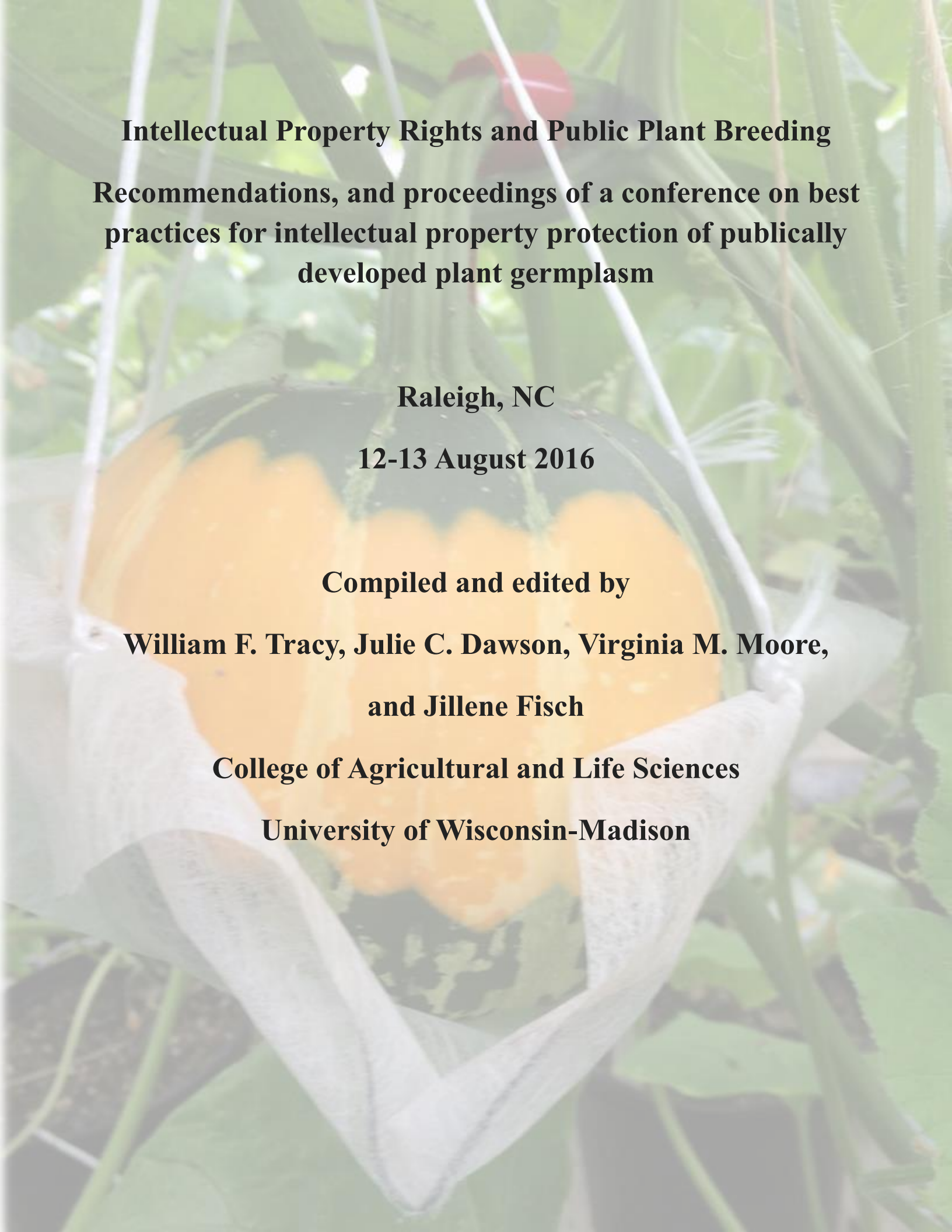

Intellectual Property Rights and Public Plant Breeding

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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Intellectual Property Rights and Public Plant Breeding

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

Organizing Committee

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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)

	Office of Tech Licensing standard policy		Florida Foundation Seed Producers cultivar-specific policy		
Recipient	<$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

*Office of Technology Licensing; **Florida Foundation Seed Producers, Inc.; ***University of Florida Research Foundation, Inc.

† Over a certain NAI, t70% designated for the "Inventor's Program" is divided among the Inventor's Program, Department and College as described.

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

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*	Totals under WCIA** model	*Breakdown under WCIA model*†	
	WARF	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%*

*Wisconsin Alumni Research Foundation

**Wisconsin Crop Improvement Association

† Shows the split in percentages of the 50% that go to WCIA and to WARF, WARF distribution to Inventor, Inventor's Department and WARF (UW Madison) follows the standard distribution system after their payment to WCIA

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

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.

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

Agenda
Raleigh, NC
August 13 – 15, 2016

Saturday August 13, 2016 (afternoon and evening)

Welcome, participant introductions and meeting expectations

3:30PM Opening talk: William Tracy, University of Wisconsin-Madison

Main points:

- Public plant breeding matters
- Public plant breeding needs adequate funding
- IPR can be one effective means for generating funding for public plant breeding

Session 1 – What are the IPR challenges?
Goal: What are the aspects of IPR that are problematic for public breeders?

4:00PM Main speaker: Adrienne Shelton, Vitalis Organic Seeds Co.

Response speakers:

- Claire Luby – University of Wisconsin-Madison
- Michael Sligh – Rural Advancement Foundation International
- Jane Dever – Texas A&M
- Jim Myers – Oregon State University
- Discussion

6:00PM Reception & cash bar

Sunday, August 14, 2016

9:00AM Session 2 – What are the funding problems?
Goal: Provide opportunities for people to express funding challenges

Main speaker: Margaret Smith, Cornell University

Response speakers:

- David Francis - Ohio State University
- Charlie Brummer – University of California Davis
- Discussion

11:00AM Session 3 – Examples of successful models
Goal: Concrete examples of working IPR and/or funding models

Main speaker: Barry Tillman, University of Florida

11:30AM LUNCH Speaker Jeffrey R. Kaufman, Open Source IP Counsel, Red Hat, Inc.

1:00PM Response speakers (session 3):

- Jim Luby - University of Minnesota
- Jeff Endelman - University of Wisconsin-Madison
- Discussion

Break 3:00PM

3:30PM Session 4 – Impact of public release mechanisms on stakeholders
Goal: Consider the range of players impacted by IPR on public cultivars

Main speaker: Elia Romano - Albert Lea Seed House

Response speakers:

- Matthew Dillon – Clif Bar Company
- Charlie Brown – Brown Seed Co., WI
- Micaela Colley – Organic Seed Alliance
- Discussion

Monday, August 15, 2016

8:00 - 11:00AM – Working sessions on IPR and funding models
IPR Goal: Develop a draft statement, similar to Wheat Breeders Code of Ethics, that lays out standards for public cultivar releases and MTAs that ensure end users have freedom to continue to breed and share public germplasm

Funding Model Goal: Develop recommendations on the most effective ways to utilize cultivar royalties to help fund breeding programs

Presentations

Keeping Public Plant Cultivar Development in the Public Interest

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Two years ago, the seeds and breeds coalition held a summit in DC. The goal of the summit was to find ways to reinvigorate public plant and animal breeding, including public cultivar development and graduate student training. The summit was styled like this one and one of the keynotes was on IPR. The IPR session generated tremendous interest especially about freedom to operate including breeding, saving seed and revenue generation to support public programs.

Two points that I would like to make for the discussion:

1. There are two major interconnected issues to address – funding and intellectual property rights.
2. We are focused on public sector cultivar development, best practices for public sector institutions and public plant breeders. Please keep our discussion focused on the public sector.

So, what is the current situation and how did we get here? Plant breeding is one of the oldest tools in the human tool kit. For at least 10,000 years, humans have been creating new and useful breeds adapted to different environments and farming systems. Until the industrial age breeding was one of the most powerful tools humans had in changing the world around them. It is still the most powerful way to create new varieties or breeds.

The power and precision of plant breeding is remarkable. Today many scientists, including biologists, marvel at the fact that 'primitive' (their words, not mine) people could make the changes that we see around us. They simply don't understand how natural/artificial selection works. Early in crop domestication, changes likely occurred in populations without conscious direction, but people quickly recognized that they could select for desirable characteristics.

For roughly the next 9,850 years there were literally millions of breeders around the globe. Simply by saving seed each farmer selected for adaptation to the local environment. Selection for local cultural and culinary needs required more conscious effort. Artificial selection along with mutation and introgression from wild relatives resulted in the enormous diversity of adaptation, morphology, and physiology we see in crop species today. While the first 9,850 years of breeding might not have been efficient in modern terms, it was highly effective.

Over the last 150 years the landscape of plant breeding has changed nearly completely. The changes can be represented by a number of trends: from all farmer breeders to nearly all professional breeders, millions of breeders to a few thousand, highly local adaptation to broad adaptation, breeding in every environment in which the crop is grown to breeding for only highly profitable areas, breeding every crop to only the few highly profitable to seed companies, decisions on breeding targets and goals by many people to very few people.

We can look at maize in North America to see these trends. Maize was domesticated from teosinte roughly 9,000 years ago in south central Mexico. The people bred for highly localized adaptation and uses resulting in roughly 300 'races' and many 1000's of landraces (cultivars) adapted to diverse environments from Canada to Chile. When the English arrived in what is now the eastern United States they found two races, 'Northern Flint' and 'Southern Dent' with many 100s of locally adapted landraces. Like all farmers, the colonists selected for adaptation and utility. When the new Americans moved into the rich savannahs and prairies in the Ohio and Mississippi valleys, they created (accidently) a new race, 'Corn Belt Dent', and every farmer began the work of adapting corn to their farm.

During the second half of the 19th century, changes came. The Hatch Act of 1887 created state experiment stations and the beginning of state supported plant breeding. By the turn of the last century most states had public corn breeding programs. Many of the new programs were designed to support on-farm breeding programs. At this time, some farmers began to specialize in seed production and breeding, which resulted in fewer farmers saving seed.

In the 1920's most universities began to experiment with hybrid corn. Hybrid corn began to be widely planted in the mid 1930s resulting in a proliferation of small seed companies across the Corn Belt, essentially putting an end to seed saving and 10,000 years of farmers breeding corn. The seed companies initially depended on inbreds developed at the State Experiments Stations, and the nearly free exchange of germplasm between public and private sectors today seems remarkable.

Over time private sector corn breeding expanded; and by the 1980's most LGU programs stopped developing inbreds and the large companies began absorbing the smaller companies.

In 2016, the trend of seed company consolidation had almost reached an endpoint with just three or four significant private sector operations. Only a handful of LGU corn cultivar development programs remain.

So, after 10,000 years we have gone from a point where millions of people each year were making breeding decisions and creating almost unimaginable amounts of local adaptation to a point that--for all intents and purposes--we have two or three companies breeding for the widest adaptation possible and making all the decisions about the future of America's principle crop and thus, essentially American agriculture. Their intense investment on corn, in effect, dooms other crops to minor status.

My first meeting on the future of public plant breeding was about 15 years ago. A small group was convened in Madison by Jack Kloppenburg. At that time, US public plant breeding was approaching, what I hoped, was its nadir. In 2003, a group of us organized the first Seeds and Breeds Summit in Washington DC. Fittingly, the same year, *Nature* published an article calling public plant breeders "a dying breed" (Knight, 2003). We had another Seeds and Breeds summit in Ames in 2005, which I remember most for the very kind and strong support we received from Don Duvick.

As evidenced by the *Nature* article the world was waking up to the collapse of public plant breeding and the loss of cultivars bred for the public good and local adaptation and the capacity to train the next generation of plant breeders. At this point I was lamenting not only lack of funding but lack of potential graduate students interested in field-based plant breeding.

In the last ten years, some progress has been made. Diverse groups realized we were in a

death spiral and have begun the hard work to pull us back. Different groups have had different motivations. The Seeds and Breeds coalition with its partners, NSAC, RAFI, NOC and others have been deeply concerned about the loss of public cultivar development and local adaptation.

The large seed companies have been more concerned with the loss of graduate student training. NGOs like OFRF, OSA, Seed Matters and others mentioned earlier are concerned with the lack of breeding for organic systems and have supported LGU organic cultivar development programs. All of these groups including ASTA are deeply concerned about the preservation and use of crop germplasm.

The voices of this diverse group have been heard across the federal government. USDA-ARS has had a long history of supporting plant breeding research and NIFA-AFRI has recently had RFAs specifically addressing plant breeding. And we now have a plant breeding roadmap. Plant breeding is now on the agenda of the NAS, the Congress and the Office of the President. The National Association of Plant Breeders has bloomed into a successful professional organization and advocate. Funding for plant breeding related research and graduate education has increased relative to the low point 10 or 15 years ago and public awareness and graduate student interest in the profession is relatively strong. As someone who remembers where we were 15 years ago these are significant and positive changes.

But, and there is ALWAYS a but, for public cultivar development deep structural problems remain, and I believe addressing these problems will be more difficult than what we have faced already. But, solving these problems is necessary if we are to develop a robust local, diversified agriculture and healthy research and training capabilities. As a public servant, I believe we must reinvigorate public cultivar development to return the investment that so many of our seeds and breeds partners have invested.

The problems are harder and more complex because there are many more moving parts: instead of the federal government we have 50 or more states to deal with, each having legislatures, deans, tech transfer agencies and clientele and commodity groups.

This is why I believe that the plant breeders must develop best practices and professional standards and create consensus documents that everyone can take back to their own universities to use in discussions/ negotiations with administrators and technology transfer offices.

Historically in the US most public cultivar development has been done by LGU faculty. As we will see in Adrienne's presentation, the numbers of cultivar developers in the LGUs continues to decline at dramatic rate. There are numerous reasons for this, but for most major LGUs, as neoliberal policies defund the universities and formula funds decline as a proportion as shown by Margaret, the LGUs look to overhead generation as a major source of revenue. Plant breeding and related applied sciences don't generate the kinds of overhead that someone competing successfully for NIH or NSF grants does. One of the reasons for the Seeds and Breeds focus on AFRI is to make hiring new plant breeders more attractive to departments and administrators. While there has been some success in increasing funding there, the amount of money is far too small to really change the LGU problem.

I have said to anyone who will listen, that given the new funding models, I do not see how applied agricultural research can survive at top tier research universities. To strengthen public cultivar development, we must identify ways to fund programs, and thus we need to talk about revenue generation, intellectual property rights and technology transfer. But, as you'll see from

the talks one size does not fit all. Crops, seed markets, reproductive biology and commodity groups will determine what works and what doesn't.

For many crops, revenue generated by the sale of seed or clones can be used to support public cultivar development. For those crops for which revenue can be generated it is critical that revenue be returned to the breeding programs. Margaret Smith, David Francis and Charlie Brummer will lay out the situation at modern major US research universities.

Many universities don't return any revenue/royalties to the breeding programs. This was the case at Wisconsin until recently as discussed by Jeff Endelman. In his keynote, Barry Tillman will discuss what I consider an exemplary program, and Jim Luby will talk about a program for woody plants that may or may not fit seed crops.

Major Goodman's and Jane Dever's papers point out that for some important crops, market exclusion and market size might make it impossible to fund a program based on royalties. So, other solutions will be needed. But, Adrienne shows that well-funded breeding programs are more likely to continue than poor ones.

Our first session touches most specifically on IPR. If possible, IPR is a more contentious subject than revenue generation and royalty collection. As discussed by our presenters most folks are OK with some level of IPR on the cultivar itself. For me the controversy arises around the genes within the cultivar. I, along with many others, believe that the genes are part of the commonwealth and therefore should be made available for breeding immediately when a cultivar is released. Many in our coalition also feel very strongly in the farmer's rights to save seed.

Another consideration on IPR brings me to make clear the distinction between the private and public seed sector. In the private sector the main goal is to generate profit for the shareholders. What is the purpose of public cultivar development? It is clear that taxpayers benefit from the development of new cultivars adapted to their state and its markets. Thus, improved germplasm developed with public funds should be available, with as few restrictions as possible to other breeders, public or private. Likewise, universities should not prevent farmers (taxpayers) from saving seed for their own use? Given the Land Grant mission the university should want the genes in its cultivars to be used as widely as possible.

It is important to note that IP developed by breeders--F_1 hybrids, plant patents and PVP--effectively, if not explicitly, make the genes available while those forms developed by lawyers--utility patents and licenses--usually tie up the genes. But, it should be recognized that patents and licensing are not the issue in and of themselves. They can actually be enabling vs. disabling. It all depends on how they are written.

A complicating factor in all this is that we are often confronted with two very different cultures. The Bayh-Dole act of 1980 said that any invention created at a university using federal funds must be offered to a technology transfer organization designated by the university. In many cases the designated agency is not knowledgeable about agriculture, breeding, seed or reproductive biology, but most importantly they often have no understanding of the land grant mission. Their main goal is to protect property. So, they consider not only the cultivar property, but also the genes. Never mind that alleles and allelic combinations have been assembled by 10,000 years of breeding mostly by farmers in the global south. We must address this culture clash between the LGU mission and tech transfer agencies.

To repeat what Julie said at the beginning, over the next day and a half, we are going to discuss:

1) The development of professional standards on intellectual property rights and release mechanisms for publicly developed cultivars,

and

2) The development of best practices for universities to return royalties or other revenue generated by public cultivars to the breeding programs that developed them, and funding streams that will support public cultivar development sustainably.

Session 1
What are the IPR challenges?

Keynote 1

Cultivar Development in the U.S. Public Sector

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ABSTRACT

Public plant breeders at land grant universities and USDA play a critical role in the development of improved cultivars for farmers in the United States. Over the past twenty years, a series of reports have documented the decrease in public plant breeding programs, breeder positions, and government financial support. Publicly funded programs allow breeders to focus on crop types, geographic locations, and management systems that are not sufficiently profitable to warrant significant investment from private industry. A survey was conducted in 2015 to understand the current state of cultivar development in the U.S. public sector. The survey respondents were public plant breeders actively releasing finished cultivars and inbred lines, and questions included: a) demographic and background information; b) germplasm usage and exchange; c) intellectual property rights; d) breeding program funding; e) institutional support and program size. Results indicate that public cultivar development is in a state of decline, with insufficient numbers of younger breeders working in the public sector today to maintain the current level of cultivar development as the most senior breeders retire. Funding public breeding programs continues to be a challenge, as is access to improved germplasm due to overly restrictive licensing agreements. Potential opportunities include re-distribution of royalty funds to bolster revenue streams, and simplifying the germplasm exchange process to increase the likelihood of successful cultivar releases.

For the full paper see:
Shelton and Tracy 2017 Crop Science
10.2135/cropsci2016.11.0961

Respondent 1

What are the IPR challenges?

The Open Source Seed Initiative: Growing Access to a Liberated Domain of Plant Genetic Diversity

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The Open Source Seed Initiative (OSSI, www.osseeds.org) aims to ensure access to crop genetic resources by embracing an open source pledge that fosters exchange and innovation among farmers, plant breeders, and seed companies in a viral fashion. OSSI engages in education and outreach that promotes sharing rather than restricting access to plant germplasm, recognizes and supports the work of plant breeders of all kinds, and supports a diversified and decentralized seed industry. OSSI aims to provide an alternative avenue for the release of plant germplasm that ensures the ability to use germplasm while recognizing the efforts of the plant breeder through registration and documentation of the variety in a database and the ability to receive benefit sharing from the sale of seed (Luby and Goldman 2016). The core strategy for achieving these goals is the dissemination and propagation of the OSSI Pledge and of OSSI-Pledged varieties, both of which preserve the rights of farmers, gardeners, and breeders to freely use, save, replant, and improve seed of OSSI-Pledged material and creates a protected commons of plant germplasm (Luby et al. 2015).

Origins and Orientation

OSSI was formally established in May, 2012, at a meeting in Minneapolis, Minnesota. The twenty people attending represented a wide variety of perspectives and interests—academics, plant breeders, the seed industry, farmers, indigenous people, the Global South—and shared a deep concern over the way in

which intellectual property rights are being used to enhance the power and control of a handful of companies over the seeds and farmers that feed the world (Kloppenburg 2013). Further, the participants shared a commitment to creating a means for ensuring that the genes in at least some seed cannot be locked away from use by patents and other restrictive arrangements.

OSSI was incorporated in the State of Wisconsin in July, 2014. It was granted federal tax exempt, 501(c)3, status in April, 2015. It received trademarks for the OSSI logo in August, 2015, and for "Open Source Seed Initiative" in January, 2016. OSSI is managed by a nine-person board of directors supported by an Executive Director. Together, this staff plans and implements education and outreach that promotes sharing rather than restricting access to plant germplasm, recognizes and supports the work of plant breeders of all kinds, and supports a diversified and decentralized seed industry.

The OSSI Pledge

The OSSI Pledge was inspired by the free and open source software movement that has provided alternatives to proprietary software (Stallman 2002). Since a formal license, while possible to develop, turned out to be impractical to use (Luby et al. 2015), OSSI created its Pledge as a simpler and more functional tool. The OSSI Pledge reads:

You have the freedom to use these OSSI-Pledged seeds in any way you choose. In return, you pledge not to restrict others' use of these seeds or their derivatives by patents or other means, and to include this Pledge with any transfer of these seeds or their derivatives.

This "copyleft" commitment ensures that the Pledge is transmitted with any further distribution of the seed or the seed of any new varieties or germplasm bred from it. The Pledge has both moral and legal force. We do believe the Pledge to be legally enforceable. In this way, OSSI preserves the unencumbered exchange of plant germplasm for breeding purposes and guarantees the rights of farmers and gardeners to save and replant seed.

We refer to seed of OSSI-Pledged varieties as "freed seed," rather than "free" seed in order to emphasize that OSSI-Pledged seed is freed with respect to use, but not necessarily free in price (Luby et al. 2015). OSSI accepts certain contracts or agreements in order to facilitate seed increase or production and/or provide benefit sharing (royalties) to breeders**.** OSSI **permits any contract or agreement for seed increase and/or benefit sharing for OSSI-Pledged varieties in which the restrictions on the use of the seeds are limited to the two contracting parties. OSSI does not accept arrangements in which there are restrictions on the seed that extend beyond the two contracting parties. Seed companies can pass no restrictions on to breeders or customers. From the point of view of breeders or customers, OSSI-Pledged varieties must be unrestricted.**

Operations

OSSI's objective is to continuously enlarge the pool of crop varieties that are "OSSI-Pledged," and so are freely available for use and improvement by farmers, gardeners, and breeders without encumbrances. In addition, OSSI spreads information about and promotes the use of these varieties. OSSI works with plant breeders ("OSSI Variety Contributors") who formally commit to offering one or more of their novel varieties only under the OSSI Pledge. The OSSI variety review committee works with the plant breeder to ensure that varieties are novel and that there are no IP restrictions on parents of the variety or the variety itself that may prevent it from being released as OSSI-Pledged. "OSSI Seed Company Partners" agree to sell at least one OSSI-Pledged variety, to market the seed by

labeling it with the OSSI logo and/or name, to acknowledge the OSSI breeder in variety descriptions, and to include the Pledge and information about OSSI in their print and on-line catalogs. On the "Seeds" page of its website, OSSI provides a list of OSSI-Pledged varieties with photos and descriptions and where seed is available. The list is searchable by crop, breeder, and seed source. Through its educational and outreach activities, OSSI creates awareness of the social value of purchasing "freed seed." Via its website and outreach materials, OSSI guides farmers and gardeners to its Seed Company Partners. For its Seed Company Partners, OSSI is thereby creating a niche market for ethically produced, "freed seed" analogous to the markets for "fair trade" and "organic" products. For its Variety Contributors, OSSI is providing public acknowledgment of their work and, via its seed list, a way to "register," announce, and promote their varieties.

2015 and 2016, OSSI's first two operational years, have been very successful. OSSI's seed list currently includes nearly 300 varieties contributed by 35 OSSI Variety Contributors. Seed of these varieties is available from 42 OSSI Seed Company Partners. OSSI's work has received extensive coverage in media outlets of all kinds.

International Cooperation

The issues that have stimulated the creation of OSSI are global in scope and significance (Aoki 2009, Bragdon 2005, Jefferson 2006, Kloppenburg 2010, Srinivas 2006). Colleagues all over the world have been excited and inspired by the potential of "open source" approaches to freeing the seed. OSSI has Variety Contributors and Seed Company Partners in Australia and the UK. However, socio-agro-legal-political environments vary considerably around the world. OSSI's deployment of open source seeds in the USA is facilitated by the fact that the USA places virtually no restrictions on breeding and subsequent sale of seed. In contrast, breeders and seed sellers in the European Union labor under the regulations of the Common Catalog (Winge 2012). These regulations forbid selling seed that is not listed in the Catalog, and the requirements for listing are such that, practically speaking, farmers, gardeners, and small seed companies find it prohibitively difficult to breed and sell their own varieties. Most nations of the Global South are now being pressed to accept similarly restrictive IPR, phytosanitary, and certification rules (Wattnem 2016). Efforts to free the seed are making gains, however, in spite of barriers. The German NGO, AGRECOL, is writing an open source license adapted to EU conditions. The Indian NGO, Centre for Sustainable Agriculture, is developing an open source license designed to complement the Indian Seed Law. OSSI is cooperating with these initiatives and others to build an international movement for open source—"freed"—seed.

Plant Breeders and OSSI Pledging Germplasm

The majority of OSSI's Variety Contributors are freelance plant breeders -- those plant breeders not working in formal institutional settings. In addition to the sociopolitical alignment of these breeders with the philosophical commitment to freed seed, OSSI also provides benefits for them that would not be realized by releasing varieties directly into the public domain. These benefits include formal recognition and registration of a variety through the OSSI website database, the ability to connect with OSSI Seed Company Partners, and the opportunity to obtain benefit sharing/royalty arrangements on seed sales (Luby and Goldman 2016).

The situation for university-based plant breeders appears to be slightly different than for freelance breeders. Many university plant breeders rely on royalties from germplasm releases to support their breeding programs

(Shelton and Tracy, 2016). University-based breeders release material through their technology transfer offices. Thus they do not always have control over how germplasm is released. Additionally, many of these plant breeders are developing material for a variety of different purposes, and open source may not be a suitable release mechanism for all of their material. As the survey by Shelton and Tracy indicated, the ability to share and obtain germplasm was essential for program success. Additionally, 2/3 of survey respondents indicated that their freedom to operate for plant breeding with material was 'strongly' or 'somewhat' restricted by material transfer agreements (Shelton and Tracy 2016). OSSI provides a potential vehicle for addressing both of these concerns since it facilitates sharing of germplasm without restrictive material transfer agreements (MTAs) and allows benefit sharing arrangements.

Tom Michaels, OSSI board member and faculty member at the University of Minnesota, conducted an informal survey of university-based plant breeder colleagues in order to assess the level of support for open source releases among this community. The plant breeders surveyed were not a random sample of plant breeders in the public sector. In response to the question: "What is your reaction to releasing finished cultivars, breeding lines, populations or other forms of plant germplasm you have developed through open source channels?" 15 of 22 of respondents were positive or somewhat positive about the potential of releasing finished cultivars, breeding lines, populations, or other forms of plant germplasm they had developed through open source channels. While it appears that many university-based breeders that were surveyed are socio-politically sympathetic to open source germplasm release, there are other factors at play for this group that may not allow them to release material – or not all of their material – in this way. In response to the question: "Please identify the top two or three (or more) thoughts that come to mind when you consider open source germplasm release," 7 of 21 respondents indicated that they had germplasm that might be a good fit for an open source release. 13 of 21 chose "Maybe for some of my releases, but not for all of them." 9 of 21 indicated that they already do this, although we believe that at least some of these respondents were conflating a public release with an open source release. Additionally, 11 of 21 emphasized that "I need to generate income from germplasm releases," and 6 of 21 responded "My department, college or university intellectual property office won't agree to this." These responses highlight that royalties are an important dimension of releasing a variety and that the release mechanism selected for any given variety may be specific to the crop and intended market for the variety. Through their open-ended survey comments many respondents expressed caution and asked a wide range of questions about what exactly open source release entailed. Additionally, university plant breeders work with university technology transfer offices on releases and do not always have the final say in how germplasm is released. Several university-based breeders have released varieties through the OSSI Pledge and have worked out arrangements with their technology transfer offices that have permitted them to do so.

Conclusions

We believe that OSSI provides a viable release mechanism for many different types of germplasm and that it can facilitate the creation of a protected commons of plant germplasm that promotes sharing and exchange of plant genetic resources for plant breeding and farmer sovereignty over seed. However, we also recognize that there are multiple factors in the release of any germplasm and that OSSI may not be considered suitable for all releases. Given the virality of the Pledge, we recognize that there are challenges to working with open source germplasm and that a plant breeder must recognize that new genotypes generated from

crosses with OSSI-Pledged germplasm are, if released, OSSI-Pledged derivatives (Luby et al. 2016). Additionally, unless the breeder focuses part of his or her program on consumer-oriented characteristics like flavor, or is targeting alternative production systems, the benefits of an OSSI-Pledged release may not be realized. This is because it is necessary for the consumer of the seed or product to value the fact that the variety is OSSI-Pledged in order to create a recognized 'brand', such as 'organic' or 'fair trade'. Raising awareness at the consumer level is a principal objective of the outreach and educational activities in which OSSI is engaged.

There are many benefits to OSSI-Pledging a variety. OSSI is building a community of plant breeders, seed companies, farmers, gardeners, and consumers who recognize the value of 'freed seed'. Increasing awareness of the origins of a variety, and registration on the OSSI website, provides recognition for the work of the plant breeder. By being able to connect with the OSSI community, there is potential for new material to be sold and distributed more widely and to provide a market for new OSSI-Pledged releases. OSSI recognizes that benefit sharing and royalties are essential for supporting the work of all types of plant breeders. When seed is reproduced for commercial purposes, the developer of a variety released under the OSSI Pledge may make arrangements to share in the benefits of that multiplication and commercial sale. These arrangements may take several forms, and are not considered to be a violation of the Pledge as long as there is no requirement other than sharing of benefit with the breeder. OSSI is working to create a protected commons of plant germplasm that supports the work of plant breeders of all kinds and that ensures sovereignty over seed. We invite our colleagues to join us!

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Respondent 2

What are the IPR challenges?

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I am Michael Sligh, and I work for the Rural Advancement Foundation, (RAFI-USA). I come from a long line of farmers and ranchers, I farmed commercially the decade of the 1970's, and have worked for the RAFI for over 30 years, working to provide tools, policy incentives and on-farm practices that can better ensure a future of farming that is sustainable, that meets the needs of farmers and gains them the respect and rewards for their practices by their customers. I come at this issue from the perspective of what is in the public interest and specifically what is in the interest of farmers and public breeders.

We all know that cropping systems are now too short, too genetically uniform, with too few varieties to choose from and too few locally adapted seed choices available. Climate change alone demands that we rapidly adapt our agricultural cropping systems toward one of much greater diversity and resilience. Ensuring more diverse, regionally adapted seeds during this period of increasingly unpredictable weather patterns is just common sense.

However, the growth of utility patents and increasingly restrictive licensing agreements are directly at odds with these societal needs and appear to be reducing farmers' and breeders' access as well as slowing innovation. Additionally, how these resources are shared within universities and the USDA also seems to affect plant breeders' capacity to meet these larger agricultural systems challenges.

At the heart of this is the urgent need for a comprehensive national public cultivar development revitalization plan, one that maximizes regional and local adaption of seeds

to ensure farmers have access to appropriate and more diverse seed choices. Along with this we need best management practices that can better encourage farmer/breeder participatory breeding work and cooperation, as well as discouraging IPR mechanisms that are reducing access and innovation.

However, it is important to put these challenges into a larger frame to fully appreciate the sweep of history that many in this room have witnessed. Just in my lifetime there have been major shifts in agriculture, in the marketplace, in federal policies, that have impacts down on the farm, all of which revolve around the rights of farmers and plant breeders and this central question of fair access to appropriate germplasm:

- As mentioned above, this major shift from farmers using integrated multi-crop/livestock rotations and saving on-farm seeds of major crops like soy, wheat and cotton to now annual purchasing from a very small handful of companies for just a very few crops.
- The changes to Plant Variety Protection Act, (PVPA), that removed farmers right to "brown bagged seeds", which hurt our and many other family-scale farming operations. Additionally, the current PVPA has up-front fees that pose barriers to smaller-scale breeders and farmer/breeders groups.
- Increased costs, seeds that have gone from being a very minor portion of your overall costs of production, to becoming a major cost.
- Loss of public funding and critical decline of the number of public cultivar developers. Some crops now have only a very few such breeders for the whole country (Tracy and Sligh 2014).
- Internationally, the multiple different versions of International Union for the Protection of New Varieties of Plants, (UPOV), and seed laws have created a recipe for farmer and breeder chaos with lack of functional reciprocity and access.
- Lack of clear and meaningful development of benefits sharing provisions of Convention on Biodiversity treaty (CBD), which at the international level is a barrier to sharing. Along with the failure of the U.S. Senate to ratify and sign the CBD, this leaves US farmers and breeders outside of the treaty opportunities and requirements. * (See Update in References).
- FAO reporting loss of over 75% of our biodiversity (FAO 2010), which many attribute to loss of habitats from development pressures and policies that encouraged farmers to abandon local varieties.
- This is coupled with the advent of GMO seeds that prohibit seed saving and farmers must "rent" these seeds every year, which contributed to the decline of Crop Improvement Associations, across the country for these major crops. And finally specifically;
- This advent of utility patents into agricultural seed development has not only slowed innovation, but most problematic is that in many cases this lack of access is for varieties that were first developed in the public domain using taxpayer dollars.

Much of this has been driven by:

- Seed industry consolidation, which as Bill Tracy has stated, has accelerated the trends toward "abandonment of the margins"; that is - that entire parts of this and other countries have been abandoned, in terms of servicing farmer's regional seed needs and;
- Failure to maintain a strong and fully funded public cultivar development system to address societal challenges.

However, it does seem that there are successful funding models in individual states where there are major crops within the states with adequate

farmer and public support for specific targeted markets. However, for minor crops, new crops, major crops in minor markets, rotation crops, greater choices within major crops, or so-called orphan crops, for all of these areas we are failing to make the mark and falling further and further behind. Restrictive IPRs are exacerbating this trend.

These are the areas that most need new strategies and supports to drive and incentivize a return toward more resilient cropping and livestock rotations. Policies that continue to reward the divorce of animals from cropping systems or the further encouragement of mono-crop systems just continues to increase our vulnerabilities.

I am somewhat surprised that the survey data presented here does not show greater current use of utility patents at Land Grant Universities, (LGUs) however, a very significant number of those surveyed did indicate IPRs are a problem. It is also my sense that there is a growing dis-connect between the goals and needs of technology transfer offices and those of the plant breeders regarding adequate financial returns to keep pace with the many demands for more regionally appropriate seed choices or to meet growing market demands for non- GMO seeds.

All of these challenges and more have led us to our current crisis where retired plant breeders may not be replaced, the next generation of such plant breeders are in jeopardy, and public funding from USDA and overall Land Grant University System capacity to support this, are at our lowest point in decades.

All of this is happening at exactly the very time that these talents, skills and improved cultivars are most needed. In fact, we have a major backlog of urgent farmer demand from all regions, in some cases for very major crops for which current varieties are no longer thriving or productive.

What is Needed

The Land Grant University System, which was established to serve the public good, is in our opinion, best positioned and best suited to addressing the macro societal seed improvements challenges especially for minor crops, for major crops in minor markets, for more regional adaption of public cultivars and enhancing for biodiversity. These are all areas where it is not in the best interest of the private sector to pursue. However, several critical improvements are necessary to begin to succeed again, in this area:

1. **New Farm Bill language** is urgently needed that re-establishes a comprehensive approach to ensuring that public cultivar development keeps pace with demand, and that the new generation of such breeders are adequately supported and encouraged. This must include USDA-wide coordination of all public cultivar developments, to ensure these cultivar needs are fully met within fully funded and dedicated program areas for conventional breeding. This must include additional capacity supports both for the LGUs and the national germplasm system as a whole to fully restore these systems to their much-needed vitality.

2. **Develop Best LGU Management Practices (BMPs) for public cultivar and breeds development, including:**

- ***Breeders' and Farmers' rights***. These rights are critical for both farmers and breeders to be able to share and improve germplasm developed in the public sector and for farmers to be able to save seeds for their own use. These rights should be strongly supported and encouraged. Additional licensing agreements that create barriers to public access should be discouraged.
- ***Participatory breeding***. Such models of farmer/LGU breeder cooperation should be

strongly encouraged and institutionalized to ensure farmer needs, ideas, and on-the-ground challenges are fully embedded from the beginning of any breeding program. On-farm varietal screening, selection, multiplication and breeding work should be strongly encouraged. This will not only quicken the pace of innovation, but can be more efficient over time, especially with scarce funds.

- ***Fair Compensation***. Breeding programs within the LGU should receive a fair share of any public support, royalties, or seed sales generated by the program to ensure on-going capacity and to keep pace with farmer demand. This amount should be sufficient to ensure on-going, innovative programs, with which to attract next generation breeders as well.
- ***Utility Patents***. Use of utility patents should be strongly discouraged, deemed inappropriate and understood as unnecessarily restrictive and a barrier to innovation for the public sector. Plant Variety Protection Act, (PVPA), when deemed necessary, should be recognized as sufficient protection.
- ***Genetic crop vulnerabilities assessment*s**. Raise the profile and priority of assessing our crops in the field for genetic uniformity. This should increase public access to improved public cultivars that are now patented because of novel traits. At the very least, allowing such varieties to be included in any public assessments of genetic crop vulnerability studies is a critical food security issue. National commitment to further diversifying our crops should be seen as a high priority.
- ***Material Transfer Agreements (MTA)***. Creative MTAs, between farmer groups and breeders are strongly encouraged to facilitate improved varieties entering into farmer marketing channels. Where required, a per bag fee can be encouraged, as opposed to lump sums up-front.
- ***PVPA***. Adjustments or additional incentives to the PVPA system are also needed to allow for and to better encourage the use of this tool over utility patents. This is especially needed to allow small-scale breeders, farmers or groups of farmers to seek and use PVPA with less up-front cost and to better encourage marketing and distribution of improved crop varieties that may otherwise not be utilized.

For all of these actions to succeed we need much deeper community-wide understanding, support and communications throughout the LGU System and the public policy community at large, to encourage these and the other needed reforms so they can be made as soon as possible. More vocal support for such reforms from the LGU establishment and the policy-makers would be very timely and welcomed by farmers, public plant breeders, and the public interest community.

Now is the time to act.

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Respondent 3
What are the IPR challenges?

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Problematic IPR issues in public breeding, from the perspective of high-value row crops with over 90% of standing crop planted to GE varieties include, but are not limited to, perceived value of germplasm independent of GE traits, value capture from limited, yet underserved, production systems, additional quality control costs for public breeding programs in a GE environment, restrictive use language in licenses/agreements, and IP restrictions on new breeding technologies.

Experience for this response draws on trends in public cotton breeding, but it is important to consider that different crop breeding programs face different IPR challenges depending on the crop, its commercial seed industry landscape, commodity support, and whether the focus is on cultivar development or basic germplasm releases.

USDA-ARS communicates more distinct germplasm exchange policies compared to land grant universities, but supports a different mission, emphasizing basic germplasm development. Whether a USDA breeding program develops primarily basic germplasm or cultivars depends on the crop, and if there is active private sector cultivar development in that crop. USDA addresses cultivar versus germplasm development by researching and working on resources and enabling technology for university breeders. USDA-NIFA grant programs on specialty crops (SCI) and organic agriculture (OREI) provide some support for public breeding programs developing cultivars for underserved sectors.

One struggle public breeders face in a post Bayh-Dole world is quantification of impact, particularly when commercial sales market share is driven by converted varieties or hybrids; and opportunity outside GE market (for organic or non-GE seed sales) is too small to be considered profitable. Germplasm value, and expected seed sales margin, has taken a dramatic turn since commercial approval of GE traits. Public breeders working in GE crops are expected to find corporate partners to get their germplasm in the hands of farmers whose production systems are adapted to GE technology, and those potential partners have invested heavily in germplasm development themselves, to drive their biotechnology traits to market.

Some universities venture to return value by using off-patent GE traits in their cultivars, but inconsistency remains among universities whether open-pollinated seed can be farmer-caught or not, with implications on the amount of value that can realistically be captured. A more serious issue is balance of investment back to the program versus societal implications of releasing varieties that might contribute to existing resistance issues.

Basic germplasm, developed outside internal silos created through restrictive plant patent IPR, has tremendous value for maintaining genetic diversity, especially as new breeding methodologies identify superior commercial cultivars for particular production systems, but winnow diversity of the standing crop down further. The actual monetary value pales in comparison to GE trait technology, and basic germplasm exchange is hindered both by industry expecting free exchange and

universities expecting compensation for value that is difficult to quantify in the commercial product. IPR strategies for public germplasm should appropriately recognize the intrinsic value of basic germplasm to sustaining genetic diversity; extrinsic value of competitive cultivars that undergo GE conversion before being sold; and cultivars developed for alternative production systems when the cost of maintaining breeder seed free from GE traits is high, and the potential revenue from limited acreage is low.

The Secretary of Agriculture revived the National Genetic Resources Advisory Council in 2011 partly to make clear the desire to ensure there is adequate diversity of high quality seeds for all US farmers, including organic and non-GE production. One problematic area, in my experience, is potential quagmire moving seed to farmers who need it under the expectation of significant royalty return when acreage is small, quality control costs are high, and in the case of cultivars, the 1994 amendment to the PVPA allows farmer-caught seed, although more restrictively than before 1994.

I complain from a tenuous position since public cotton breeders have good commodity group support. Near half of respondents from the survey on cultivar development in the public sector report germplasm from other public breeding programs is their predominant source of new breeding material. Cotton Incorporated sponsors the Regional Breeder Testing Network, and labored diligently to coordinate a master material transfer agreement signed by all participating entities, with much difficulty, that allows breeders who conduct a testing location to cross with test entries, albeit with no commercial rights until negotiation with the germplasm originator. Public breeding reaction to increased value in germplasm related to GE traits, and subsequent application of more restrictive IPR in the private sector, has been a trend toward releasing germplasm with 20-year use limitation.

Even where technology licensing offices strive to simplify material transfer agreements and evaluation agreements, use restrictions are open-ended, which is practical in the sense that commercial success can be unpredictable at early development stages. Uncertainty about negotiation outcomes on material transfer licenses, especially between public breeding programs and industry partners, can hinder even basic germplasm exchange. Efforts to balance IPR and germplasm utilization should address this uncertainty.

The survey also indicates material transfer agreements are not restrictive on marker-based genotyping, and use of sequences or genes. However, while Romay et al. (2013) makes the comprehensive genotyping of the USA national maize inbred seed bank public, Keygene, via US patent #8,815,512, protects the sequencing by genotype method used. The USPTO *ex parte* examination initiated by Cornell University upheld the patent claims in April, 2016, verifying protection of methods for simultaneous polymorphism discovery and genotyping including SBG, BBS, RAD, ddRAD, and related methods. Keygene will license, but also actively defend and enforce SBG IPR position. The readily available license explicitly excludes any use of application of the patent for any commercial purpose, for either the licensee itself or for the benefit of any third party, further complicating use in cultivar development by public programs, outside of basic research. This utility patent methodology IPR impact is expected to extend to other new enabling technology for breeding. IPR in public breeding should encompass enabling technology based research at universities, to protect breeding methodologies that could be used in public cultivar development.

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Respondent 4

What are the IPR challenges?

Utility Patents' Effects on Public Plant Breeding Programs

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The intellectual property (IP) landscape for crop cultivars is constantly evolving. Most plant breeders are familiar with plant patents and plant variety protection (PVP), but in industry especially, utility patents are now the most commonly used form of IP protection. From a private sector perspective, utility patents provide a very robust means of IP whereas PVP is regarded as relatively weak protection. In particular, the private sector views breeders' and farmers' exemptions as problematic. If a breeder spends decades assembling a genetic package that is clearly superior to others on the market, they do not want their competitors to immediately cross with their new variety and have competing varieties on the market in a two or three years' time. Utility patents afford a degree of protection that can prevent this from happening for up to two decades. Another reason for private companies to prefer utility patents is that if a patent with broad claims can be obtained, many cultivars may be covered by that patent, thereby reducing patenting expenses.

From a public sector perspective, utility patents may prevent access to enabling germplasm and thereby slow innovation and genetic progress for the crop. The first-to-file requirement of utility patents forces breeders to be circumspect in discussing their work in detail in public thereby stifling communication and cooperation among public researchers. Breeders may be reluctance to engage in research in areas where patents have issued because of uncertainty as to what research may be carried out unencumbered, and from a fear that a patent may surface that claims their area of research. Finally, utility patents have contributed to barriers to international germplasm exchange from reluctance of partners in developing countries to provide their genetic resources when they see them coopted directly for patents or used in breeding without compensation after commercialization of derived varieties.

From my perspective, there are three problems with utility patents. These are the use of broad claims in patents, the lack of a breeder's exemption in utility patent law and patents that claim germplasm in the public domain, including that curated in the USDA-National Plant Germplasm System.

Broad patent claims arise from patent attorneys' highest priority of seeking the broadest claims possible, expecting that patent examiners will narrow these claims before the patent is granted. This does not

always happen, particularly when a patent examiner is not familiar with a particular discipline. While patents with broad claims are generally not common they have, and do continue to issue at a steady rate.

Unlike PVP, utility patents have no provision to allow breeders other than the inventor to use a patented variety in crosses (in principle, claims could be written to allow this, but in practice, this is never done). In Europe, certain countries in the European Union (EU) now have a breeders' exemption in utility patents, however, unlike that in PVP, applicants who use patented germplasm are required to negotiate a license if they commercialize a variety developed from that germplasm (Bjørnstad, 2015).

A number of trait patents claim the use of genetic resources in the public domain in the breeding of new varieties. These claims effectively prevent anyone else from using that germplasm as a source of that trait. Such claims that cover use of public domain germplasm abrogate the federal government's mission to maintain and distribute germplasm for the public good.

Over time, the use of utility patents has surpassed that of PVP with almost double the number of utility patents compared to PVP filed in recent years. While total number of utility patents on crop plants have plateaued at around 1,000 per year, the use of PVP shows a downward trend in the past four to five years. The private sector is essentially driving this trend with very few utility patents sought by the public sector and the PVPs obtained by the public sector continuing to increase. The majority of utility patents are for cultivars alone with a small proportion for traits combined with varieties, some of which have broad claims. The majority of patents for field crops are for field corn and soybean while the majority for vegetables are for lettuce. For lettuce and soybean, the reason for the extensive use of utility patents is that both of these crops are self-pollinated and it is not commercially viable to produce F_1 hybrids.

Utility patents must meet the criteria of novel, useful, nonobvious and not in the prior art. With the Leahy–Smith America Invents Act of 2011, the definition of prior art was broadened to include any published work anywhere in the world, thus making it easier for the patent examiner to find materials that challenge claims in a patent. However, patent examiners may not always be aware of what prior art resources are available to them, and to this end, it would be helpful to allow examiners to draw upon the expertise of the research community perhaps through the use of nondisclosure agreements.

As presently practiced, the imposition by utility patents on sharing of genetic resources will retard the contemporary rate of genetic gain compared to what was achieved in the latter half of the 20th century. As such, it is doubtful that another green revolution could happen. The public and private sectors have responded in different ways to attempt to regain access to elite genetic resources. Public breeders have called for agreements among public breeding program that recognize the need to exchange and use germplasm for crosses, and one group has initiated the Open Source Seed Initiative (OSSI) with the goal of ensuring that genetic resources remain in the genetic commons. The private sector has formed consortiums to facilitate the exchange of materials under license agreements. It is unclear whether either of these avenues facilitate public-private sector exchanges of germplasm. The hybrid model under utility patent law being forged in the

EU, where germplasm is shared while providing compensation to the originating breeder, is a hopeful sign that we may regain some level of germplasm exchange in the near future.

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Session 2
What are the funding problems?

Keynote 2

What Are the Funding Problems?

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Public sector plant breeding programs at universities historically have been supported by a combination of funding streams, with considerable variation from state to state. What appears to be universal is that the amount of funds available to support applied plant breeding (defined here as variety development efforts) has declined over time. This decline results from a combination of many factors, some of them strictly fiscal and others related to bureaucratic demands on people's time (which amount to an erosion in the salaried time available to breeding programs). This paper aims to lay out the trends that have resulted in current funding challenges that face applied plant breeding programs. Some of the trends will be considered at the federal level. Those factors where the specifics are much more idiosyncratic (but often the general patterns are quite universal) will be discussed using one university as an example.

Funding to support applied plant breeding efforts at land grant universities several decades ago came in part from state funds, which often supported the salaries of faculty and (perhaps even more importantly) of long term field technicians and research farm support staff – the highly specialized and broadly talented people who are able to help keep crops, machinery, field plots, and breeding programs thriving, well organized, and effective. Federal Capacity Funds (formerly Federal Formula Funds or Hatch funds) provided a reliable annual allocation to support the core annual expenses of a breeding effort. For many crops, there was supplemental funding (from sources such as competitive grants, industry, commodity groups, crop-specific grants, special projects, etc.) that was less predictable, but allowed breeders to build onto the relatively predictable state and federal framework of funds.

The challenge that breeders face now is a result of the erosion or elimination of pieces of that essential framework upon which a breeding program can be built. Federal Capacity Funds are allocated to states to support research "basic to the problems of agriculture in its broadest aspects, … having due regard to the varying

conditions and needs of the respective States" (Hatch Act, amended 1955). These funds are ideal for supporting the locally-specific efforts that are integral to successful variety development. Federal appropriations to Hatch have grown dramatically in dollar value over the past 60 years, from about $19 million in 1955 to about $228 million in 2015 (Kerr 1987, USDA-NIFA 2000, USDA-NIFA 2015a, USDA-NIFA 2015b). However, converting these annual appropriations to constant 2015 dollar values gives quite a different impression and reflects more accurately the potential purchasing power of the total Hatch research budget (*Figure 1*). The current federal Hatch appropriation is slightly less than what was available in 1956!

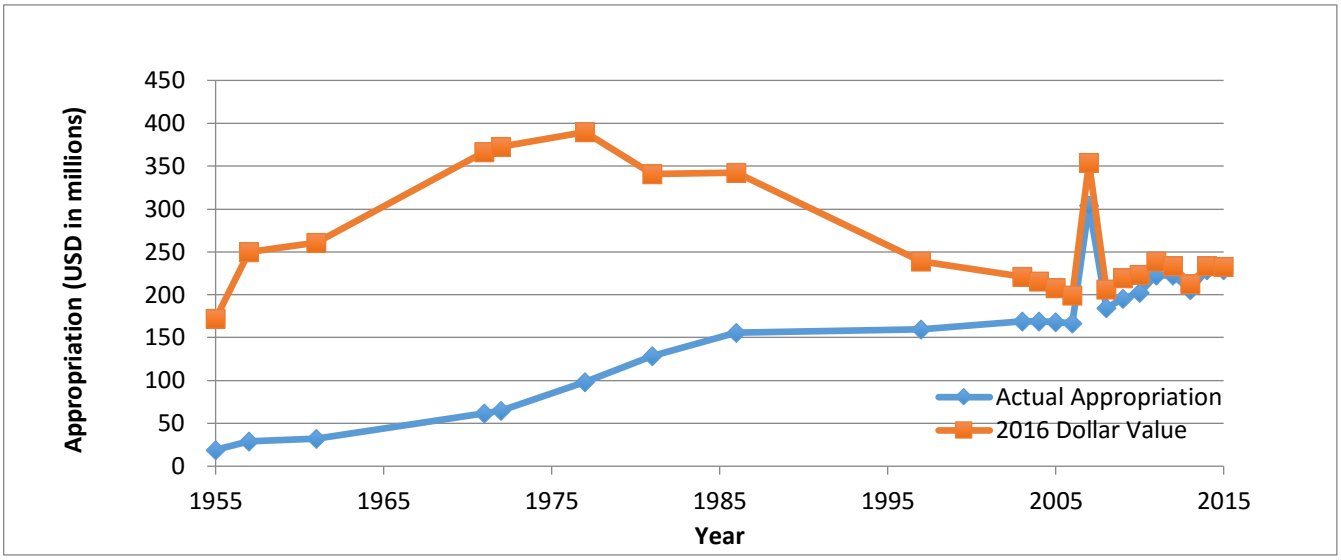

Figure 1. Federal appropriations to the Agricultural Experiment Stations as Federal Capacity Funds (Hatch), 1955 to 2015. (*Note:* where no dot is present on the line there is no appropriation data – lines serve simply to connect time points for which data could be found). Blue line: actual dollar appropriations. Red line: appropriations converted to 2015-equivalent dollar values. Sources: data from USDA-NIFA (pers. comm.: L. Fortis and K. Sellers), Kerr (1987); dollar conversions using http://data.bls.gov/cgi-bin/cpicalc.pl.

This graph leaves no doubt that the purchasing power of Federal Capacity Funds as a whole has declined dramatically from the mid-1970s onwards. At the same time, constant-dollar Hatch allocations to individual breeding projects have had to cover increasing salaries, and thus have covered a declining share of salaries for critical support staff who provide continuity, experience, and knowledge of the germplasm to breeding programs.

State allocations to land grant universities have covered some faculty and/or support staff salaries for many university breeding programs. However, there has clearly been a national trend towards decreasing state allocations to land grant universities. As an example, the state allocation to Cornell's College of Agriculture and Life Sciences has declined in both actual dollars and even more so in inflation-adjusted dollars (e.g., see *Figure 2* for annual figures from 2007 to 2012 – decreases were 25% in actual dollars and 33% in 2016-equivalent dollars over this 6-year period). We now call ourselves a "state assisted College" rather than a "state supported College". The faculty salaries are still provided by state funds – no small contribution. Our Department of Plant Breeding and Genetics chose to take repeated state budget cuts over the years in areas other than field technician support, because we recognized the

critical importance of experienced, long-term employees to breeding programs. Despite that, the College has now withdrawn all state funds from supporting technician positions in individual research programs. Their support must all come from grant sources. We are fortunate that our Hatch funds continue to contribute, but Hatch allocations at the federal level have clearly declined in real dollar terms and requests to the Cornell University Agricultural Experiment Station for such support have increased. Thus both federal and state portions of "core" support to breeding programs have steadily declined.

As funds that supported the core of breeding programs gradually eroded, fees charged to private companies and/or growers became part of the funding mix that sustained breeding programs. For example, breeders began charging seed companies for part of the cost of extension variety testing, as a means to help support the infrastructure and personnel needed to test both commercial varieties as well as the products of their own breeding efforts. With the intellectual property provisions of Bayh-Dole legislation, universities began to view plant breeding programs as potential revenue generators through licensing and royalties that could be charged on their varieties. The hope for major revenues was bolstered by examples such as the University of California – Davis strawberry breeding program, which reportedly took in $50 million in royalty payments between 2004 and 2013 (Charles 2014). However, the structure of the strawberry industry and associated breeding efforts is entirely different from that for agronomic crops, and also different from that for many horticultural crops other than strawberry. In any case, breeding programs came to rely more heavily on these revenue-based sources of funds as other sources declined.

At Cornell University, the next blow to funding came in the form of changes in policy that affected both variety testing fees and royalty income. University policy with respect to extension variety testing shifted much closer to policy governing industry-sponsored research, reflecting a profound lack of understanding of the extension mission that variety testing serves. University administrators had entirely lost sight of the fact that extension variety testing was established as a service to farmers, not a means to provide industry sponsors with proprietary data on their varieties at their behest. These changes meant that partial indirect costs and full

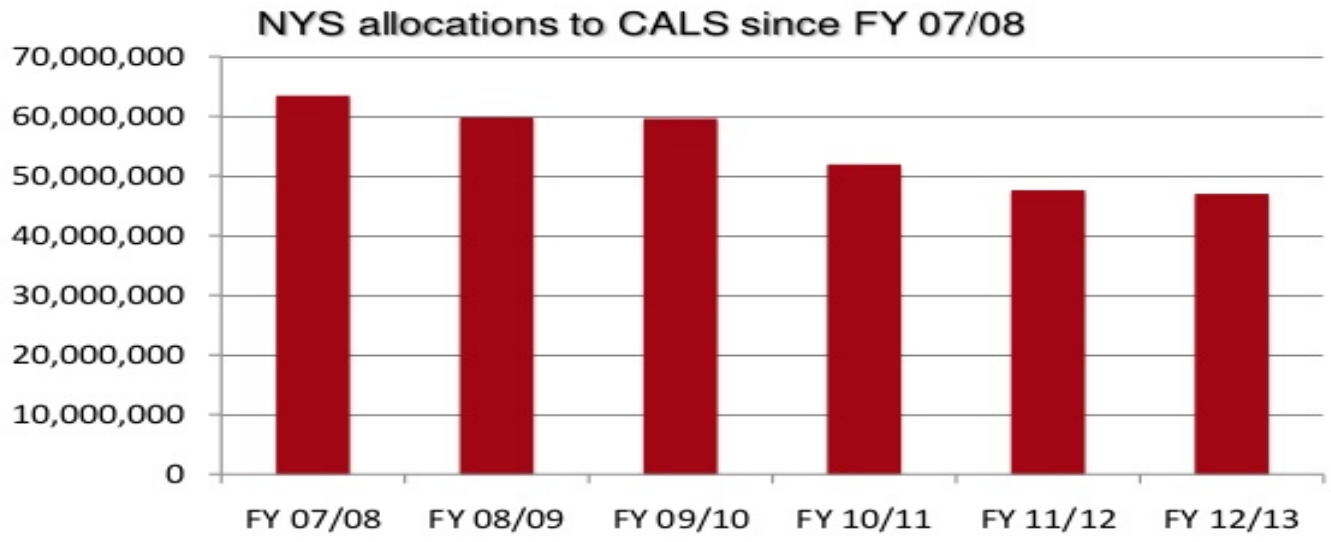

Figure 2. New York State allocations to Cornell's College of Agriculture and Life Sciences (CALS) from 2007 to 2012. Source: Boor, K. 2013. CALS: State of the College presentation, 9 December 2013 (http://www.slideshare.net/ashleyhenn/cals-state-of-the-college-1292013).

fringe benefits were now taken out of these fees, decreasing their purchasing power dramatically.

On the royalty side, Cornell University policy had initially allowed 90% of royalty income to flow directly back to support breeding programs. This policy was changed in the late 2000s to where none of the royalty income was directed back to the breeding program. Rather, two-thirds was directed to the technology office and to University and College administrative functions, and one-third was assigned to the breeder(s) personally. For those breeders whose programs had significant royalty income in the five years prior to this change, programs were "held harmless" through the change by allowing the breeder to donate an equivalent amount of royalty income from the breeder's personal share back to the program. The breeder still had to personally cover the income tax obligations associated with personal royalty income. For those breeders who did not happen to have much royalty stream in those years, there is the option to donate royalty income back to the breeding program, but these donations are charged 18% overheads, thus losing almost a fifth of the value to the program. Aside from the highly questionable ethics of compensating an employee personally, beyond their full time salary, for the job they are assigned and paid to do, this again cut into funds that had been available to support breeding programs.

On top of all these changes and losses, Cornell (along with many of its sister institutions) has made changes to "save money" at the institutional level by distributing administrative tasks back onto the shoulders of the faculty and technicians who are trying to manage breeding programs. These administrative burdens cut into their time, thus effectively reducing "core" salary support to needed personnel even more.

This history has left breeding programs relying predominantly on grants, check-offs, and special projects for the entire cost of running a breeding program. Although most faculty members' salaries are still provided by state funds, the time they have to devote to actually being plant breeders has been impinged upon by grant writing, reporting, and numerous administrative tasks.

The current mix of funding sources, in some cases and for some crops, can help to maintain or expand a breeding program. However, these funding avenues are not available in all cases (e.g., some states and crops have no provision for check-off dollars, and grants and special projects may not be available for the particular crop or trait of interest), are unreliable (e.g., any given grant proposal or project often has a small chance of actually being funded), and they are short-term in nature (i.e., awards are typically for one to three year time periods). Although funding of this short-term and variable nature can reasonably supplement a well-established breeding program, it cannot possibly provide the long-term, continuous core funding that is essential to a successful breeding enterprise.

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Respondent 1

What Are the Funding Problems?

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In this symposium, we focus on Intellectual Property Rights (IPR) in plant breeding due to the unique role of plant germplasm and varieties in the research portfolio of Agricultural Universities. Plant Breeding, as a discipline, has a strong track record of deliverables and of a capacity to generate royalty income. Plant seed, varieties and germplasm are a foundation of Land Grant University technology transfer, accounting for 20% of IP portfolios and 92% of IP royalty income at peer institutions (*Figure 1*). Plant varieties are one of the most effective ways of delivering University research to stakeholders in the state, country, and world. As such, plant breeding is among the most effective forms of translational research that we can undertake in the public

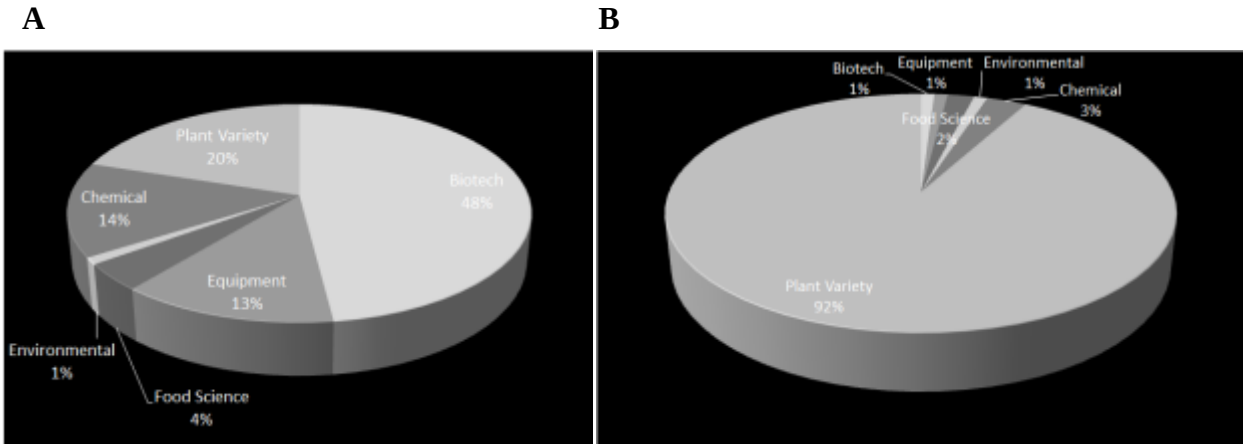

Figure 1. Distribution of Land-Grant University Intellectual Property portfolios (A) and Royalty Income (B). Source: UC Compilation of IP for top tier Ag. Universities vis OSU's Office of Technology Licensing.

sector. The main purpose for managing intellectual property in public research is to nurture innovation (Krattiger, et al., 2007). The objective assessment presented by Dr. Smith suggests that we are failing in this goal. The issues highlighted in Dr. Smith's paper accurately describe the current funding dilemma facing all agricultural research in public Universities.

Funding of public research has traditionally been based on a mixture of state, federal and industry support. In agricultural research these three sources are diversified, with federal support in the form of Hatch allocations and competitive grants. Competitive grants themselves are diverse. For example, support for breeding ranges from ARS funds allocated to potato breeding projects, includes NIFA foundational programs, and extends to more basic research funded through NSF. Industry support is likewise varied, including fees for variety evaluation and extending to check-off programs directly supporting development research. State support has traditionally been through faculty salaries, staff and infrastructure support, and internal grant opportunities. All of these funding sources have suffered in recent years through direct cuts, because increases fail to track with an increased cost of doing business, or because Universities are taking a larger share of funding as indirect costs. Arguably, pursuit of overhead dollars has had a major impact on breeding programs as faculty hires are shifted towards more basic research. A major issue, rarely discussed, with state support being replaced by Federal competitive grants is that the state and regional research portfolio is set by granting agencies and the peer panels that they convene rather than by local stakeholders. Likewise, emerging problems are not effectively managed through the current competitive grant infrastructure.

Management of IPR is sometimes viewed as a solution to the funding dilemma. Based on the "peer survey" conducted by the University of Florida in 2012, royalty return to University breeding programs ranges widely (from 0-90%) (Peer Review Survey 2012, Payne 2013). Even with best-case scenarios of royalty return to breeding programs, it is not reasonable to assume that this funding source will sustain public plant breeding. There are many reasons to justify the existence and continuance of University breeding programs; economic viability based on variety sales is not likely to be one of the most compelling. In fact, many public programs exist because the needs of specific regional markets are not being met by commercial entities due to a lack of profit margin. At the same time a failure to funnel royalty income back to programs is also counter to the goal of fostering and sustaining innovation within public research.

As a concrete model of IPR management in support of public breeding, the remainder of this response will describe the practices in place at The Ohio State University (OSU). The OSU model is one in which state support has been shifted to Federal and Industry partners. Faculty salaries for key breeding programs are largely allocated to Hatch dollars, while technical support is funded from grants, industry support and royalty return. Faculty are semi-autonomous entrepreneurs with a "license to hunt". Under the OSU model, state support has both declined in terms of real dollars, and more importantly suffered from reallocation into the bureaucracy *of the contemporary University.*

Within the OSU model there are some positive features of IP management, including the 85:15 "breeder's exemption" to University technology policy. Under the exemption, 85% of royalty dollars return to support breeding programs (Patent Policy

2016, CVRDC 2001). This model acknowledges the fact that if royalty funds do not flow back to programs, there is simply no incentive to release improved germplasm and varieties. Further, there is an acknowledgement that release of germplasm and varieties is a concrete outcome which maintains a positive image with stakeholders in the state. As a model for sustaining programs, it has not been highly successful. There has been a reduction in breeding programs due to faculty attrition and only a third of current programs can be said to be operating from royalties. The majority of programs' budgets are funded by a combination of industry support and competitive grants.

At OSU, variety release is governed through the Crop Variety Release and Distribution Committee (CVRDC). The make-up and governance of the CVRDC are described in Special Circular 178 (CVRDC 2016). The rules governing variety and germplasm release are purposefully aimed at balancing the need to protect germplasm, generate royalty return, and foster collaborations with industry and public sector peers. Since the late 1990's there have been few, if any, PVP applications. This situation arose from an institutional decision not to pursue PVP rights in light of evidence of violation. Subsequently faculty desired to save costs in response to a no defense precedent. Germplasm is therefore currently protected through Material Transfer Agreements (MATs) and licensing agreements.

There are strengths and weaknesses of the OSU approach. Among the strengths are multiple release mechanisms including public release, branded release and germplasm releases. The approved MTAs support sharing of germplasm among public and private breeders, with no restriction placed on progeny from crosses. This later approach may also be a weakness, and is perhaps naïve in light of current business practices. "No breeding" language has occasionally been added to agreements when partners are aggressive with their own IP demands. Another weakness of the OSU model is the decline in participation on the committee. Committee structure holds positions for the Ohio Department of Agriculture and OSU administration, yet members from these stakeholders rarely attend the biennial meeting. Like any physical or biological system, entropy dictates a drift towards disorganization without an input of energy. It is this latter issue that causes the most concern in our present spending climate: how do we renew the commitment of state and University partners in the endeavor of public plant breeding and public agricultural research?

Another positive feature of the OSU model has been the outlying branch farm structure which provides high quality support for field research at no-cost or minimum cost to faculty programs. In many ways the outlying branches are viewed as core-facilities, with staff, expertise and equipment. Like all core-facilities cost recovery is a concern, though current policies are free from fees allowing field breeding activities to occur under high quality agronomic and horticultural conditions and with the space and scope to permit gain under selection. It is through support for these facilities that OSU has demonstrated a commitment to agricultural research.

In conclusion, funding will continue as a collaboration between state, federal and private interests. Many of us would like to believe that part of the solution to funding could come from the reduction of University overhead and an increase in agricultural research spending as a percentage of GDP. However, there are no indications from

recent history that this dream may become a reality. Therefore in the near future, best practices will involve diversified sources of support, including royalty return directly to research programs, competitive grants, and industry support. As a community we can advocate for incremental changes, including improved collaboration between the National Plant Germplasm System and state Universities. In some instances, working with stakeholders to fund faculty endowments may be possible as a way of providing support. As a recommendation of IPR best practices, royalty return directly to research programs is an important step toward nurturing innovation within public research in general and plant breeding specifically.

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Respondent 2

What Are the Funding Problems?

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The fiscal challenges facing public plant breeders have been amply demonstrated by Dr. Smith and amplified by Dr. Francis in his response. Although I too am dismayed at the funding situation facing plant breeders, I also realize that we have had better support than our colleagues elsewhere in the university and even elsewhere in the agricultural colleges. This (rapidly disappearing) disparity suggests that public plant breeding programs have a special reason for existing – they are not only conducting research, teaching courses, and mentoring students.

Instead, public plant breeding programs exist to release germplasm and/or cultivars that are useful directly by farmers, gardeners, or others or indirectly as breeding material for other breeding programs. Failure to develop useful plant materials has killed support for more than one publicly funded breeding program in the past. If a plant breeder chooses to primarily conduct breeding or genetic research – which is certainly a worthy and important goal – then funding through competitive grant mechanisms seems appropriate, as it is for our colleagues elsewhere in the sciences.

Given that Margaret and David have done an excellent job highlighting some of the issues with funding, I'm going to present a number of options that exist or that could be developed to successfully fund a public breeding program. In none of these cases will we return to the "good old days." But, maybe, in reality, they weren't so good. – I'll leave that for someone else to consider or rebut.

Here are six possible sources of funding.

1. Royalties. Royalties are usually held up as a possible source of funding for a public breeding program. In some well known cases, such as strawberries at UC Davis and peanuts at the University of Georgia, cultivars generate large royalty streams, and even a relatively small percentage returned to the program can sustain a full fledged breeding effort. But these are the exceptions to the general rule that royalties are not going to keep most breeding programs going. And further, until cultivars are developed, no royalties are coming in.

Royalties generally depend on licensing agreements. Depending on the crop, an exclusive license may mean the licensee will expend more effort promoting and marketing a cultivar, thereby expanding the royalty flow over what might be expected from non-exclusive licensing. In any case, licensing that is set up in a way to return royalties in some manner to the institution (and institutional policies that return royalties to the program) can have a positive impact on maintaining breeding programs. Further, if technology transfer offices vigorously pursue licensing opportunities, they can perhaps further extend the opportunities for getting public cultivars into commerce. Universities are traditionally poor at marketing cultivars to possible licensees. But my experience with various forage crops shows that there are usually several small, often local or regional, companies that would very much like to license cultivars that they can call their own. Though royalty flows from individual cultivars may be small, collectively, this stream can be rather favorable to a program, and licensing

several related cultivars to different companies can further enhance royalty flows.

The University of Georgia has a unique system whereby a portion of cultivar royalties goes into a single pool from which all breeders can apply for support. Only breeding activities are supported, not research. But in this way, new breeding programs or breeders whose royalty flow is small still have a base level of funding to keep the program active. This system is far superior to one where a program's royalties only go back to that program, which makes the rich richer and keeps the rest high and dry. Unfortunately, the latter system is the more common, in my experience.

2. Direct contracts. Because royalty streams don't start until cultivars are commercialized, a way to fund a program up front is important. One possibility is to work directly with companies who are interested in marketing a certain product but who don't have resources to breed the cultivar themselves. Institutions may vary, but generally, an agreement that provides a company the first right of refusal is developed, whereby the company funds development of a product and the university then offers the resultant product to the company. The contract may preclude the university from working with other partners on a similar product, but that does not necessarily have to be the case. An upfront agreement can be specified that indicates the cultivar trait targets, that specifies royalty flows, and that provides an indication of the market opportunities. This process has a number of very favorable aspects, including the clear path to market and the funding to sustain the program over time. Downsides include the exclusivity given to one company, but without this funding nothing at all could be produced. Which is better? I have worked with several companies in the past on this type of project and I believe these arrangements can be very positive.

3. Commodity boards. Some commodities support breeding through check-off funds – breeders of these commodities are the lucky ones! This funding is typically tied to trait targets, is closely aligned with grower needs, and usually offers long-term support. Cultivars produced by commodity funds usually are non-exclusively licensed, but at least some royalty is collected to augment board support of the breeding program. Depending on the commodity board, funding may be focused on germplasm development rather than cultivar development, with the explicit goal of the public breeding program being the hand-off of germplasm containing specific traits to the commercial industry. But even so, this funding still produces useful products and can still support student training. The germplasm may be licensed or even made publicly available, depending on the interests of the commodity board.

4. Industry support. In addition to contract breeding work mentioned above, the seed or nursery industry can offer other support that can help breeding programs. In-kind nurseries, evaluation sites, disease screenings and other forms of support are frequently possible, and breeders who build strong relationships with the relevant industry partners can often get considerable support. Some commercial breeders view public programs as "competition." In these cases, breeders should forthrightly discuss program goals with industry breeders and determine ways to work together productively. In addition to in-kind support, industry often provides funding for graduate students or for specific projects. While this support may be targeted, involving the supported student in the breeder's cultivar development program is both important for training and can help keep the project running.

5. New niches. Funding may not be available to breed crops well-served by commercial breeding companies, but niches usually exist that industry is not serving, not only of minor/specialty crops as noted by Shelton and Tracy earlier in this symposium, but also of

major crops. The organic community is one source of funding that has been extremely helpful for numerous public breeders. The key with niches is finding someone willing to put up enough money to keep a program going. In the case of organics, the support of the community has resulted in several competitive grants programs and breeding opportunities, including the Organic Research and Education Initiative program at USDA. Niches may need to be funded by government grants, but community support may help increase or target funding for these programs.

6. Competitive grants. Admittedly, being on a 3-5 year time horizon does not make for a secure, long-term breeding program. Yet, until a few years ago, getting plant breeding oriented grants was not likely at all. Today, several programs, in addition to the OREI program mentioned above, have plant breeding as a focus area, including the AFRI foundational program in Plant Breeding, the Specialty Crops program (SCRI), and others. Grant funding does not preclude licensing, so universities can proceed as their normal practice to get germplasm or cultivars that were funded, at least partially, by competitive grants to the marketplace. Further, funding for graduate assistantships through National Needs Fellowships at USDA or similar programs elsewhere can add funding for personnel to a breeding program, even if not for support.

Creativity is the name of the game today. Cobbling together funding from disparate sources isn't necessarily fun, and keeping the program going over the long term is not easy. Nevertheless, by setting up a program with several streams of funding, a successful program can be maintained. In my program, everyone works on what needs to be done at that time, and by helping out across crops or projects within my group, we can accomplish breeding objectives that would not be possible. There is definitely a critical mass of people needed to keep everything moving forward and finding that balance between achieving a critical mass and becoming wildly overextended is always challenging (at least for me).

Without funding, there are no cultivars and hence, no need to worry about intellectual property. So, funding is paramount. The truth may be that the crop we most want to work on just isn't something anyone wants. If this is the case, then it's going to be very difficult to get funding, regardless how close to our own hearts the crop or the target traits lies. But, we should be on the lookout for opportunities in other crops. True, more crops dilutes effort on any one crop, but with some funding on two crops, perhaps a critical mass of technical help can be hired to assist with the overall program.

Finally, I believe it is imperative that we release materials that are used. Publicly released cultivars that do not get into commercial production are useless. If an exclusive release results in a marketing plan and a commercialization strategy that otherwise would not exist, then exclusive releases are very positive for public programs. As the diversity of funding sources expands, however, the possibility for different funders to have different ideas on how products from the program are released arises. These issues should be sorted out before products are developed to avoid problems – delays or even shelving of releases – when commercialization is at hand.

Session 3
Examples of successful models

Keynote 3

The University of Florida Cultivar Release, Licensing, and Royalty Program

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Introduction and Summary

The University of Florida, Institute of Food and Agricultural Sciences (UF-IFAS) has maintained traditional breeding programs for various crops since the late 1800's. For most of that time, public release of cultivars was the norm until federal legislation enabled Intellectual Property Protection (IPP) specific to plants. Federal legislation regarding IPP of plants developed over more than 60 years beginning with the 1930 Plant Patent Act which allowed for protection of asexually propagated plants. Sexually propagated plants had no IPP equivalent to the Plant Patent until the 1970 Plant Variety Protection Act. In 1980 the Supreme Court, in *Chakrabarty v. Diamond,* ruled that living organisms such as those produced by genetic transformation could be protected. Prior to 1995, UF-IFAS, did not have a uniform policy to account for various methods of IPP available for the products of plant breeding. Additionally, it was clear that the survival of plant breeding programs was uncertain given the decline in public investment. Licensing and royalty collections based on the IPP instruments available were viewed as alternate sources of support for plant breeding. Motivated by the potential to develop a uniform policy that included both seeded plants and asexually propagated plants and which provided financial support for plant breeding, UF-IFAS plant breeders organized themselves in 1993 to begin discussions toward a common cultivar release policy. An excellent summary of the history of the development and details of the UF-IFAS policy was written by Joyce et al. (1995). Other than brief background information, the subject of this paper is the subsequent implementation and results of the *University of Florida Policy for Program Support and Royalty Distribution from Released Cultivars,* which was implemented in 1995.

History of the University of Florida Plant Breeders Work Group

The need for new policy led the UF-IFAS plant breeders to organize a series of meetings beginning in 1993. Although not the only subject on the agenda (graduate education was of primary concern), Intellectual Property Protection and its impact was a major topic of discussion. In practice, mode of propagation (sexual vs. asexual) dictated the IPP avenue and potential licensing and royalty returns of UF-IFAS cultivar releases. There was a desire to unify policy and create a system in which allowed for IPP, licensing and royalty collection for cultivars from all programs.

As a result of these meetings, the University of Florida Plant Breeders Workgroup (UF-PBWG) was formed. Although not an official body within the UF-IFAS system, the UF-PBWG elects officers, meets annually, organizes internal grant opportunities, and its officers meet quarterly with UF-IFAS administration and are heavily involved in shaping operational policy regarding plant breeding.

Management of Intellectual Property at the University of Florida

Utility Patents

Empowered by the 1980 Bayh-Dole Act, the goal of the highly successful UF Office of Technology Licensing (OTL) is to create start-up companies to license, develop and market inventions from UF research. New discoveries, which are protected by Utility Patent, can be unique and require a new company, or they are potential new products in the hands of a large corporation as might be the case in pharmaceutical or engineering discoveries. Although OTL is a world class office dedicated to developing research discoveries into marketable products, plant cultivars do not fit their model regardless of their mode of reproduction. A large part of the OTL "currency" is the number and success of the startup companies which are enabled by university discoveries and inventions. The potential for rapid change in cultivars prohibits starting a new company for every new cultivar. Instead, a 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. Moving plant cultivars into the marketplace is a different process with different metrics.

Plant Patents and Plant Variety Protection

The late 1980's and 1990's marked a time of diminishing state and federal funding for agricultural research, including plant breeding. Plant breeders within UF-IFAS recognized the need to develop policy that could utilize Federal IPP laws to encourage development of improved cultivars and to facilitate their commercial adoption. In comparing the disparate royalty policies within UF, it was apparent that the OTL policy disbursed the majority of royalties to the inventor personally and to the University of Florida whereas the UF-IFAS policy for asexually propagated cultivars dispersed all royalty income to various parts of the university (Florida Foundation Seed Producers (FFSP), the inventing breeding program, the unit [Department or Center] and the IFAS Dean for Research) but none to the inventor personally. A new policy was needed which would provide incentive for developing improved cultivars and help to fund the breeding programs. As described below, the UF-IFAS plant breeders would craft a new policy that 1) incentivized the breeder personally, but at lower level than the OTL policy, 2) provided much needed returns to the inventing breeding program, and 3) recognized the vital role of FFSP and administrative units (Departments/Centers and the IFAS Dean for Research). This policy has served the UF-IFAS plant breeders for over 20 years.

Two Pathways for Intellectual Property Protection of UF-IFAS cultivars

Within the current UF system, a potentially protectable discovery or invention will follow one of two distinct pathways depending on the type of IPP for which it qualifies. Federal law allows cultivars of seeded and tuberous plants to be protected under the Plant Variety Protection Act (PVP) and cultivars of clonally (asexually) propagated plants to be protected by Plant Patent. The Utility Patent is the instrument used to protect inventions of every scope imaginable including a plant cultivar. *Figure 1* outlines the basic pathway used within the UF system through which plant cultivars are protected and licensed.

Although rare, cultivars can be protected by Utility Patent and either PVP or plant patent as dictated by their mode of propagation. If a cultivar is protected by Utility Patent, the OTL will manage IPP and licensing. Although the licensee could be a party outside of the UF-IFAS, it is likely that FFSP would be the exclusive licensee because their business model has been developed specifically for successful commercialization of plant cultivars. In most cases, the cultivar would be protected by both Utility Patent and either PVP or Plant Patent. If protected by both Utility Patent and either PVP

or Plant Patent, royalties would return to OTL first and then to FFSP based on the agreement between OTL and FFSP. Both the OTL and FFSP are Direct Support Organizations of the University of Florida. Direct Support Organizations are formed by and for the benefit of the University of Florida under Florida Law and are considered component units of the University.

More commonly, cultivars are protected by either PVP or Plant Patent and are released by the University of Florida directly to FFSP which will apply for IPP, develop licenses and collect and disburse royalties. It is this dual system (OTL and FFSP) and the dual royalty disbursement models (one for UF through OTL and one for UF-IFAS through FFSP) which is unique among Land Grant Universities. *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 inventors program when total royalties amounts are lower and divides them more equitably when royalties increase. *Table 2* presents an illustration of the monetary differences between the two distribution schemes given various royalty income. 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 UF-IFAS plant breeding programs to grow and thrive.

Impact of the UF-IFAS Royalty Policy

Impacts of the *University of Florida Policy for Program Support and Royalty Distribution from Released Cultivars* can be measured in terms of the number cultivar development programs, the number of licenses, and the number cultivars released, and finally, monetarily.

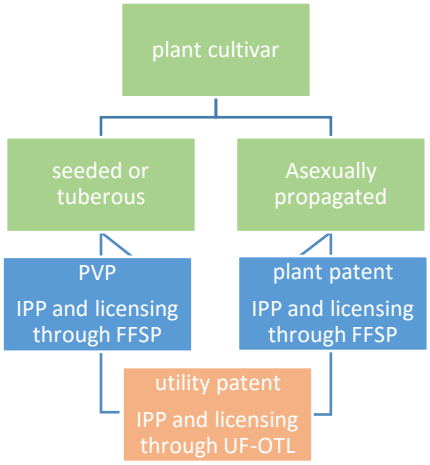


Figure 1. Flow of Intellectual Property Protection in the University of Florida System. OTL stands for Office of Technology Licensing. FFSP stands for

Impact on Cultivar Development Programs

As of 2015, UF-IFAS had 18 faculty members whose research program was devoted in part to cultivar development and who were actively developing breeding populations with the goal of cultivar release. Several other faculty members work intermittently or tangentially in cultivar development or cooperate significantly with plant breeders in cultivar development (plant pathologists, entomologists, physiologists, molecular biologists, etc.). Over the past several years, at least three retiring breeders were replaced and other plant breeding positions have been created or resurrected with the aim of providing improved cultivars to underserved crops in Florida. Both maintaining and adding plant breeding positions at the University of Florida is due largely to the fact that this program has been so successful.

Cultivar Releases and Licensing

The productivity of UF-IFAS plant breeding programs can be measured by the number of cultivar releases. The number of cultivars released from UF-IFAS varies considerably from year to year with a low of 11 in 2001 to over 50 in 2014. If compiled by decade, UF-IFAS released over 100 cultivars each decade beginning in 1980 through 2009 and has

Table 1. University of Florida distribution policies for royalty income.

	Royalty distribution based on percentage of Net Adjusted Income (NAI)				
	NAI - OTL*		NAI- FFSP**		
	<$500,000	≥ $500,000	≤ $71,428	$71,429-$214,285	> $214,285
Inventor(s)	40%	25%	20%	20%	20%
Inventor's Program(s)	10%	10%	70%†	50%	33.3%
Inventor's Department	7.5%	10%	--	25%	33.3%
Inventor's College	7.5%	10%	--	25%	33.3%
University or UFRF***	35%	45%	--	--	--
FFSP	--	--	10%	10%	10%

*Office of Technology Licensing; **Florida Foundation Seed Producers, Inc.; ***University of Florida Research Foundation, Inc.

† Based on the amount of NAI, the 70% designated for the "Inventor's Program" is divided among the Inventor's Program, Department and College as shown in the final two columns.

released over 180 from 2010 to present. As mentioned previously, IPP, licensing and royalty collections from these cultivars is accomplished through the FFSP. The FFSP has executed over 100 licenses annually since 2008.

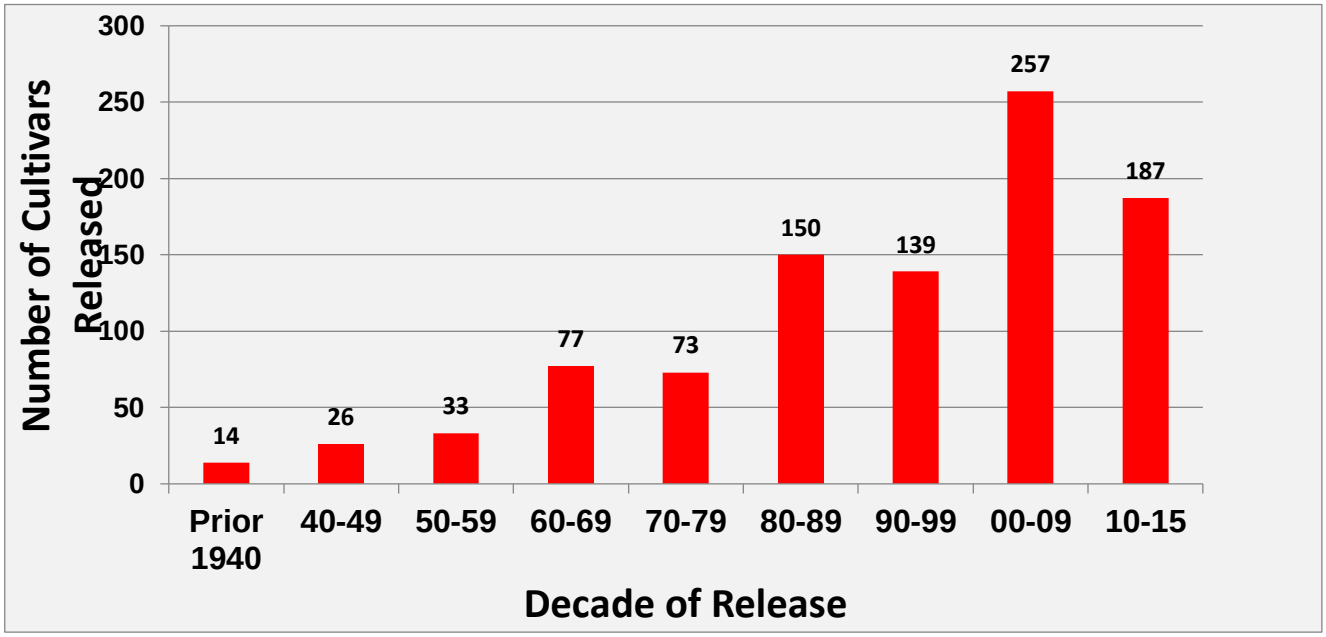
Royalty Income

Fueled by productive breeding programs and made possible by the current policy, royalty income from licenses has grown from less than $100,000 annually from 1985 through 1995 to over $10 million in fiscal year 2015. *Figure 2* details the growth in royalty income through cultivar licensing. Although this is a large sum, it must be understood that over 85% of cultivar royalty income is generated by only three plant species. Plant breeders with UF-IFAS work with over 60 plant species. This means that most breeding programs receive modest, albeit important, levels of royalty income.

Other Impacts

Technology	Policy	Total Royalty	FFSP/OTL	Program	Unit	College	Inventor
Cultivar 1	FFSP	$ 50,000	$ 5,000	$ 35,000	$ -	$ -	$ 10,000
Cultivar 2	FFSP	$ 400,000	$ 40,000	$143,333	$ 68,333	$ 68,333	$ 80,000
Cultivar 3	FFSP	$ 1,000,000	$100,000	$283,333	$208,333	$208,333	$200,000
Invention 1	OTL	$ 50,000	$ 17,500	$ 5,000	$ 3,750	$ 3,750	$ 20,000
Invention 2	OTL	$ 400,000	$140,000	$ 40,000	$ 30,000	$ 30,000	$160,000
Invention 3	OTL	$ 1,000,000	$450,000	$100,000	$100,000	$100,000	$250,000

Figure 2. Number of cultivars released by the University of Florida, Institute for Food and Agricultural Sciences by decade.



Graduate training in plant breeding within UF-IFAS has benefited from the IPP policy in two distinct ways. First, the capacity of UF-IFAS plant breeders to engage graduate students is enhanced by royalty returns. Second, royalty funding has helped to focus programs in the direction of cultivar development and release in addition to the traditional academic endeavors in plant breeding such as research into trait inheritance, heritability, and Quantitative Trait Loci. Training students within the context of a program focused on cultivar development gives them a full perspective in modern plant breeding. In addition to the practical focus of UF-IFAS plant breeding programs, royalty income pool has been established and utilized to provide internal grant opportunities for UF-IFAS plant breeding faculty members to train graduate students. Each breeding program contributes to the pool based on the proportion of royalties that their program generated up to $100,000 annually. The UF-IFAS Dean for Research matches that amount to create a pool of $200,000. Each year, three to four new students are accepted as a result of this program called the UF Plant Breeding Graduate Initiative.

Summary and Conclusions

The success of the UF-IFAS plant breeding programs over the past 20 years is due, in large part, to the financial resources and interactions with UF-IFAS administration afforded by the *University of Florida Policy for Program Support and Royalty Distribution from Released Cultivars* as described herein and by Joyce et al. (1995). The policy has created synergies among the faculty engaged in plant breeding and between the UF Plant Breeders Workgroup and UF-IFAS administration. The result has been a steady to growing cadre of faculty members engaged in cultivar development, an increase in

Table 2. Example of royalty distribution schemes administered by OTL and FFSP within the University of Florida System.

the number of cultivars released and licenses executed, an increase in royalty returns, and an increase in the number of graduate students enrolled in plant breeding programs.

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Respondent 1
Examples of successful models

Fruit Crops Breeding at the University of Minnesota

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The University of Minnesota (UMN) has supported fruit crop cultivar development for over a century. The fruit crops breeding and genetics program relies on several revenue sources including appropriated state funds, grant funds, and gifts from industry and individuals. Licensing revenue from cultivars, however, has become the largest single component of funding. State appropriations largely provided the continuous investment needed over the last century to develop our germplasm base in several crops. Grant funds, while excellent for advancing specific projects and educating students, are less useful in funding a perennial plant breeding effort due to their limited time frames and unpredictable and low obtention rates. Licensing revenues from cultivars have the advantage of being somewhat projectable in the long term based on minimal annual payments or milestones incorporated in contracts. They also provide flexibility to fund operational or emergency needs in a program and some larger capital needs. Revenue from fruit crop cultivars has also become consequential for the UMN and in 2015 accounted for over 10% of the gross revenue from intellectual property (IP). In contrast to much other UMN technology, cultivars are market-ready and motivated licensees are relatively easily engaged.

Intellectual property policy at the University of Minnesota

Cultivars resulting from all UMN plant breeding programs are considered "technology" which, in contrast to scholarly works, is the property of the UMN per Regents' policy. The Regents' policy charges our Office of Technology Commercialization (OTC) with the responsibility and authority to properly protect and license cultivars and other technology. An OTC management team evaluates whether the UMN should pursue IP protection on each invention, including cultivars. If the UMN determines not to pursue IP protection for a cultivar, the rights are waived to the inventors. If the UMN, pursues IP protection and commercialization, after direct costs for IP application and prosecution are reimbursed, remaining licensing revenue is shared via a formula that funds OTC off the top (15%) and splits the remaining revenue among the Office of the Vice President for Research (28%), inventors (28%), and the department/program (22%) and college (7%) of the inventors.

Cultivar commercialization at the University of Minnesota

OTC currently has a licensing manager and an IP manager appointments dedicated to managing and licensing IP associated with horticultural and agronomic crop cultivars. They work closely with breeders to develop optimum protection and licensing strategies. The UMN Office of General Counsel is another critical partner with advice and oversight responsibilities for IP management, license development, and infringement prosecution or litigation.

Our fruit cultivars are commercialized under two broad models that we term "open cultivars" or "managed cultivars" (Luby and Bedford 2015). A strategic plan is developed for each new cultivar that considers which of these models will be used, the territories for commercialization, IP protection that will be sought, and general contract terms that will be negotiated with licensees. Most University of Minnesota fruit cultivars have been commercialized using the open model. Certain apple and blueberry cultivars have provided us with opportunities to develop new models to mitigate limitations of the open cultivar model.

Open cultivar commercialization

In 1990, 'Honeycrisp' apple tree was the first fruit cultivar for which the UMN received a US plant patent (Luby and Bedford 1990), followed by plant variety rights in other countries. 'Honeycrisp', and many of our other patented "open" fruit cultivars, are licensed to US nurseries on a nonexclusive basis. The licensee pays the University a royalty for each plant sold. While licensing of open cultivars is relatively simple and inexpensive, the practice has several features that can limit return to research and development for the variety owner (Luby and Bedford 2015):

- Commercialization proceeds slowly, minimizing compensation during the limited monopoly period provided by plant patents.
- When any party can grow, produce and sell fruit of a cultivar in any way they like, poor quality fruit can easily enter and disrupt the market and reduce the value and popularity of a cultivar.
- Royalty income is paid as a one-time collection of a modest fee when a tree is sold so that the variety owner recovers only a small fraction of the consumer value of a new cultivar.
- Infringement of propagation rights is difficult to monitor with the cultivar in the hands of multiple licensed nurseries and potentially hundreds or thousands of fruit producers.
- Ownership and control of competition of essentially derived varieties that arise as sports or mutations is complicated or impossible in the US.

Managed cultivar commercialization

In contrast to open cultivar commercialization, "managed cultivar" commercialization not only relies on IP protection that employs plant patents, trademarks and contracts, but also on managed access and production that attempts to align incentives of the cultivar owners, producers, and marketers to ensure rapid and orderly product introduction, manageable crop volumes and high quality. Minnesota growers are licensed with few limitations. Exclusive or semi-exclusive partners are selected to manage U.S. and foreign production and marketing. For apples, cultivars can be sufficiently distinct in phenotype such that consumers can recognize them and develop preferences. In addition, a cultivar can be available for an extended marketing period so that continued repurchase can reinforce a favorable consumer experience. Consumer cultivar recognition presented an opportunity for apple variety owners, including universities, to manage a new cultivar as a consumer product and brand and capture a share of value beyond the farm gate. The 'Cripps Pink' cultivar (Cripps et al. 1993), whose fruit are often sold under the Pink Lady® trademark was the first major "managed cultivar". Over the past decade, each of the three U.S. universities with major investments in apple breeding (Cornell University, Washington State University and the University of Minnesota) have developed new managed cultivar commercialization models that capitalize on cultivar branding and consumer recognition.

Success and challenges

Our success in cultivar commercialization and in developing managed cultivar models is

largely due to (and in some cases limited by) several key factors:

- University administration committed to supporting the necessary IP management, licensing and infringement prosecution.
- Relationship building with current and prospective partners including testers, growers, nurseries and marketers.
- Strategic planning of local, national and global testing commercialization.
- Efficient pipeline for clean stock movement to U.S. and foreign partners.
- Attentive oversight of plant patent and trademark prosecution and enforcement in multiple territories.
- Careful license crafting that includes milestones and annual payments.
- Revenue streams composed of both payments for plants when an orchard is established and annual payments based on planting area or fruit production.

Our approach has not been without challenges. The activities cited above require significant time commitments from the breeding team as well as commercialization staff. Competence and continuity of university technology commercialization staff is critical as is recognition by the university that technology commercialization is an important activity for academic staff.

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Respondent 2
Examples of successful models

Intellectual Property Protection and Licensing of New Potato Varieties at the University of Wisconsin-Madison

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The public sector is heavily involved in potato cultivar development in the US. There are ten faculty members at land-grant universities (OR, ND, WI, MN, TX, CO, MI, NY, ME, NC) and four USDA-ARS scientists (WA, ID, MD, WI) who manage varietal breeding or pre-breeding programs based primarily on sexual hybridization and phenotypic selection. In the round white chip processing market, public varieties account for about half of the seed acreage. In the French fry and fresh markets, over 90% of the seed is public varieties.

PVP certificates are typically obtained for new potato varieties in the US. Although potato is asexually propagated, it was excluded from the Plant Patent Act of 1930. The nursery business was the driving force behind the legislation, which was drafted by Paul Stark of Stark Brothers Nursery (Bugos and Kevles 1992). Stark was a business associate of Luther Burbank, and when Burbank died in 1926, Stark acquired his farm containing hundreds of unreleased tree fruit and ornamental varieties. Although Burbank also bred potatoes (the variety bearing his name has dominated the US market for a century), they differ from nursery stock in an important respect: the planting stock is widely traded as food. Stark thought it would be difficult to enforce patent restrictions on tubers and feared this could undermine enforcement for nursery stock (Bugos and Kevles 1992). Potato was also excluded from the PVP Act of 1970, which only applied to sexually propagated crops. In 1994 the PVP Act was amended to include tuber-propagated crops.

Since 1995, the commercialization of new cultivars at UW-Madison has been managed by a nonprofit organization known as the Wisconsin Alumni Research Foundation (WARF). From 1995 to 2008, WARF and the Graduate School allowed for 70% of the first $100,000 in revenue per licensing agreement to be returned to the research program that generated the invention. In 2008 this "lab share" program was eliminated, and the new revenue distribution formula became 20% to the inventors, 65% to the Graduate School, and 15% to the department.

To address the loss of revenue, plant breeders at UW-Madison developed an alternative licensing arrangement through the Wisconsin Crop Improvement Association (WCIA). WCIA was one of the first seed certification agencies in the US and helped spawn the national Association of Official Seed Certifying Agencies (AOSCA). Because of its role in foundation seed production, WCIA has a long history of facilitating the commercialization of new varieties, particularly for small grains. Although in some states the AOSCA portfolio includes seed potatoes, in Wisconsin the crop is handled by a different organization—the Wisconsin Seed Potato Certification Program—that evolved separately from, but

contemporaneously with, the AOSCA, in the early decades of the 20th century.

Instead of licensing the variety directly to growers, under the new model WARF exclusively licenses the variety to WCIA, which in turn sub-licenses it to seed growers. The first $10,000 of licensing income per variety is returned to the breeding program. Above this threshold, WCIA retains 15% to cover administrative costs and the balance is split evenly between WARF and the breeding program.

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Session 4
Impact of public release mechanisms on stakeholders

Keynote 4

Impact of IPR on Stakeholders for Publicly-Released Cultivars

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Many groups are affected by the continued availability of publicly-released cultivars and the method with which these cultivars are protected through intellectual property rights (IPRs). Grouped broadly, the list of stakeholders includes plant breeders, foundation seed groups, seed companies, farmers, grain and food processors, and consumers. This paper will briefly address the relationship each of these groups has with publicly-bred cultivars. It will also discuss how the different cultivar release mechanisms (and the IPRs associated with these release mechanisms) affect these different groups.

Breeders

Plant breeders are clearly one of the primary stakeholders in this conversation. There are a couple things essential to breeders when considering the methods for releasing cultivars to the public. Mainly, breeders need to get paid for their time-consuming work (both because they deserve health insurance and so that they have the resources to continue their work) and at the same time need to be able to legally share their work with other plant breeders. The need to capture the value of their plant breeding work can set up a direct conflict with the importance of sharing this very work:

The exclusivity conferred to inventors by intellectual property rights (IPRs) provide an ex ante *incentive for innovation, but the*

resulting market power yields an ex post *inefficiency (because it limits use of the innovation). Strong IPRs may also affect innovation by limiting access of proprietary knowledge in research aimed at new inventions and discoveries, which raises the question of whether IPRs should have an experimental use or research exemption (RE) provision.* (Moschini and Yerokhin, 2008)

From a layman's perspective it seems the Plant Variety Protection (PVP) system, if it could be modified to have both a strong breeders' exemption and a low entry cost, is the most workable model to allow for both a revenue source for breeders while still allowing for access to a cumulative body of work. Patents, while a good form of protecting a breeder's invention, do not foster sharing and collaboration on a greater body of work that many individuals can improve upon. The Open Source Seed Initiative (OSSI) is an exciting concept and definitely allows for the most collaboration between breeders, but the question remains how do breeding programs recoup their investment and fund their future breeding work.

Foundation Seed Groups

Foundation seed groups often serve as the gatekeepers for cultivars protected by intellectual property rights. They oversee the licensing, propagation, and fee collection for protected cultivars. This group includes State Seed Departments, independent grower groups, and privately held companies.

State Crop Improvement Associations and State Seed Departments have been the primary outlet for cultivars released from land grant universities. They often handle the licensing, Foundation seed production, distribution, and royalty collection for most "public releases" (cultivars available for anybody to license). This is a good fit because often the University offices of technology and licensing are not specific to agriculture. The fact that the Crop Improvement Associations are agriculture-specific often makes them a better fit for working directly with seed companies and farmers, a notoriously independent demographic. Crop Improvement Associations will often handle cultivars from multiple breeding programs. For example, the Minnesota Crop Improvement Association oversees licensing and propagation for oat varieties from seven different breeding programs. One of the biggest challenges for them (and for seed companies) is the varying restrictions for propagation. In 2016, there were eight different methods of propagating oat varieties and certifying the production acres was the responsibility of the MCIA.

Pro Seed Genetics is an interesting example of a small, independent, privately-operated Foundation seed group. This is a grower cooperative made up of seed growers who also retail seed. This group of growers banded together to create a sales and marketing group with enough volume to be able to in-license germplasm (from both public and private programs). Individual growers are responsible for procuring their own foundation seed, growing the varieties, cleaning and packaging the seed and retailing it to farmers. A royalty is paid to Pro Seed Genetics for testing and marketing. What originally gave this group a competitive edge was exclusive rights to a forage oat variety bred by the University of Wisconsin called "Ensile"; currently Pro Seed Genetics has exclusive rights to a variety called "Forage Plus" which is also a University of Wisconsin release. They also promote and sell a number of soft red wheat varieties from public and private breeding programs. The difference in royalty cost

between public and private breeding programs is significant. “Kaskaskia”, a public soft red wheat variety released from the University of Illinois, has a royalty cost of .60 cents per bushel while soft red wheat varieties out of private breeding programs require a $3.00 to $4.00 dollar per bushel royalty. This group is a good example of how an exclusive arrangement with a breeding program can give a seed retailer an advantage in the marketplace.

MBS Genetics LLC is an example of a privately-held genetic “supply house” or licensing organization that does little or no breeding work of its own, and does not have a retail arm. MBS in-licenses primarily corn and soybean germplasm from small to large companies which they then propagate, out-license, and sell to retail seed companies who use the Foundation seed to produce seed which will be planted by farmers. MBS serves a very useful role for small and medium-sized seed companies that are hungry for elite corn and soybean germplasm but may have limited breeding programs of their own. MBS also serves an important role for small breeding programs, which may not have the resources to market and out-license the germplasm they develop. Currently, the majority of the germplasm in-licensed and out-licensed by MBS is patented and cannot be used in other breeding programs.

The different release mechanisms and IPRs will affect the different Foundation Seed Groups in similar ways. State Crop Improvement Associations and Seed Departments have historically done better with seed release mechanisms and IPRs that allow them to make money by propagating and selling Foundation Seed. It seems likely that these organizations could thrive with either utility patents or PVP, but would struggle with an approach such as the OSSI. Small private Foundation groups such as Pro-Seed Genetics in WI or Pulse USA in ND will probably be affected by release and IPRs in much the same way as State Seed Departments. Genetic supply houses such as MBS will be bound by the licensing agreements forced onto them by the genetic originators. They could continue to provide their valuable function under a utility patent or PVP model of IPR.

Seed Companies

Small and medium-sized seed companies are major beneficiaries of publicly-released cultivars. There has historically been a very good working relationship between seed companies and Land Grant Universities (LGUs). Small seed companies often lack the resources to invest in internal breeding programs. They also tend to have a regional footprint that requires regionally-adapted varieties. For these reasons, LGUs have been a good source of genetics for small and medium-sized seed companies. The system works like this: seed companies work with the Crop Improvement Association to license public varieties. While adhering to various propagation requirements the seed companies take breeders seed (foundation seed) and grow this out for one or two generations at field scale. The seed produced from these seed production fields is then harvested, cleaned, and sold back to farmers for general planting purposes. In this scenario a company without vast resources can focus on testing and evaluation, selecting competitive cultivars with a regional focus while avoiding the high cost associated with long-term breeding efforts.

Now, breeding efforts in the major crops (corn, soybeans, cotton, canola, sugar beets) have shifted away from public breeding programs and into the hands of private companies. The funding for breeding work in the public sector has shifted as well. As

USDA funding declines, industry funding for breeding efforts in the public sector is increasing. These trends create some potential problems. One major problem with the current trend is that there is less money overall in the public sector for traditional breeding efforts. Industry money is often earmarked for other types of research. The direction of research is usually dictated by the companies funding it and the conclusions from the research are more likely to be "Pro Industry". Genetics released from private breeding programs are often "encumbered" which precludes crossing them into another breeding program (without licensing agreements that can reach forward forever), and there is limited opportunity for independent evaluation. Possibly the most immediate problem is that minor crops have less opportunity, as private companies have less incentive to fund research on crops with less economic return or crops planted on fewer acres. In the current environment, it is important that breeding work in the public sector continues to service marginalized areas of agriculture and minor crops with smaller economic return.

Seed companies have been major benefactors from increased Intellectual Property Rights applied to seed cultivars. Patents have become increasingly popular with seed companies that have private breeding programs. Patents offer maximum revenue and protection although they have led to some public relations issues with farmers and consumers. The PVP system is a well- established model that still works very well for small and medium sized seed companies. OSSI gives seed companies good access to cultivars and allows for some exciting seed company/farmer collaborations for regional cultivar development.

Farmers

Farmers are another primary stakeholder in this conversation. There are many farmers who have a lot to gain from the additional money being spent by private industry on breeding in major crops, but it is not all upside for all farmers. Seed cost has been steadily rising. Twenty years ago, the average cost of a bag of hybrid seed corn was about fifty to sixty dollars. In 2016, a farmer spent between one hundred and fifty and four hundred dollars per bag on seed corn. In addition, farmers are no longer able to save seed of many of the varieties of soybeans they plant as most varieties are protected by patents. Organic farmers are potentially some of the biggest losers in this conversation. With private breeding efforts focusing on genetic modification and other gene editing techniques, organic farmers are unable to use the lion's share of the cultivars that are available to conventional farmers. In addition, organic farmers are mandated to use a more diverse crop rotation so they rely more heavily on small grains and legumes, which are two crops that have seen a reduction in funding in recent years. Again, we return to a serious problem that public breeding programs can help to solve. There is a need for continued breeding efforts using techniques that are not excluded by the Nation Organic Program and there must be continued breeding efforts across all crop types including the ones that offer less economic return.

Farmers can benefit from patents because of the strong incentive it offers private industry to invest in breeding, but this system of release can also be restrictive and potentially invasive to farmers due to the "Technology Use Agreements" that farmers must sign to purchase many patent protected varieties. The PVP system allows farmers good access to germplasm in a well-established system. For farmers, the phrase "blue tag" is well known and is often synonymous with higher

quality seed. OSSI allows for farmer breeding efforts and for saving seed. The limited economic return could lead to less investment in the development of new varieties.

Grain and Food Processors

Grain and food processors still rely heavily on publicly released cultivars. In 2016, all SunOpta food soybeans contracted in southern Minnesota were Iowa State releases. As private breeding efforts focus almost exclusively on genetically modified crops, the public sector has been able to maintain a strong presence in the non-GMO and specialty trait cultivars. There has been a long tradition of food companies working directly with public breeding programs:

We have gone to meet with Dr. Jim Orf every year that I have worked here. We give feedback on varieties, what we are seeing in the field and also tell them what we are looking for in new varieties. (Tony Schiller, SunOpta)

The food and grain industry is dependent on public programs for many of the same reasons small seed companies are:

The food soybean market is so small at this point no company could afford the cost of their own breeding program. (David Springer, Grain Place Foods)

There are a couple current examples of grain and food companies providing financial support to breeding efforts in the small grains. Pespi, who owns Quaker, is providing funding for an oat breeder in MN. Grain Millers, the largest processor of organic grains in the United States, is paying for oat variety testing in MN and IA. Continued cooperation and funding for public breeders by industry will be vital going forward, but it does not seem like this by itself is a sustainable or impartial solution for funding public breeding programs.

Grain and food processors depend on some form of variety protection in order to protect their investments in end use markets they cultivate. If they sell a specialty use grain based on nutritional content or other characteristic, it is important to them that another company or farmer cannot easily move in and compete with them. They do this primarily through the use of "branding." Both the utility patents and PVP methods of release serve equally well for this purpose. The OSSI release mechanism could provide more freedom to breed, leading to the potential of developing geographically specific or nutritional niche varieties, both of which could be interesting to grain and food processors.

Consumers

Consumers have a stake in this conversation because they expect a diversity of choice and are more often pushing for improved taste and nutritional value in their food. Getting consumers' feedback and involving them in breeding efforts is an exciting concept. You can see this playing out all over the country with both on farm breeding collaborations and the farm to table movement in urban areas. A couple examples of this are shown in the Organic Seed Alliance collaboration with farmers, breeding sweet corn and cabbage varieties specific to the Pacific Northwest, and Michael Mazourek's mini squash variety being showcased by Dan Barber at his New York City restaurant, Blue Hill. You can see evidence of this trend in grains as well with a resurgence of demand in ancient grains that are appealing to consumers for their low gluten content and their flavor. If consumers and marketers of consumer packaged goods are able to be involved in this conversation, this will be a big win for all stakeholders.

Both the OSSI and PVP models could be used successfully to help breeders meet the demands of consumers. It is hard to envision

a patent model meeting the needs of geographical and/or niche nutritional markets.

Conclusion

There are some running themes across all stakeholders in this conversation. There needs to be a sustainable funding model for public breeding programs that does not rely heavily on private industry. There is a strong need for continued breeding efforts in minor crops, as private companies do not have the economic incentive to breed crops that are not as widely planted. There is a need for continued breeding efforts in major crops using "conventional" breeding methods that will not be excluded by the National Organic Program. Land grant universities, smaller breeding programs, and on-farm breeding can play a role in ensuring that farmers and consumers have cultivars across all crop types in the future.

References

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Respondent 1

Impact of IPR on Stakeholders for Publicly Released Cultivars

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Public breeding programs once played a more pivotal role in the development and release of cultivars, but fundamental shifts in ownership of crop genetics, funding for LGUs, and mechanisms for release of finished products has diminished public capacity. And yet we need the public sector and an overall greater diversity of actors in seed development than ever before. The challenges we currently face in agriculture – population pressure, climate change, resource scarcity and degradation – are projected to be amplified for future generations, and as such we have an urgent need to formulate an approach to public plant breeding that addresses IPR and funding constraints, and has the highest probability of best serving the penultimate stakeholder – future generations.

We should be careful to not create false walls between public and private sector breeding when it comes to assessing IPR mechanisms and their value or constraints. We cannot improve the dynamic of public sector IPR without addressing the inequity and flaws in the private sector model. Current models of IPR for the private sector have been developed to serve the immediate needs of immediate stakeholders, with shareholders being perhaps the most powerful stakeholder. It could be argued that in fact a subgroup of shareholders - often the board of directors (10-12 individuals with significant equity in the company), CEO and executive team (compensated in shares) – exercise more direction in decisions about research and product development than all other stakeholders combined. When developing for shareholders, the goal is to extract as much

value from genetic resources as possible in a timeline that is pressured by quarterly earnings, annual sales, and the competitive landscape of other large genetics firms. This model of IPR does not serve future generations, and it is an unfortunate reality that public sector research can often be constrained by these mechanisms.

It is well past time to develop a new model of cultivar development that is less extractive, and instead focused on building intergenerational equity (this includes respecting and compensation for the value that the past generation added to a resource, as well as strategies that add value into the future). We should not sell short the shares of future generations. Current IPR mechanisms are inadequate. While it is important to try to work within the world, we also have to serve current stakeholder needs. We must also envision improved models of IPR and cultivar development for the future.

Valuing Public Good

When, as a populace, we examine the rationale for investing in a public good we should not be constrained by the immediacy or conditionality placed on private sector investment. Let's take public primary education as an example. First, the stakeholders in primary education are not only the children and families that a district serves, but also the larger social sphere and in particular the future society in which these children will live and work as adults, and the generations that they affect into the future. It is for this reason that we all – whether we have children or not – pay taxes that fund public primary education.

Secondly, we do not run our primary schools as a business, demanding that their quarterly business reports (QBRs) meet a specific metric as outlined by investor projections. The return on investment is not measured in the immediate goods or services that the stakeholders (the students) of these public services provide, but instead we recognize that investing in primary education has long-term equity, paying social and economic dividends over decades. Most certainly, we as institutional investors expect results. We should hold ourselves accountable for public institutions, ensuring that they deliver quality education that meets the projections for long-term dividends. At present our society is debating ownership of this public good - privatization via charter schools or greater "publicization" (what some deridingly call socialism) via increasing the social services provided in school systems for families. It would be a dangerous decision to cede control of a public good to private systems, with their inherently narrow perspective of valuation and returns. Instead we strive to develop a system that will leave future society better than it is today; this is intergenerational social equity.

With public investment in plant breeding we may also need to take a step back from the narrow immediacy and conditionality of markets. If we want to increase the certainty that we serve not only the current stakeholders but also the penultimate stakeholders, then we need to consider serious structural shifts in approach to IPR of crop genetics. Focusing on mechanics and impacts of PVP, utility patents, and OSSI is akin to focusing on the type of text books and testing standards used in public schools. It is important and useful, but we must also look at the underlying infrastructure and gauge if it is functional in adding intergenerational equity. We should hold ourselves accountable for future society and question the means of funding, ownership, and release of all cultivars. It is possible that the current system may not be fixed by

alterations in the mechanics, and instead we may need radical reform.

The Current System is Failing

Prohibitive IPR in crop genetics has helped foster concentrated ownership of seed, with negative impacts for farmers such as limited choice of cultivars and increased price of seed. For independent and public plant breeders there are also negative impacts including challenges accessing germplasm and fear of unknowingly infringing on another's IPR. There is inadequate funding for the long arc of public research, and a narrowing of scope as public universities adapt the private paradigm and focus on innovation in major crops that will provide them the greatest return on investment. Minor crops and emerging markets are underserved. The equity of crop potential we inherited from previous generations diminishes. The equity of public knowledge and capacity at our LGUs diminishes.

Radical Reform – Optimizing Intergenerational Equity of Crop Genetic Resources

It is necessary to work within the legal confines of IPR today, and work to improve access and benefits to all stakeholders, but we must also try to envision a more ideal and equitable future. I will suggest one option worthy of modeling and testing for feasibility, and while it may have fatal flaws, I hope it has value in stimulating others to think of new models that will optimize long-term equity of crop genetic resources, and increase breeding capacity for underserved regions, crops, markets and farmers.

The USDA should create a public utility for animal, plant, and microbial genetics. Utilities are an excellent management model for industries that need long-term capital expenditures, serve a public good, and have slow returns on investments. This germplasm utility will function as the "owner" and steward of these resources, ensuring that they will be improved upon in perpetuity. An evaluation should be made of the current value of the national collections (materials and information), as well projections for future equity if value is added via information services, genotyping, phenotyping and pre-breeding.

A bond market should be created so that the germplasm utility can make improvements, while giving investors the opportunity to get returns on improving a resource that will always be in need of innovation and commercialization. Using the existing regional collections we will create regional public utility commissions (PUC). Each region shall have the capability of selling bonds. The funds from sales will go to improving the collections and the returns will come from licensing agreements with breeding companies and seed production firms. Public sector researchers shall be allowed to access the collection for no charge, and be allowed to release finished varieties to private sector, but all sales of these products shall include a retail royalty fee per unit sold, with the dividends split (percent TBD) between the university breeding program and the PUC.

The regional PUCs shall determine and prioritize investments for their collection (with federal oversight), and determine how much to charge private sector for usage of materials based upon commercialization and market potential. For example, if a breeding company develops a cultivar using PUC materials and does not want an exclusive license, the fees for usage will be lower than if they wanted an exclusive license. The utility may determine that for certain crops there are traits and characteristics that are so essential to basic food security as to severely

limit exclusivity, or even disallow it in extreme cases.

The utilities have a strong incentive (bond ratings and returns) to manage well, and add value to their collections via improvements and information services. The private sector has an incentive to use the utility as it is a valuable source of material (and they will have lost the ability to restrict these materials with patents or other IPR, and thus be dependent on these public materials). The public breeders have incentive to use the collections and develop cultivars that will accrue royalties. Independent breeders have access equal to the biggest multinationals.
There are challenges with this model, including international treaty ramifications and the need to determine a mechanism to return a percentage of the value from these collections to indigenous communities and the countries from which this crop diversity originated (these are not reparations, but rather a valuing of past sweat equity). Valuation of current collections and fair projection of futures would be tricky. Buy-in from the private sector that at present controls federal policy and therefore, decisions at USDA, may be insurmountable. Regardless, we must press forward with ideation, testing, and development of new models for managing public agricultural genetics and funding improvements. We are the interim stewards, and it is our job to serve all stakeholders, especially those not yet on the planet.

Respondent 2

Impact of IPR on Stakeholders for Publicly Released Cultivars

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Background
I would like to thank Bill Tracy for his part in organizing this Summit and the opportunity to participate. I am here to learn, to share my experiences as an IP holder, and hopefully contribute to the goals of this important Summit. I have worked in the seed industry for 50 years, I am a third generation seedsman, and our company is 105 years old. We started corn breeding efforts in 1996, moving to full-time in 2004. We use classical breeding techniques, MAS and have used off-season locations in Hawaii, Chile, and Puerto Rico. Breeding focus is <100 DRM yellow dent non-GMO, and hybrids containing our non-GMO lines are being tested in US, Japan, eastern Europe, Ukraine, and China. We also focus on our unique discovery in 2000 of a set of genes that cause hybrids to express 300% more oil and 30% more protein than #2 yellow. We have been working on this for sixteen years, or twenty-eight cycles. For these value-added output traits we own three utility patents. We have recently signed a LT agreement with a large dry-mill ethanol company and are in proof-of-concept trials with two major seed companies. In 2017 we will for the first time exceed 3.0MM bushel demand for our genetics in pre-commercial trials in ethanol and chicken broiler markets. My comments here are directed towards hybrid seed corn.

Elia has done an excellent job describing the impact of IPR on stakeholders from the breeder to the consumer. I would like to add a few comments from a small, independent corn breeder perspective addressing the

impact of IPR on breeders and a few suggestions to build on his conclusion, "there needs to be a sustainable funding model for public breeding programs."

Whereas I agree with Romano that the utility patent may not be the best IPR protection considering societal needs, there are occasions when it is a necessary tool for the developer. It is absolutely necessary for the developer, especially a small program, to recoup costs and capture value from the IP. For example, our patents were awarded in 2006 at a cost of $28,000 per patent-just the legal, not including field and lab assays. As we move towards commercialization, we had not only the line development to accomplish, but had to create a market as well. For example, it took six years to move from bench-trial status in a large ethanol company to commercial plant trial. Ten years seemed to evaporate. We still have two years to full commercialization. If we do not protect the IP, the millions we have invested in development and market we have created will be lost in a very short time.

Regarding making IP available quickly after IPR are issued for societal development potential, this is an admirable goal, however market forces will dictate. For example, it is ironic that in 2008, we attempted to make our IP available with two major seed companies to co-develop the IP jointly, in collaboration hopefully faster, and both declined. Now both are in proof-of-concept trials with us eight years later. Perhaps this is an example of quarterly profits dictating breeding strategy and letting a small company take all of the risk of development. Perhaps IP availability is not simply a black and white issue but more of a case-by-case consideration.

Note also the PVP Certificate does allow for protected IP development within an organization not for distribution, prior to Certificate expiration, which is valuable. However, a complicating factor and current reality is that when the IP becomes available to the public, either PVP or Utility Patent, other agreements by germplasm and trait originators restrict future use of the IP.
Twenty years of IP protection in the perspective of corn breeding is really not a long time. Currently well-adapted lines coming off PVP are being combined with off PVP lines and current elite industry lines. Interestingly, the resulting hybrids are competitive with current industry non-GMO hybrids. I know of a seed company in year two of selling such hybrids who has built 20,000 unit sales. Society has not suffered due to the delay. $3.50 corn has also helped a lot.

It is a practice to extend the IPR protection window by receiving multiple forms of IPR. For example, first obtain a patent for an inbred line, then wait a few years and obtain a PVP certificate for same line, then a few years later obtain a patent for a hybrid containing same line, thus extending the IPR much longer than twenty years. This is causing a lot of anxiety to breeders receiving lines from the National Genetic Resource Program (NGRS). A suggestion I would like to make is to change this practice so a line could only have a maximum of one form of IPR, at the choice of the developer.

I agree with Romano that "there needs to be a sustainable funding model for public breeding programs." Here are a few ideas, again, directed towards corn breeding, but perhaps applicable to other crops as well.

First and foremost, we need to understand that the urgency to fund current corn breeding programs is paramount. A breeding program is not a spigot that can be turned off and on, and the time to act is now. Do

people really understand the dire situation public breeding faces? Do we need some coordinated high power messaging to the public? Can we lock arms and create a national voice to support a national effort across many Land Grant Universities (LGUs)? We need to work together, as the intelligence of an organization is the shared information. Something such as this cannot fall to the breeders at the LGUs, since they are already over-worked. Who could coordinate something like this?

We need to find new sources of funding. I agree with Romano that we need less dependence on private industry or perhaps we need other players in private industry beyond the seed industry. Are there more opportunities with food companies, commodity groups, grain suppliers, farmers, and consumers? They are all benefactors of a strong germplasm base. Who could coordinate something like this?

Infrastructure for Innovation: Public/Private Partnerships

The LGUs have infrastructure which could be a tremendous benefit to private breeding programs, especially small ones, where much innovation originates. There are many ways to find mutually beneficial projects that could bring in new funding to the LGU and assist all sizes of breeding programs. One example is something we did with a LGU. They offered us discounted yield trials and robust statistical analysis in exchange for an *ex post* royalty share downstream. Another example is a seed company who offered the hiring of a technician intern, on-site at the LGU, ½ time for the seed company and ½ for the University.

Two fee-for-service projects we utilized at three different LGUs were use of NIR and wet chemistry lab equipment for cash payments and in-kind calibration development. The LGU received not only cash and hard to obtain samples, but training for students.

Perhaps there could be setup in the Technology Transfer Department or other appropriate University office a 'Collaboration Center' with agronomy students, marketing students, law students, staff, etc., that would be an incubator for potential partnerships with deserving companies wanting to access LGU infrastructure, in a streamlined process, focused on breeding. Public good for public good. In other words, if you access public resources, the public is going to benefit through the Technology Transfer and down-stream IP.

As our society moves from a petroleum-based economy to a biologically-based economy, this could be a very exciting time for public breeding. The challenge is to find funding for best-in-class public genetics and proper mechanisms for their development, distribution and use.

Respondent 3

Impact of IPR on Stakeholders for Publicly Released Cultivars

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I am pleased to submit this response to Elia Romano's paper addressing the impacts of intellectual property on stakeholders for publicly released cultivars. Romano provided an excellent overview as well as specific examples of the need to ensure there is an economic model that supports public plant breeding while also delivering the greatest benefit to society. Important stakeholder benefits include access to diverse food options as well as environmental benefits provided by inter and intra specific crop genetic diversity.

Organic Seed Alliance is a non-profit breeding program

I submit this response from the perspective of Organic Seed Alliance (OSA) with a focus on non-profit and university-based public breeding partnerships. OSA is a non-profit organization founded in 2003 with the mission to advance the ethical development and stewardship of agricultural seed. We achieve this mission through three program areas: research, education, and advocacy. For the purposes of this paper I will focus on our research program, which involves professional plant breeding projects that aim to expand access to high-quality organic seed through collaborative breeding and variety trial networks. The participatory plant-breeding (PPB) model we embrace emphasizes the role of farmers as key collaborators in addition to university breeders, seed industry partners, and other agricultural organizations. Our research aims to fulfill the following goals: (1) advance organic plant breeding methods, (2) bring new and improved organically bred varieties to the commercial seed marketplace, (3) collect data on how different varieties perform in organic systems, and (4) train farmers and other stakeholders in organic plant breeding methods and principles.

OSA believes that decentralized and diversified participation in plant breeding is essential to ensuring that farmers and other stakeholders have access to seed appropriate to their farming system. Our staff has trained hundreds of farmers in traditional, on-farm plant-breeding and plant variety improvement methods. This education has fostered dozens of formal and informal PPB projects between farmers and formal plant breeders. Some of these projects have resulted in finished cultivars that are now available in the marketplace, but too many have not made it to market because of the difficulty in understanding and navigating release mechanisms, as explained below.

Public plant breeder partnerships

Public plant breeders have been essential to the success of our organization. OSA currently partners with 10 public plant-breeding programs on crop improvement projects that emphasize the needs of organic agriculture. These public breeders provide major benefits to these projects and the broader public good, including: (1) expertise on crop-specific, traditional plant breeding methods, and (2) germplasm collections, including elite material and finished cultivars with traits important to organic agriculture. The benefits of this shared knowledge and access to genetic resources are especially important to breeding programs with limited financial and genetic resources, including farmer projects, non-profit breeders (like OSA), and small seed companies.

Therefore, financial support of public breeding programs is essential for these breeders to continue serving in these roles. As Romano pointed out, royalties from public releases are an important way to diversify financial support for public breeders in an era of decreased public

resources and increased private industry investments. (Private investments to public breeding programs may not be bad on their own, but the dramatic decrease in public investments that support cultivar development is troubling.) Public releases with royalty agreements can be managed to provide broad access to new cultivars rather than the exclusivity of a single industry investor. I agree with Romano that PVPs are an appropriate mechanism for recouping royalties without inhibiting access to genetic resources. I would add that public breeders have an obligation to ensure that cultivars are released in a manner that benefits stakeholders broadly and not only large-scale industry or select stakeholders. In other words, both the profit and public benefits must be dually considered in the terms of cultivar licenses and royalties. It is also imperative that the PVP system does not impinge on farmers' right to save seed and breeders' right to use protected material for research purposes. The USDA must act on any evidence that PVP's are being enforced inappropriately. Finally, utility patents on publicly released cultivars do not allow for diverse and decentralized participation in plant breeding nor do they support breeders' ability to share genetic resources and expertise.

Participatory plant breeding for organic agriculture

In 2013, OSA conducted an assessment of the organization's impacts over the first decade of operation in an effort to strategize program development and maximize future impacts of the organization. We recognized that our PPB approach had resulted in many new cultivars for farmers as well as a significant increase in farmer participation in on-farm variety improvement, plant breeding, and seed production. However, the vast majority of these new varieties were primarily being planted exclusively by the farmer-breeder or a few others who had informally received the variety. The varieties that were commercialized by seed companies included very few instances where the recognition for innovation or financial return on investment was benefiting the farmer-breeder and/or formal breeders.

Appropriate intellectual property protections may help remedy this issue and get more PPB cultivars into the hands of farmers and planted to more acres. OSA also recognized that the vast majority of financial resources that supported new organic PPB varieties were from USDA grants and private foundations. Grants often don't provide sufficient long-term funding for finishing a cultivar or incentivizing farmers' ongoing plant-breeding work after the grant period ends. OSA decided to explore developing a commercial variety release program in an effort to address these and other issues.

OSA's commercial variety release program

The primary goals of our variety release program are to (1) develop a model that provides economic incentives for organic plant breeding, and (2) create a pipeline for commercializing new organic cultivars to ensure they reach their full market potential and broadly benefit organic farmers and other stakeholders. The question remains as to which intellectual property protections are most appropriate for supporting the release of finished organic cultivars developed through PPB models.

Utility patents

I agree with Romano's points that the negative impacts of utility patents can include blocking access to genetic resources for public and private plant breeding and creating barriers to integrating patented

varieties into research. It is imperative that crop genetic resources are allowed to continually evolve with changing environmental conditions. Furthermore, diverse participation in crop development is necessary to address the different needs of stakeholders. Patents, as Romano points out, are often applied to varieties with methods excluded in organic production systems and thus provide little to no benefit to organic farmers. Romano also points out that such restrictive intellectual property protections may benefit producers of major crops by incentivizing investments in plant breeding, but I would argue that it does not justify the negative impacts to farmers, including restricting farmers' right to save seed and inhibiting innovation with protected material. Furthermore, utility patents on traits that also occur in nature – common traits such as "heat tolerance" in broccoli or "red leaf" lettuce – is a concerning trend that should be viewed as an abuse of utility patenting.

As Romano points out, the need to maximize profits tied to high economic investments results in a lack of breeding focused on minor crops, regionally adapted cultivars, and cultivars appropriate for organic agriculture. I would add that it additionally does not address the need for breeding varieties that deliver ecosystem benefits, such as cover crops and cultivars with environmentally beneficial traits, unless they are driven by economic incentive. In light of the negative impacts of restrictive utility patents, I argue that patents are not only inappropriate for releasing publicly bred cultivars, but of little benefit to all stakeholders except for the narrow pool of patent holders and their investors.

PVPs

Historically PVPs were implemented with the intent that breeders may recoup the financial benefit of commercializing new varieties while not encumbering farmers' right to save seed for their own use or non-commercial sharing and plant breeders' right to access genetic resources for the development of new varieties. PVPs, as well as utility patents, also expire. The primary opportunity for financial gain is recouped by the breeder, but eventually the cultivar may be widely commercialized facilitating long-term stewardship of the cultivar. In this manner a PVP cultivar may even become an "heirloom," such is the case with 'Sugar Snap' peas and many other early modern varieties from public programs. I agree with Romano that in this light PVP is an appropriate mechanism for releasing public cultivars. There are two primary downfalls of the PVP system: (1) the cost of PVPs is a barrier to most farmer-breeders, non-profit breeders and smaller seed companies, and (2) the PVP system does not securely protect crop genetic resources from utility patents of cultivars or genetics of traits derived from the PVP cultivars. This is the protection gap that the Open Source Seed Initiative aims to address.

Open Source Seed Initiative (OSSI)

Romano points out that OSSI provides the benefit of broadly sharing genetic resources but lacks a mechanism for economic benefit. OSSI is not actually a "variety release mechanism" but a pledge, stating:

You have the freedom to use these OSSI-Pledged seeds in any way you choose. In return, you pledge not to restrict others' use of these seeds or their derivatives by patents or other means, and to include this Pledge with any transfer of these seeds or their derivatives.

Unlike PVPs and the patent system, OSSI's pledge does not provide a legal mechanism for enforcement. The greatest benefit of

OSSI, from my perspective, has been increasing public awareness of the negative impacts of patents. OSSI originally strove to develop a legally enforceable mechanism based on the open source model of copyright law, but the working group found that the nature of seed sharing prohibits capturing copyright agreements every time a seed is transferred or a crop is cross-pollinated. The documentation of OSSI varieties through descriptions and promotion hopefully is a disincentive for any attempts to patent OSSI materials, particularly as it would present a prime opportunity for negative publicity around patents.

OSA's breeding program supports the intent of the OSSI pledge, but also desires a mechanism for plant breeders to benefit economically from cultivar releases in a manner that is fair and supports ongoing breeding efforts. The OSSI pledge does not prevent a plant breeder to release pledged cultivars with contract royalty agreements or theoretically with a PVP; however, none of the current OSSI varieties have PVP protection. The perception that OSSI restricts any royalty agreement has caused some confusion among small seed companies that assume all OSSI varieties may be freely commercialized without royalties to the plant breeder. I suspect that this perception also deters university technology transfer offices from participating in OSSI.

Cultivar release and foundation seed management

The role of public plant breeders is to breed new varieties, not to manage stock seed production and the commercialization of new cultivars. Romano points out that foundation seed programs, crop improvement associations, and private seed programs provide a critical service of handling the actual cultivar release and commercialization. These programs are dependent upon royalties, so without royalties attached to public cultivar releases, their capacity to maintain the quality and purity of publically released cultivars would be at risk.

The organic plant breeding system is hindered by a lack of foundation seed programs that handle certified organic variety releases and foundation seed production. This is a barrier to the public release of organically bred varieties as plant breeders are dependent on organic seed companies to handle the production and maintenance of organic cultivars. Many of these companies may lack long-term capacity to ensure the quality and security of foundation seed. To address this gap in capacity, OSA is partnering with Washington State University (WSU) Extension on a new program called the Organic Germplasm Consortium. The concept is that WSU Extension will provide the service of long-term storage and regeneration of genetic resources that serve organic farming systems, including breeding accessions and finished cultivars. Organic Seed Alliance compliments this regional conservation program by providing training in on-farm utilization and development of crop genetic resources. The funding mechanism and operations of this program are still in development, but if successful, the program may serve as a model for supporting the release and maintenance of organically bred public cultivars in the future.

OSA's commercial release mechanisms

To date, OSA has participated in the public release of two finished cultivars that were bred in partnership with farmers and public plant breeders: 'Who Gets Kissed?' sweet corn and 'Abundant Bloomsdale' spinach. These varieties were released to organic

seed companies with contracts for royalty payments but are not protected by PVPs or any other intellectual property protection. 'Abundant Bloomsdale' is also released with the OSSI pledge. These varieties are generating some royalties to support OSA's program, public plant breeders, and farmer-breeders, but the long-term financial return is unclear as the limited intellectual property rights may not provide enforcement of royalties by companies who pick up the variety from commercial seed purchases.

Conclusions

Romano provides an excellent overview of the impacts of various release mechanisms on diverse stakeholders. OSA agrees overall with Romano's perspective and in particular that:

1) Utility patents are overly restrictive and should not be applied to public cultivar releases.
2) PVPs are still the best fit for developing economic models to support plant breeding programs while not inhibiting diverse participation in future innovations. However, PVPs are prohibitively expensive for farmers, non-profits, and small seed companies. Other mechanisms and models are needed.
3) The principles of OSSI are important for ensuring broad access to genetic resources and preventing the utility patenting of materials developed for the public commons.

There remains a need for mechanisms of cultivar release that protect genetic resources in the commons and provide models for economic return to support ongoing plant breeding activities. There also remains a need for supporting the development of organic, environmentally beneficial, and minor crops. One potential solution to address this issue would be for the PVP office to provide a sliding scale for PVP licenses to enable broader use. The ability to legally defend OSSI should also be considered for long-term protection of genetic resources pledged through OSSI. It may not be the purpose of OSSI to provide a mechanism for the release and commercialization of cultivars, but the USDA and PVP offices should consider the potential of implementing enforcement mechanisms for OSSI or a similar protection of genetic resources in the public domain.

Thank you to the summit planning committee for the opportunity to comment on these issues and to Elia Romano for his thoughtful and informative coverage of the impacts of intellectual property on stakeholders.