clear focus on public
 cultivar development.
- Encourage proposals for farmer-participatory, on-farm plant and cultivar/breeds evaluation to expedite the adoption of research innovations by industry.
- Establish a White House Office of Science and Technology policy liaison for public plant breeding.
- Direct USDA's Research, Education and Extension Office (REEO) to coordinate public plant breeding research activities within and between REE agencies and in close coordination with NGRAC to track and monitor progress toward the reinvigoration of public cultivar development.
- Establish an agency-wide public cultivar advisory team within USDA that includes external stakeholders from the farm and public plant breeding communities.

Encourage the Secretary to convene regular stakeholder listening sessions to provide recommendations on national and regional priorities for pubic cultivar development and NIFA competitive grant programs.

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- Require a minimum of \$50 million per year in total NIFA research funding with explicit support for public cultivar development research.
- Reauthorize the National Genetic Resources Program with the explicit charge of establishing a national strategic germplasm assessment and utilization plan.
- Expand duties of the National Genetic Resources Advisory Council (NGRAC) to provide guidance to the Secretary on USDA funding for public cultivar development, the state of our "in-field" crop genetic diversity, and resources needed to sustain the next generation of public cultivar developers.
- Ensure that all cultivars developed with public funds protect the rights of farmers to save seeds and the rights of breeders to share and improve such germplasm and breeds.

Agricultural Appropriations:

- Increase Hatch, Evans-Allen and all other such Land Grant University capacity funds by 10% with the explicit charge of supporting public cultivar development and the training and ongoing retention of the next generation of public cultivar developers.
- Increase funding for the National Genetic Resources Program by 20% to address significant backlog of existing accessions deemed critical to preserve viability and public access.
- Increase AFRI starting with the FY 2018 budget with the goal of reaching the full level of authorized funding of \$700 million by the end of the upcoming term.

USDA and Administrative:

- Develop a distinct program for public plant breeding research within the AFRI Foundation Program with a clear requirement for the development and release of publically bred cultivars.
- Expand support for graduate student-led public plant breeding research through AFRI, OREI, SCRI
 and other funding mechanisms for graduate and post-doctoral research, with a clear focus on public
 cultivar development.
- Encourage proposals for farmer-participatory, on-farm plant and cultivar/breeds evaluation to expedite the adoption of research innovations by industry.
- Establish a White House Office of Science and Technology policy liaison for public plant breeding.
- Direct USDA's Research, Education and Extension Office (REEO) to coordinate public plant breeding research activities within and between REE agencies and in close coordination with NGRAC to track and monitor progress toward the reinvigoration of public cultivar development.
- Establish an agency-wide public cultivar advisory team within USDA that includes external stakeholders from the farm and public plant breeding communities.

Encourage the Secretary to convene regular stakeholder listening sessions to provide recommendations on national and regional priorities for pubic cultivar development and NIFA competitive grant programs.