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## Insights into Plant Variety Protection and Variety Licensing

The formal presentation will begin at Noon Eastern

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## Insights into Plant Variety Protection and Variety Licensing

**Speakers:**

**Mojdeh Bahar,**  
*Agricultural Research Service (ARS), United States Department of  
Agriculture (USDA)*

**Paul Zankowski,**  
USDA, Plant Variety Protection Office

January 24, 2017

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**Mojdeh Bahar**  
*Assistant Administrator*  
Agricultural Research  
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**Paul Zankowski**  
*Commissioner*  
**USDA Plant Variety  
Protection Office**



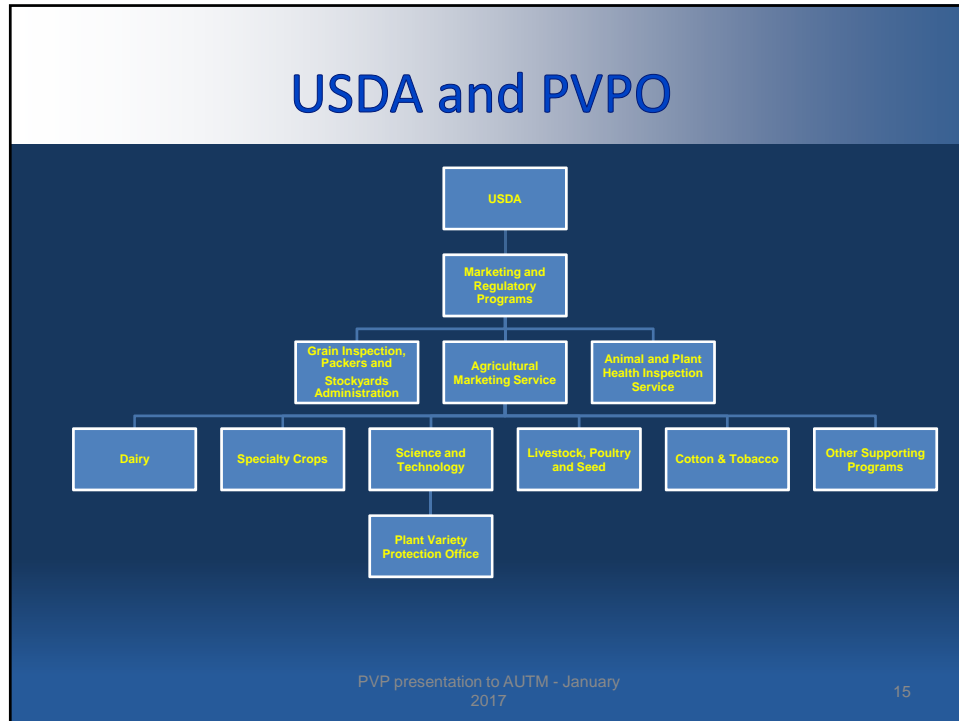

## Plant Variety Protection



Breeders Rights = Farmers Benefits  
USDA is an equal opportunity provider, employer, and lender.<sup>3</sup>

## The Plant Variety Protection Office (PVPO)

- Administers the Plant Variety Protection Act
- Part of the Science & Technology Program of the USDA Agricultural Marketing Service (AMS)
- Completely User Fee Funded
- Located at the USDA Headquarters (South Building) in Washington, DC
- 10 staff members
- Website = [www.ams.usda.gov/PVPO](http://www.ams.usda.gov/PVPO)

## Plant Variety Protection (PVP)

- What is it?
  - Intellectual Property Protection granted to breeders of seed and tuber propagated varieties of plants
  - PVP enables breeders to exclude others from marketing their variety for 20 (25) years
  - A PVP certificate is awarded after a PVP Office examination confirms that a variety is **New, Distinct, Uniform, and Stable (DUS)**.

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## PVP is 1 of 3 types of Intellectual Property Rights Protection Available in the United States

- PVP (1)
  - USDA
  - For seed and tuber propagated plants
- Plant Patents and Utility Patents
  - Commerce Department
  - Plant patents (2) – for asexually propagated varieties (cuttings, grafts, etc.)
  - Utility patents (3)– for any invention with utility (purpose)

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## Differences Between PVP and Patents

The table below highlights some of the differences between PVP and Utility Patents. This information does not constitute legal advice.

	PVP	Utility Patent
<b>Requirements</b>	New, Distinct, Uniform, and Stable	New, Non-Obvious, Useful
<b>Novelty (New)</b>	1 year of sale in U.S. / 4 years sales outside the U.S.	Up to 1 year (for the patent applicant) from disclosure (e.g. sale, public use, publication)
<b>Years of Protection</b>	20 years after issuance - for most plants; 25 years for trees or vines	20 years (can be modified under certain circumstances; e.g. regulatory review)
<b>Protection after Filing</b>	Yes, full protection while the application is pending	Some protection after filing and before issue (see 35 USC 154(d) for more information)

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### Differences Between PVP and Patents

	PVP	Utility Patent
<b>Estimated Filing Costs</b>	\$5,150 – No annual maintenance fee	Varies depending on the patentee corporate size - can range from \$8,000-\$20,000. <b>Maintenance fees required</b>
<b>Essentially Derived Varieties (EDV)</b>	Provides for EDV	No EDV Provision, but claims can protect certain derivative products
<b>International Acceptance</b>	Can be accepted to speed PVP filing in 70+ (UPOV) countries and PVP can be used to establish priority.	Not accepted worldwide

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### Differences Between PVP and Patents

	PVP	Utility Patent
<b>Research for plant breeding</b>	Research is allowed unless excluded by other agreements or patents	No research allowed, depending on issued claims
<b>Farmer Saved Seed</b>	Allowed to use on own farm unless excluded by other agreements or patents	Not allowed, depending on issued claims
<b>Public Usage in a Crisis</b>	Secretary may declare a variety open for public use	No provision

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## Differences Between PVP and Patents

	PVP	Utility Patent
<b>Germplasm deposit requirement</b>	Seed or tuber deposit required (including any propagating material necessary for propagation of a variety) - which only becomes publicly available upon PVP expiration	Seed or propagating material deposit may be required to fulfill a patent's enablement – this material may be available to the public after patent issuance.
<b>Time to Grant</b>	Approximately 1-1.5 years	Approximately 1-3+ years
<b>Who may file</b>	Anyone can file a PVP application including breeders, farmers, and legal representatives	Usually a legal representative that is registered to practice before the Patent Office

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## PVP Criteria - New

- **New** = variety hasn't been **sold** for
  - more than 1 year in the U.S.
  - more than 4 years outside the U.S.
- "Sale Clock" starts when propagating or harvested material have been sold
- Two exceptions:
  - 1) if the variety was transferred/sold to determine its unique features
  - 2) if the variety was transferred/sold to increase supply



2013

2014

2015

2016

2017

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## PVP Criteria - Distinct

- Clearly different from all varieties of common knowledge
- Difference needs to be consistent and clear.
- “Currently” differences in molecular marker profiles cannot be the sole basis for distinctness – but can be used as supplementary evidence
- Examples:
  - a variety that produces violet flowers would be clearly distinguishable from a similar variety that produces pink flowers

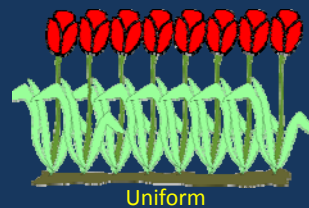
Example of 3 Distinct Tomato Varieties



Each row is a distinct variety based on a combination of fruit shape and size

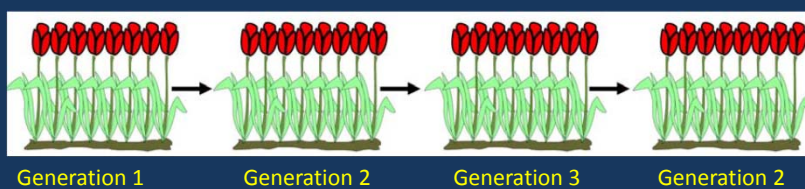
## PVP Criteria - Uniform

- All plants of the variety look alike
- Any variations
  - Describable
  - Predictable
  - Commercially acceptable



## PVP Criteria - Stable

- Stable = true to type



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## PVP Benefits

- For Breeders:
  - Protects breeder's right for their varieties
  - Breeder Friendly
  - Allows for the establishment of mutual priority with other countries
  - Low overall cost



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## PVP Benefits

- **For Plant Breeding:**
  - Internationally accepted by over 70 countries
  - Protects the breeder's rights but also allows research in new variety development
  - Provide dispute resolution



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## PVP Benefits

- **For Society:**
  - Encourages new variety development
  - Provides a farmer's right to save seed
  - Creates an incentive to find ways to increase food production
  - New varieties are important in improving rural income and overall economic development



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## PVP Exemptions

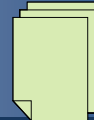


- Crop or Farmers Saved Seed Exemption - Seed can be saved for use on a farm but NO transfer to others for reproductive purposes  
*PVP Act Sec. 113. Right To Save Seed; Crop Exemption*
- Research Exemption: Others can use the variety in plant breeding or other research  
*PVP Act Sec. 114. Research Exemption*
- Public Use in case of National Emergency - the Secretary of Agriculture may declare a protected variety open to public use, when the Secretary determines that such declaration is necessary  
*PVP Act Sec. 44. Public Interest in Wide Usage*

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## How To Apply for Protection:



- The owner of a variety submits an application describing its characteristics and compares it to a similar variety or varieties
- The application must contain information that shows the variety is New, Distinct, Uniform and Stable.
- The application form, required fees, and information about how to apply can be found at [www.ams.usda.gov/PVPO](http://www.ams.usda.gov/PVPO)
- Germplasm (seeds or tissue culture for potatoes) of the variety is deposited at an approved repository as part of the application

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## Applicants Provide

- Complete PVP Application (ST470) Form and the Following Variety Development Information (= PVPO's exhibit A)
  - A full disclosure of the breeding history including the breeding method and stages of variety selection;
  - A statement of **uniformity** reporting the level of variability in any characteristics of the variety (commercially acceptable variability is allowed);
  - A statement of genetic **stability** showing the number of cycles of seed reproduction for which the variety has remained unchanged in all distinguishing characteristics;
  - The type and frequency of genetic variants observed during reproduction and multiplication.

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## Applicants Provide

Variety Information (= Exhibit B) to establish the applicant's basis of distinctness

General Format:

- Compares the **MOST SIMILAR** comparison variety or varieties to the **APPLICATION** variety
- State traits and values to distinguish
- Provide evidence:
  - Differences are clear, uniform, stable
  - 2-3 generations of statistical evidence
  - Color chart readings

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## Applicants Provide

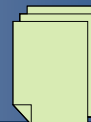
Variety Descriptive Information (Exhibit C) using PVPO provided crop specific form

- PVP Office examines the exhibit C responses
- Ask the breeder questions / more details if discrepancies occur
- PVP Examiners
  - enter the variety's descriptive data into a crop specific database
  - conducts a distinctness search against all the varieties in that crop database
  - confirm distinctness

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## PVP Fees



\$518	Filing Fee
\$3,864	Search/Examination Fee (Both paid together)
\$768	Certificate Fee (paid when issuance is allowed)

TOTAL = \$5,150

Other typical fees may include extension, reconsideration, and late fees

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## How Protection is Granted

1. The PVPO accepts PVP variety applications - both electronic (email, fax and soon ePVP) and hardcopy are accepted
2. PVP examination team
  - reviews the application for completeness, ownership, signatures; and
  - makes a determine if the new variety is new, distinct, uniform and stable
  - Verifies that other application information is consistent:
    - Genealogy or Breeding History – Parents and crosses made to create the variety
    - Selection criteria – what the breeder was selecting for during the variety's creation.
3. After thorough examination and determination that all requirements are fulfilled a certificate of protection can be issued

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## PVP Priority Contests, Protest Proceedings, and Appeals



- Priority Contest = The PVP process for determining the question of priority between two or more parties claiming development or discovery of the same novel variety.
- Protest = The opposition by any person to the granting of PVP while the application is pending and within the first 5 years following issuance.
- Reconsideration / Appeal to the Commissioner = The reconsideration following an adverse action by a PVP examiner.
- Appeal to Secretary = The reconsideration to the Secretary following a denial by the Commissioner

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## PVP Enforcement

- It's the responsibility of a variety owner to enforce their PVP right
- It's an infringement to perform any of the following acts without the authority of the variety owner:
  - Sell or market the variety
  - Import into or export from the U.S.
  - Multiply the variety for marketing
  - Use the variety to produce a hybrid
  - Condition the variety for propagation
  - Stock the variety

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## PVP Statistics

- Overall PVP Certificates Issued since 1970: 11,100
- Average Number of Incoming Applications per Year: 480
- Crops Examined: >180
- Top Incoming Crops: soybean, corn, wheat, cotton, potato
- Top Applicants: DuPont-Pioneer, Monsanto, Syngenta
- PVP Application Processing Time: 1.4 years
- Current Application Inventory (Backlog): 230

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## PVP Board

- 14 advisory board selected by the Secretary
- Representatives from the seed industry, public institutions, and farmers
- Provides advice on
  - PVP Regulations and Fees
  - Appeals to the Secretary
  - Questions about making a protected variety open to public use
- The 2015-2017 PVP Board will expire in May 2017 - the PVPO is soliciting nominations for the 2017-2019 Board

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## Current PVP Issues

- Interface between PVP and UPOV
  - The U.S. PVPO and PTO regularly attend UPOV sessions
  - UPOV's Electronic Application System
  - Molecular Markers for PVP
- U.S. PVP Cooperation with other countries
  - EU
  - Canada
  - South America

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## Discussion

Questions?

or contact Paul Zankowski at

Email: [paul.zankowski@ams.usda.gov](mailto:paul.zankowski@ams.usda.gov)

Phone: 202-720-1128


Breeders Rights = Farmers Benefits

USDA is an equal opportunity provider, employer, and lender.<sup>41</sup>

# Insights Into Plant Variety Protection and Variety Licensing

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AUTM Webinar  
*January 24, 2017*



Mojdeh Bahar, J.D., M.A., CLP  
Assistant Administrator  
Office of Technology Transfer

## Road Map

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- Type of Legal Protection for Plants
- Criteria for Seeking Protection
- Quick Refresher on Plant Patents and Examples
- Quick Review of Utility Patents (for plants) and Examples
- Context at USDA-ARS
- Commercialization Models: 1, 2, 3 & 4
- License Revenue Distribution
- Q&A

### Plant & Utility Patents

U.S. Dept. Commerce-  
U.S. Patent & Trademark Office

<http://www.uspto.gov/web/offices/pac/plant>

### Plant Variety Protection Certificate

U.S. Dept. Agriculture-  
Agricultural Marketing Service

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STE LDEV3002796>

## Types of Protection for Plants

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- Cultivar protection
  - ✓ Plant Patent
  - ✓ Plant Variety Protection Certificate
- Traits, genes, plant parts, etc.
  - ✓ Utility Patent

## Cultivar Protection in the US

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Asexually propagated plants: **Plant Patent**

Sexually propagated plants:  
**Plant Variety Protection Certificate**

## What, if any, type of protection should be sought?

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- How is the cultivar different from and/or better than the closest currently available cultivar?
- Would protection likely play a significant role in making the cultivar available to growers and consumers beyond what could be achieved through public release?
- Is protection needed to maintain genetic identify or to assure the appropriate maintenance of unique traits, such as high oleic acid soybeans? For seed propagated crops, what class of certified seed is required?
- What is the point of view of key stakeholders, such as commodity groups, growers, university partners, seed companies, and nurseries, regarding protection.
- Is there current commercial interest in marketing and producing the cultivar for sale or a high probability of commercialization in the future?
- Is the potential market for the cultivar of sufficient size to warrant protection?
- Is foreign protection needed?
- If co-owned, what is the co-owner's opinion?

## Plant Patents (PP)

35 U.S. Code §§161-164

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- Asexually reproduced plants (not including tuber propagated plants)
- Variety must be new, distinct, & stable
- Variety has not been sold or released in the US more than one year prior to the date of the application.



## Plant Patents (PP) cont'd

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- Right to exclude others from making, using, selling, offering for sale and importing the plant, or any of its parts
- Protects a single plant and asexual progeny for 20 years
- Allows use as parent in breeding new varieties

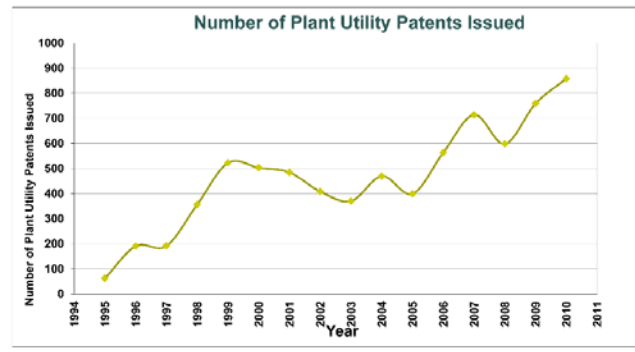
## PP Exemptions

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- Crop Exemption or Farm Saved Seed: NO
- Breeding Exemption: YES



## ↑ New Plant Varieties and Technologies



## Utility Patents (UP)

35 U.S. Code § § 111 (101,102,103,112)

- Must be **ELIGIBLE** subject matter: process, machine, manufacture, or composition of matter (Sec. 101)
- Claims must be **NOVEL** and **NON-OBVIOUS** to one of ordinary skill the art (Sec. 102 & 103)
- There must be a sufficient written description with **DEFINITE** and **ENABLED** claims (Sec. 112)

## UP (cont.)

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- Right to exclude others from making, using, selling, offering for sale, and importing the patented technology in the granting territory for 20 years after the effective filing date
- Possible to protect cultivars having specific traits, plant parts, and methods of producing or using plant cultivars

## UP Examples Related to Plants

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- Particular traits
- Whole plants expressing a particular trait
- Plant parts, components or products with particular trait
- Methods of producing or using plants/varieties, including plant breeding methodologies

## Utility Patents: Breeding Examples

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- 5,523,520 Mutant dwarfism gene in petunia (Goldsmith Seeds)
- 5,824,864 Maize gene and protein for insect control (bt Pioneer)
- 6,949,698 Gene combinations that alter the quality and functionality of soybean oil (Dupont)
- 6,646,183 DNA encoding for a disease resistance gene from common bean and methods of use (Michigan State University)

## UP: Examples on Breeding Methods

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- 8,991,098 Method for improved plant breeding method for high throughput analysis of plant phenotype and genotype (BASF)
- 8,996,318 Using oligonucleotide microarrays to analyze genomic differences for the prediction of heterosis  
Structural variation analyzes of the genome are used to predict the degree of a heterotic phenotype in plants (Pioneer)
- 6,946,586 Genetic trait breeding method method for screening for a trait associated with the altered gene expression (Mendel)

## UP: Examples of Conventional Cultivars

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- 6,828,493 B1: Wheat Variety 25R47  
Conventional soft red winter wheat cultivar  
(Pioneer)
- 8,309,830 B2: Wheat Variety Ruby  
Conventional soft white winter wheat cultivar  
(Michigan State University)

## UP Exemptions

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- Crop Exemption or Farm  
Saved Seed: NO
- Breeding Exemption: NO

## Cultivar Protection Outside the US

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- International Union for the Protection of New Varieties of Plants (UPOV)
- **Plant Breeder Rights** is the equivalent outside the US of a Plant Variety Protection Certificate and a Plant Patent
- Done on a case-by-case basis, generally at the request of the licensee

## Metrics-Context

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- About 40% of our PVP licenses are co-owned with a university
- About 52% of our plant patent licenses are co-owned with a university
- About 48% of our plant licenses (PVP and PP) are co-owned with a university partner

## Commercialization Model 1

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- Most common
- Licensing of PVPC, Plant Patent or Utility Patent
- Licenses can be non exclusive or exclusive, determination is made on a case by case basis
- Examples:
  - Elkton Potato
  - Sunpreme
  - Black Pearl



### 'Elkton' Chipping Potato

- Resistance to Internal Heat Necrosis
- Suitable for chipping directly from field in southern locations

1. Solely owned by USDA-ARS, further tested under a CRADA, and protected by USDA Plant Variety Protection (PVP).
2. Exclusively licensed to a for profit company.
3. The PVP protects the commercial investment in the production of pathogen-free stock for a small, but very important, segment of potato farmers.



#### 'Sunpreme' Raisin Grape

- Dries on the vine naturally
- Pruning easier than typical grapes
- Raisins larger and fruitier in flavor than classical raisins

1. Solely owned by USDA-ARS and protected by USPTO Plant Patent.
2. Non-exclusively licensed to for profit companies.
3. The USPTO Plant Patent protects the commercial investment to redesign commercial production protocols for raisins.



#### 'Black Pearl' Pepper

- Unique black foliage
- Vigorous upright bushy grow habit
- Round, black fruit maturing red with very hot flavor

1. Solely owned by USDA-ARS, further evaluated under a CRADA, and protected by USDA Plant Variety Protection (PVP).
2. Exclusively licensed to a for profit company.
3. The PVP protects the commercial investment in marketing to consumers a new type of ornamental plant.



## Commercialization Model 2 USDA / University Arrangement

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- Many USDA plant breeders are co-located on University campuses. Long-standing arrangement between USDA and University for USDA plant breeders to utilize University infrastructure and resources.
- Historically, many USDA and University plant breeding programs are coupled where USDA primarily does germplasm enhancement and the University primarily does cultivar development.
- USDA no longer does seed increase or plant indexing and relies on University Foundation Seed Services (produces breeder / foundation seed) and Foundation Plant Services (produces disease-tested plant propagation material).

## Commercialization Model 2 USDA / University Arrangement...cont'd

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- Co-owned Cultivar  
Generally, USDA takes the lead in protecting the co-owned cultivar and the University takes the lead in licensing the co-owned cultivar.
- USDA solely owned Cultivar  
USDA protects solely owned USDA cultivars. The University MAY take the lead in licensing solely owned USDA cultivars that are developed on their campus. A Federal Register Notice is required.



'Cara's Choice'  
Rutgers University & ARS



'Vernon'  
University of Georgia &  
ARS



Pinto Bean  
North Dakota State  
University & ARS



Peach 'Gulfsnow'  
University of Georgia,  
University of Florida & ARS



Peach 'Gulfcrimson'  
University of Georgia,  
University of Florida & ARS

### Commercialization Model 3

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- USDA and 3 public universities developed many different variety of potato
- All entities are co-owners
- A non-profit entity is in charge of marketing, licensing, industry interaction and royalty collection
- Established to enhance the impact of the collaborative research



Potato 'Clearwater Russet'



Potato 'Alturas'

## Commercialization Model 4

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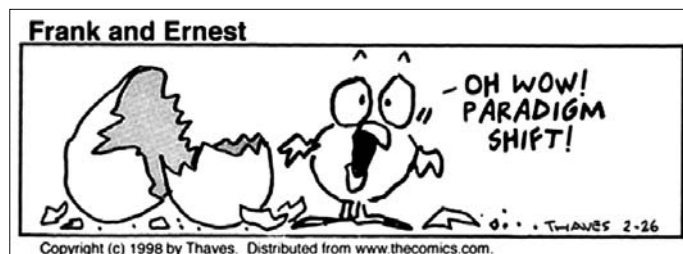
- Partnering with our university partner who partners with a non-profit organization that based on an MOU offers foundation seed services and seed certification services and has actively produced and sold seed
- USDA scientists are co-located with and collaborators of the University
- Non-profit has licensed many of USDA varieties

## Licensing Revenue Distribution

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- Co-breeder's Institute/Company
- ARS
  - ✓ Inventor(s) incentive award
  - ✓ OTT operating expenses
  - ✓ Innovation Fund


- Determine if you have freedom to operate
- Develop evaluation strategy
- Develop release strategy
- Protection the IP



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# Questions? Comments?



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# Discussion and Q&A

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- Basics of Technology Transfer for Licensing Professionals
  - Basic Patenting 101
- Copyright Law and Content/Software Licensing
  - Equity Based License Agreements
  - Financial Conflicts of Interest
- Marketing: Whether By Traditional or Social Media, the Value Need to Know Basics of Technology Transfer for Support Staff
  - Negotiation of License Agreements
- Nuts and Bolts for Compliance Under Federal Funding Awards
  - The Basics of Open Source Licensing
  - Tips for Managing MTAs
  - Triage
- Valuation of Inventions and Patents
  - (More Added Monthly)

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### AUTM Region Meetings



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July 10-12  
Swissotel Chicago  
Chicago, IL

**Registration Opens in April!**



**AUTM Eastern Region Meeting**

October 2-3  
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August 29 – 30, 2017  
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## AUTM 2017 Annual Meeting

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## AUTM Professional Development Programs

### Have an Interesting Topic?

The Online Professional Development Committee is seeking proposals and speakers for potential webinars.



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## Get Involved

**We need your help. The Online Professional Development Committee is seeking professionals interested in joining their committee.**



**Interested? Please contact  
Barb Gunderson at  
[bgunderson@autm.net](mailto:bgunderson@autm.net)**

