

Plant Variety Protection (PVP) Board Meeting Minutes – December 7-8, 2015

USDA Plant Variety Protection Office (PVPO)  
Water Tower Room of the Hyatt Regency Chicago Hotel  
151 East Wacker Drive  
Chicago, IL

Board Members attending (with affiliation):

Charles Brown; Brownseed Genetics, LLC  
Joonhyung Cho; University of North Carolina at Chapel Hill  
Eloy Corona; Bayer Crop Science LP  
Emily Dierking; Indiana Crop Improvement Association  
John Duesing; DuPont Pioneer  
Elizabeth Lee; University of Guelph  
Stevan Madjarac; Monsanto Company  
Jose Re; RiceTec, Inc.  
Wendell Shauman; Shauman Farms  
Bernice Slutsky; American Seed Trade Association  
Katherine White; Wayne State University  
Alternate: James Sutton, Georgia Department of Agriculture

Absent:

Jianli Chen; University of Idaho  
Danielle Conway; University of Maine  
Jose Costa; USDA/ARS  
Alternate: David Burns, Burns' Farms, Inc.

USDA staff:

Ruihong Guo, Deputy Administrator, USDA/Agricultural Marketing Service (AMS)  
Science and Technology Program  
Paul Zankowski; Commissioner PVPO  
Jeff Haynes, Deputy Commissioner, PVPO

Others Attending:

Marymar Butruille, Monsanto  
Amy Curtis, Monsanto  
Stephanie Greene, USDA-ARS NCGRP  
Lorne Hadley, Canadian Plant Technology Agency  
Pam Howlett, Monsanto  
Susan Jayne, Dow Agrosience  
Brad Kurtz, DuPont Pioneer  
Ricardo Machado, Brazil PVP Office  
Mariana Menoni, Uruguay National Seed Institute  
Paul Nelson, Monsanto  
Anthony Parker, Canada PBR Office

## Plant Variety Protection (PVP) Board Meeting Minutes – December 7-8, 2015

Rodolfo Rossi, Nidera Seed Company  
Fabricio Santos, Brazil PVP Office  
Karen Stevenson, University of Iowa  
James Weatherly, Seed Innovation Protection Alliance

### Call to Order, Introductions, and Opening Remarks

Opening remarks were made and the meeting agenda was adopted. The three main functions of the Board were discussed.

### PVP 2015 Accomplishments

A report describing the PVPO's accomplishments, application processing, incoming application overview, 2016 budget, and the 2016 Business Plan was reviewed. In 2015 the PVPO received 502 new applications and processed 514 resulting in 335 applications left in the inventory. The average application processing time was reduced from 2.3 years in 2014 to 1.6 years in 2015. Also the average weekly PVP application inventory was 326 applications in 2015 compared to 464 average applications in 2014.

In 2015 three PVPO examining staff began serving on the Small Grains, Grass/Sunflower, and Soybean/Alfalfa/Legumes variety review boards. PVPO staff traveled to 3 different crop field trials to observe and gain a better understanding of plant breeder's issues during the variety development process and gained practical experience in PVP field trial observations. The PVPO also established partnerships with external parties to fund the staff's participation at 1 domestic and 4 international stakeholder events after undergoing a USDA Ethics review.

### PVP 2016 Business Plan

The PVPO will actively process PVP applications by examining at least 450 applications to maintain the inventory below 400 for the year and will reduce the average application processing time by 5%. The Office will move the electronic PVP (ePVP) system forward by 1) developing a plan to refresh data for crops that have a Microsoft Customer Relationship Management (CRM) database, 2) implementing a plan for entering non-PVP variety records into the CRM database, and 3) devising a plan for crops that do not have a database. The Board asked if CRM would be available for public searches – currently CRM will be for internal PVPO use, but in the future public searches may be possible.

The PVPO will explore customer payment account options by 1) looking into establishing an applicant deposit account for PVP users to withdraw fees and 2) inquiring about additional payment options that provide more efficient fee payment.

## Plant Variety Protection (PVP) Board Meeting Minutes – December 7-8, 2015

The PVPO plans to improve customer services by 1) streamlining the potato application process and 2) improving the PVPO's variety name verification process in conjunction with the USDA Seed Regulatory and Testing Division and European Union's (EU) Community Plant Variety Office (CPVO). The Board suggested that the PVPO posts this type of information on its website – including changes to its procedures and to let PVP users know useful facts. It was also suggested that the PVPO improve its website Frequently Asked Questions (FAQ) page.

The PVPO will leverage the PVP Board to address program challenges to strategize on PVPO's future and to better establish a strategic vision. The PVPO will also hold brainstorming sessions for its staff to help develop a future strategic vision.

The PVPO will improve domestic outreach by 1) conducting quarterly meetings with the U.S. Patent and Trademark Office (PTO), 2) participating in intellectual property association meetings in conjunction with the PTO, and 3) reaching out to intellectual property rights offices of major universities. The Board mentioned that university licensing managers often overlook PVP as a form of intellectual property protection and that there may be an opportunity to improve PVP's understanding with better interaction with university plant breeders and licensing offices. It was commented that small independent breeders who don't have access to intellectual property rights (IPR) lawyers might benefit from a better understanding of the PVP process.

The PVPO will continue the promotion of the PVPO as a worldwide leader by continuing to work with international partners to increase PVP cooperation / acceptance of examination results, and by being actively involved in the UPOV Electronic Application System (EAS) for lettuce, soybean, and potato.

The PVPO plans to expand the staff's expertise by 1) developing their ability to present information about the US PVP program and 2) providing the staff with online and classroom training opportunities on the use of molecular markers in PVP. The Board asked how molecular training would be accomplished – the PVPO will reach out to the seed industry, university (UC Davis Seed Biotechnology Center), and USDA partners to develop a training program. The PVPO will also develop learning criteria for its staff to become competent in DUS field trial observations during crop tours.

The Board asked how the PVPO benchmarks its business plan versus its goals – the Office conducts quarterly and yearend reviews of each goal/accomplishment. The Board asked how the PVPO will measure if it accomplished university outreach – this is done by reviewing the action plan results especially – who reaches out, which university, and how many different universities.

Electronic PVP Application System (ePVP) Update

The ePVP Application was initially completed in April 2014 with a migration of data for the PVPO's top 55 crops; however migration errors occurred with the transfer of data from the PVPO legacy 31 year-old STAR database to the new Microsoft Customer Relationship Management (CRM) database. The initial ePVP goal was to launch in April 2014 but the data was not accurate and the portal setup was not user friendly. The PVPO and the Information Technology Service staff worked on solutions to correct these errors and to complete a clean migration of a 28 crop subset (including soybean, pepper, peanut, bean and 24 other crops) with data refreshment. The first phase of the new ePVP system was released December 18, 2015 with the PVPO's examiner variety distinctness search process switched from the legacy STAR database to CRM for those 28 crops.

The next ePVP steps will encompass additional programming to include non-PVP variety records and to migrate an additional 19 crop databases that had minimal migration errors. A third release of the software will require additional programming in CRM and will include the last 8 crops. Crops that are not included in the 55 crop database are either infrequent user of U.S. PVP or are new crops where a database has not been developed yet. Crops without databases will be examined manually. Releases 1 – 3 of the ePVP system will each involve a migration step and an examination switch from the old database to the new system. Our current plan is to completely switch all crop examination to the new ePVP system within the next two years.

The Board commented that the PVPO should be congratulated on the migration from the STAR database to CRM. The PVPO wants the Board and seed industry to be comfortable with the ePVP system and its application. The PVPO also decided not to do another contract to migrate incorrect or new data but instead manually entered the data for 375 applications.

The Board asked if the ePVP could accommodate molecular marker data – there are extra fields that could accommodate this data. The Board also commented that the PVPO's ePVP experience could be shared with others such as the Seed Association of the Americas (SAA) countries. The Board mentioned that PVP applicants might already have data in an electronic format that could be provided to the PVPO instead of needing staff to manually enter data.

Seed Association of the Americas (SAA) and International Union for the Protection of New Varieties of Plants (UPOV) Updates

The PVPO was active in SAA meetings held in Argentina – May 2015 and Mexico – September 2015 and participated in discussions on cooperation among SAA countries regarding electronic PVP application systems and the use of molecular markers.

The PVPO has been very active in the Geneva UPOV meetings in conjunction with the U.S. Patent Office (PTO) as well as the Vegetable (TWV meeting - France – June 2014) and Molecular (BMT meeting - Korea – November 2014) meetings.

UPOV Electronic Application System (EAS) Update

The goal of the EAS project is to develop a multilingual electronic form containing questions important for each participating country's PVP applications. As a first step UPOV developed a prototype electronic (lettuce) form that covered all the information required for a PVP application for those interested UPOV countries and with questions translated into the relevant languages. The next steps for UPOV will include payment, different languages, adding other crops (potato, rose, apple, and soybean), testing communication with existing and external systems, and security requirements. UPOV is making excellent progress with the EAS for lettuce; the U.S. has requested that soybean be incorporated into the EAS next. The Board asked if the PTO is participating in the EAS – no the PTO is involved in multiple country patenting using the Patent Cooperation Treaty (PCT) system for utility patents however plant patents can't participate in the EAS or PCT due to its application requirements.

UPOV International System of Cooperation (ISC) Proposal

The ISC proposal as put forth at UPOV focused on systematizing the filing and initial processing of PVP applications while reserving the final decisions on grant and term of the right to each UPOV member country. The initial goals of the ISC were to streamline international PVP filing and to maximize the effectiveness of PVP worldwide

Under this system the UPOV Office would administer the system and collect administrative fees. UPOV would accept an application form and technical questionnaire information for all selected UPOV members via its EAS. The process would have an applicant selecting 1) the UPOV members in which to make an application, 2) a preliminary examination office, and 3) a DUS examination office.

The role of a Preliminary Examination Office would be to make a determination of novelty and variety denomination. This would not be a DUS (distinct, uniform, stable) test. The role of the DUS Examination Office would be to perform specific variety DUS

trials or examinations and report their findings to the specific UPOV members. Each UPOV member would have the final decision on the grant and term.

In order to gain a better understanding of an ISC from PVP users UPOV conducted a survey among 61 respondents from the International Seed Federation, International Community of Breeders of Asexually Reproduced Ornamental and Fruit Varieties, and CropLife encompassing 21 countries. There was no clear pattern from respondents on their potential use of an ISC. It was mentioned that the survey would need to encompass many more companies and countries.

The Board asked if the timing to file PVP priority is a consideration within the ISC – no, it was more a consideration of countries accepting each other DUS results as equivalent. It was also stated that each country has specific requirements such as having an in country representative that might not work under an ISC.

UPOV indicated that several concerns arose following the survey around the issues of 1) sovereignty, 2) breeder representation, 3) the number of applications to be received, and 4) the economic viability for UPOV. For Sovereignty - it was explained that an ISC would not affect the grant and protection of breeders' rights since each UPOV member would decide whether to participate; furthermore an ISC should not be expected to result in a single DUS examination being sufficient for all UPOV members and for all species. For Breeder Representation – UPOV explained that survey respondents were predominantly looking at agricultural crops, vegetables, ornamentals, fruits – based on responses from 21 countries and applicants generally filing 1-9 PVP applications within 6-10 UPOV countries. For the Number of Applications – the survey indicated that 39% of respondents made applications in all UPOV countries for which those varieties had value for farmers/growers and that this project would be Economically Viable for UPOV since only 480 applications at 500 Swiss francs/application would be required for UPOV to break even. UPOV discussed the establishment of an ISC Working Group to explore questions and topics further.

It was mentioned the ISC would act as a venue for multiple PVP applications but that cost savings would arise from process streamlining and DUS examination cooperation, especially for asexually propagated ornamentals. It was also suggested that there would be a net increase in overall incoming PVP applications resulting from an ISC.

The Board recommended that the U.S. delegation to UPOV continue to support the ISC proposal and that the U.S. should be part of the ISC Working Group. The Board also discussed that molecular markers may offer a good ISC alternative to field trial DUS

determination and could become an international basis for DUS arising from one country.

The Board discussed that there are 2 unique factors for U.S. PVP – the PVPO doesn't conduct DUS trials and the full PVP payment is made upon certification (no annual fees); an ISC may force the PVPO to change to fit into an international PVP system.

The Board asked about the status of the U.S. lead representation to UPOV by the PTO – and that this should be discussed with the PTO since UPOV issues focus on PVP, not patents. It was mentioned that there is statutory language that establishes the Director of the PTO office as the U.S. representative on intellectual property matters. The Board wanted to know if there is a MOU between the PTO and PVPO regarding UPOV representation – there appears to be none. The Board reiterated that it is critical that the PVPO participate in as many UPOV functions as possible.

### Molecular Markers in the Context of PVP

Applicants for U.S. PVP are required to distinguish their variety from similar varieties using one or more identifiable morphological, physiological, or other characteristics; under this definition - molecular markers can be considered as an “other” characteristic. The PVPO has not used markers as the sole determinant for distinctness, however some PVP applicants have used molecular markers as supplemental data to help distinguish their variety from other similar varieties. Molecular markers are unique sequences of DNA that can be found with probes that identify the discrete order of these DNA pieces occurring somewhere in the genetic language (genome) of a plant.

The types of molecular markers can include isozymes, RFLP – Restriction Fragment Length Polymorphism, SSR -- Simple Sequence Repeat (also referred to as microsatellites), RAPD -- Randomly Amplified Polymorphic DNA, AFLP – Amplified Fragment Length Polymorphism, and SNP – Single Nucleotide Polymorphism. Molecular markers are identified with a complementary DNA probe that binds to a unique sequence of DNA

### Joint PVPO/ASTA Joint Molecular Marker Subcommittee Update

Background - During the December 2014 PVP Board meeting – the Board recommended that “the PVPO should accept molecular marker similarities in deciding on distinction between varieties, in cases where the new variety is facing a phenotypic tie with existing PVP varieties”. The Board’s Molecular Marker Subcommittee was established in the fall of 2013 and merged with the ASTA Corn Variety Identification

Subcommittee in 2014 to form the Joint Molecular Marker Working Group (WG). The PVPO has asked the subcommittee to further clarify this recommendation – by establishing scientifically acceptable data and thresholds for the pairwise comparisons.

John Duesing summarized the activities of the WG. International and national PVP institutions have supported marker use as part of the PVP process since there are clear benefits from incorporating markers into the process. Each international PVP Office or Agency (e.g. France – GEVES and South Korean PVPO) is deciding how to use molecular markers. Determining how to use markers for PVP requires planning, investment, resources, and time. Furthermore, incorporating markers into the PVP process may require PVPO policy and protocol changes. The objective of the WG is to determine how to make the PVP marker process as simple as possible with minimal impact on the PVP applicants and the PVPO.

The value of markers in the PVP process include that they are 1) quick, precise and reproducible, 2) not influenced by environmental conditions, 3) additive to morphological characteristics, 4) able to resolve phenotypic ties, and 5) have the potential to reduce time / costs for applicants and the PVPO. Markers also provide a tool to judge the “distance” of one variety from another based on the underlying genomic condition.

Markers have the power to define differences at the genomic level for two varieties that appear morphologically the same. This is important since the germplasm base for many different crops is relatively narrow especially for varieties developed by one company. Markers can be added to the PVP process for use as “tie breakers” when morphology is inconclusive (i.e., phenotypic ties) and to prove distinctness when no morphological differences exist.

The incorporation of markers into the PVP process has been discussed through the WG by 1) aligning on when to use markers and which markers to use, 2) defining and aligning on respective roles of the PVPO and applicants, 3) specifying the procedures and protocols for analysis, and 4) agreeing on the standards for transmitting marker outcomes. There will be planning and work required for the PVPO to be ready to accept and analyze marker data.

The WG has been focusing on a crop-specific, standard SNP marker set (on a chip) that is being developed based on recent and current U.S. germplasm. The WG is aligning on 1) the percent marker difference (threshold) required for that variety to be judged as distinct and 2) to be judged as not “essentially derived”. It was commented that markers could have been proprietary for each company, but the WG is focusing on a standard

set of crop specific public markers. There is a plan for the recommendations to come from the WG for both corn and soybean by June 2016.

It was commented that there would be different marker thresholds for each crop and that markers may not be beneficial for some minor PVP crops. The Board asked how distinctness differs with regards to essential derivation – it was answered that essential derivation was more important for between company differences versus within a single company.

In order to establish a readiness for markers in PVP – there may need to be a policy for when and how molecular markers should be used for phenotypic ties between companies and within a company. Policy recommendations will come from the ASTA IPR Committee and will be communicated to the Board. Important considerations are that 1) marker usage for PVP should be voluntary, 2) shouldn't be cost prohibitive, and 3) the markers should be publicly available. The instances of morphological ties is becoming more common both within the U.S. and other countries because the morphological characteristics may be limiting. It was asked if international germplasm was incorporated in current U.S. analyses – no, however germplasm from outside the U.S. would most likely have morphological differences that could be used for distinction; the best use of markers is for a narrow germplasm base.

In summary markers are an important additional tool for PVP use. Markers are being validated for use with corn and soybean by the WG. The PVPO is already receiving and considering markers for soybean. Policy and protocol changes will be required to use/analyze markers. The PVPO needs to prepare for readiness to implement and use molecular markers. Reporting of markers as a percent difference from the most similar variety versus actual raw marker data – is the simplest way to provide a meaningful difference to the PVPO.

#### The Canadian Plant Breeders' Rights System and Opportunities for Cooperation

Anthony Parker, Commissioner of the Canadian Plant Breeders' Rights (PBR) Office described the Canadian PBR system. In Canada the PBR holder has a right to protect their variety in the marketplace and receive fair remuneration (royalty) for their innovation. Royalties are charged from fees embedded in the price of certified seed or for ornamentals based on every plant sold. Increased harmonization with other PVPOs has encouraged foreign breeders to protect and release varieties in Canada.

Canada's PBR Act was first passed in 1990 and was based on UPOV 1978 convention. The PBR Act was amended to conform to UPOV 1991 on February 27, 2015 and

## Plant Variety Protection (PVP) Board Meeting Minutes – December 7-8, 2015

Canada ratified UPOV 1991 on June 19, 2015 becoming bound by the Convention on July 19, 2015. The PBR Office communicated the benefits these changes to producers. All plant species have been eligible for protection in Canada since December 1998, except bacteria, algae and fungi. Having PBR legislation based on a UPOV Convention fulfills Canada's World Trade Organization (WTO) obligations with regards to Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement Article 27.3(b); "an effective sui generis" form of protection. Canada has played an active role in the UPOV TWA, TWF, and TWO working groups.

Canada has a breeder based DUS testing system but breeders can also arrange for a trial coordinator to conduct the testing on his/her behalf (usual foreign applications). Breeders conduct the majority of the DUS trials for agricultural crops whereas for fruit crops many DUS trials are done by trial coordinators. Most of the ornamental DUS trials are conducted by 2 private DUS testing companies and private DUS testing company specializes in potato trials. The PBR Office provides breeders and trial coordinators with crop specific Technical Guidelines (TG) before they initiate trials (Canada follows the UPOV established TGs). It was commented that under its current requirements DUS trials must be conducted in Canada, except that one year of a foreign DUS trial may substitute for one of the two required Canadian trial years.

Canadian PBR examiners visits all trials to confirm they are conducted properly and that the new variety is distinct and uniform (approximately 250-300 visit per year during June through August with about \$40,000 in travel). The Examiners take observations, measurements and notes on the distinguishing characteristics and confirms that the reference varieties were appropriate. The breeders/trial coordinators also submit complete variety descriptions and comparative photos to PBR Office. The PBR office doesn't view its function as regulatory, but rather as case workers to help applicants meet the requirements of the PBR legislation.

The Canadian PBR Office also publishes Plant Varieties Journal (PVJ) quarterly which lists all recent grants of rights, accepted, rejected, withdrawn applications and detailed description with photos for all varieties in DUS trials. There is a 6 month objection period (novelty, DUS, reference varieties, etc.) following the publication date in the Journal after which the application moves to the DUS phase and then another 6 month objection period occurs. The objection period provides an opportunity for input from other experts for public scrutiny; if no objections occur then the variety is eligible for grant of rights. In the Canadian PBR system – breeders file their application first and conduct DUS trials latter.

Fees for Canadian PBR are \$250 – application, \$750 – examination, \$500 – grant of rights, and \$300 – annual renewal fee. The annual revenue is \$800,000-900,000 and covers the direct costs for operations and 7 employees of the PBR office. The fees have not changed since 1991. The annual fee is useful since it forces the breeder into a decision every year about whether the variety still has value and generates about 60% of the PBR office's revenue. (The annual fee is not charged during the period of provisional protection – but it may be charged in the future to incentivize breeders to move their application ahead.) Potatoes and fruit trees usually continue their PBR for 20 years, whereas cereals only would like 6-8 years – so total annual fees collected vary depending on the crop.

The number of incoming applications have been in the 250-700 range over the past 10 years with about 70% of these from ornamentals. It was commented that Canadian PBR applications may have increased when enforcement was improved. The highest PBR application user are potato, rose, pelargonium, canola, and impatiens.

Possible areas for cooperation with the Canadian PBR Office include promoting intellectual property by raising awareness with breeders on the need to protect their varieties both north and south of the Canadian-US border (if sales are occurring in both countries since there is “leakage of varieties” across borders). Also it is important to cooperate in variety naming in that UPOV Article 20 (5) specifies that “a variety must be submitted to all Contracting Parties (countries) under the same denomination”. Lastly it may be time to look at best practices or systems of recognition to better support the Canadian and U.S. “breeder-run” DUS testing including expanding talk of Canada-U.S. cooperation, sharing DUS test results, and being a model for other UPOV countries regarding breeder-run DUS testing.

It was asked if DUS field trials could be visited by a Canadian examiner when the trial is in the U.S. or accrediting U.S. PVP examiners to visit and approve those trials for Canada. It was commented that the U.S. and Canada have been discussing how to show other countries that the breeder-run DUS testing has quality management in order to create confidence in those test results. The Board asked if the Canadian PBR law had flexibility to use molecular markers – the law does not preclude using markers to assist in establishing distinguishability. Currently Canada will accept molecular markers as supporting data, but it's not accepted as the exclusive information.

It was asked about the Canadian farmer's privilege – Canada created regulation making r authority subservient to the legislation and in future regulations may be created that could put conditions or restrictions on farmer's privilege – including an end point royalty system – this hasn't been exercised yet. It was commented that there is a program in

Canada where farmers give up their privilege by contract – for specific wheat varieties with a wheat midge tolerance gene stewardship program that requires a refuge – farmers are allowed to save seed for 1 generation and use it for 1 year – the farmers have shown 95% adherence.

#### Canadian Plant Technology Agency (CPTA)

Lorne Hadley, Executive Director discussed the functions of the CPTA, It has a mission “to promote an environment within Canada where a robust and globally competitive framework of intellectual property protection is valued and respected” to encourage continued research investment and sustainable innovation, benefiting Canadian farmers, consumers and the plant science industry. (The Seed Innovation Protection Alliance is a similar organization in the U.S.) CPTA was formed in 1997, it is non-profit, with 25 members across Canada, and it only works with field crops. Through monitoring, enforcement and education, CPTA finds and stops illegitimate sellers of protected seed varieties. CPTA’s objective is to change behavior and upon discovery of infringement, it reports to the rights holder, and recommends action. CPTA coordinates enforcement activities; it does not have the authority to enforce PBR. CPTA gathers facts and makes recommendations regarding infringement but the responsibility / authority to take enforcement action rests with rights holder. Damages for infringement – includes the damage for 2 years prior to the infringement plus court allowable costs (investigation/consulting costs and legal fees).

#### Brainstorming on the State of the PVPO and Its Future Direction

##### Background

The current state of the PVPO is good in that the applicant inventory is under control, the ePVP system is well underway, the staff is well trained, the office is exploring cooperation with other countries, and the PVPO is listening to users’ ideas about molecular markers. Ongoing challenges for the PVPO include 1) the relatively stagnant number of incoming PVP applications (450-550), 2) small customer base (3 key customer provide over 60% of the applications, there were 90 different applicants in 2015), 3) continued seed industry consolidation, 4) PVP customers changing their IPR strategy away from PVP to patents, and 5) improving the credibility of U.S. PVP system. In a future state the PVPO is looking at new business opportunities, modification to its fee structure, cooperation through the UPOV ISC, and being competent and ready to accept/examine using molecular markers.

The PVPO has a goal of getting from good to great and creating more financial stability.

The Board members and attendees split into 4 different groups to identify 4-6 key goals that the PVPO should focus on strategically for the next 5 years. Each presented their identified goals Here is a summary of the ideas that were presented:

#### Group 1

- Increase PVP revenue
  - o Focus on public institutions – the PVPO should have a systematic plan to target institutions with breeding programs and functioning licensing programs
  - o Educate technology transfer offices on PVP and connect with agriculture experiment stations, deans of Agriculture schools, and the Association of University Technology Managers (AUTM)
  - o Look into making IPR a part of key public institutions breeding curriculum especially UC Davis (Seed Biotechnology Center)
  - o Fee structure – evaluate if a maintenance fee can be added to the PVP fee structure
  - o Target specific crops with more opportunities – i.e. rice and wheat
  - o Target independent breeders – they attend Independent Professional Seed Association (IPSA), US Testing Network (USTN), and Independent Seed Testing Association (ISTA) meetings
  - o Get PVP into courses where independent breeders go for certification – UC Davis – Breeding 101
  - o Target small company breeders who go to independent ag law firms – these firm often recommend patents over PVP
- Continue with process improvement –
  - o make U.S. PVP more amenable to breeders who want to apply in different countries
  - o structure U.S. DUS testing to be more compatible with other countries' systems
  - o expand molecular marker usage
- Build alliances
  - o Have very clear FAQs
  - o Make the PVP message simple
  - o Explain the difference between PVP and Patents
  - o Continue to participate in international activities – SAA, CPVO, UPOV meetings
  - o Look into developing seed markets in China, Eastern Europe, Southeast Asia to provide advice on DUS testing and examination
  - o Have a US presence at UPOV Technical meetings
  - o Work with other USDA agencies especially FAS and ARS

## Plant Variety Protection (PVP) Board Meeting Minutes – December 7-8, 2015

- Use PVP customers as advocates – “train the trainer” concept
- Leverage the PVP Board as a resource

### Group 2

- Identify key PVP benefits
  - PVP crops have higher value
  - PVP broadens genetic diversity
- Look to way to mitigate PVP’s limitations
  - Farmer’s exemption – extend contractual limits on saved seed
  - Breeder’s exemption – gap on getting commercial licenses
- Assist with PVP enforcement – broaden molecular marker usage
- Virtual marking (currently used for patents) – using website to cover instead direct seed bag labels
- Cost effectiveness – streamline U.S. DUS testing
- Continue with cooperation and harmonization activities especially the EU and the Americas countries – help to identify third party DUS testers that could conduct trials acceptable to the U.S. and other countries
- PVP education, especially about how it increases genetic diversity
- Get more involved inn IPISA, the National Association of Plant Breeders (NAPB), and AUTM

### Group 3

Major challenges include 2-3 major applicants, IPR through patents instead of PVP, fees make the PVP system vulnerable

- Add asexually propagated plants to US PVP through an amendment to the PVP Act
- Change the PVP fee structure
  - Tiered fee structure
  - Annual maintenance fee
- Build stronger ties to seed certification
- Broaden the PVP customer base
- Provide more guidance on conducting DUS tests
- Connect breeders to existing resources (DUS testers, Agriculture Experiment Stations, Universities, etc.)
- Accept other country’s DUS test reports

### Group 4

Envisioning the Future State of PVP (perhaps 2025)

- No next UPOV Convention, instead all countries move their laws to be UPOV 1991 compliant
- Regional harmonization and cooperation (like the CPVO) in

## Plant Variety Protection (PVP) Board Meeting Minutes – December 7-8, 2015

- Americas
- Africa
- Asia (not much cooperation right now)
- Simple electronic filing fully deployed through UPOV or at least regionally
- Reduced applicant costs and resources required to file and to prosecute regionally and globally

The bottom line is increased total global PVP filings

### PVPO Opportunities

- International and regional champion for / model for the use of markers and electronic filing
- Advocate for the ISC – not quick or easy
- Have a venue to bring regional PVPOs together to collaborate on molecular markers (Can all harmonization move to the US model or could the US PVP add something to its system to better align toward other countries? Some countries view the US PVP system as an office action that has not had a field audit – therefore the US data set will be under greater scrutiny.)
- Communicating / training about PVP to students, stakeholders, and lawyers about the process to obtain PVP – may have ASTA involvement to targeted stakeholders (it was mentioned that in Brazil their PVPO has trained professor/agronomy about PVP) – perhaps reach out to land grant and cooperative extension

Comments following these breakout sessions:

The PVPO asked what changes is the seed industry willing to accept for the U.S. PVP system to move closer to other country's systems? There is a balance to meet – smaller companies depend on the US PVP system not changing– instead it was suggested that U.S. PVP should build upon an existing system and offer alternatives that are equivalent. Since the U.S. PVP system is unique perhaps alternatives can be offered to applicants around DUS testing and the use of the database. Perhaps the PVPO could audit DUS tests which would require changing processes and have people with different expertise on staff.

The PVPO asked should it accept foreign DUS results – that would help foreign applicants, but might not help US applicants. It was suggested that there be mutual acceptance of DUS trials using contracting parties to get to the same end point without

overhauling the U.S. system (this might work with specific countries that would accept these results most likely Canada and the SAA countries).

It was mentioned that Canada has used private sector DUS testers who are knowledgeable of both US and Canada requirements. It was suggested the PVPO could identify qualified persons (like the Australian PVPO) with enough experience and knowledge to fulfill the U.S. DUS requirements, make them known to the public, and to audit them as needed.

The Board mentioned that molecular markers also have the potential to reduce costs and resources when the right balance is found. The Board asked at what point could applicants move from 2 seasons or 2 locations for DUS trials to 1 season/1 location by using molecular markers (markers could be used to show both distinctness and uniformity) since this would reduce cost by half. It was commented that if the U.S. adopts 1 season/ 1 location this may deviate from the UPOV guidance and may move the US further out of alignment with other countries.

The PVPO is looking for some “low hanging fruit” perhaps through providing DUS trial guidelines (i.e. how to conduct a DUS trial for U.S. PVP) to create a perception of order and to have audits. The PVPO can also gather information about resources (state universities, research stations, etc.) to conduct DUS trails on behalf of applicants. It was commented that the PVPO may need outreach to convince public institutions about the value of PVP first since they may not appreciate IPR (both PVP and patents) through their technology transfer offices.

The PVPO asked what discrete tasks can the PVP Board members help with to provide the highest value for the Office. The Board suggested focusing on DUS testing and a fee structure to help the application process while elaborating that PVP can be marketed as providing more genetic diversity. The Board also thought that asexually propagated plants should be considered for PVP. ASTA can help on both of these topics and reach out to partner associations. The Board suggested that the Office look to diversifying PVP applications by using its resources wisely - determine where opportunities are and do not invest resources if there isn't a good chance of return on that investment.

The PVPO asked what can PVP Board members do individually – education and outreach to technology transfer. ASTA can reach out to land grant universities. PVP Board members can also act as spokespeople and use a standard presentation on PVP to address audiences during their travels. It was suggested that a communication intern

could improve the PVP outreach presentation. The PVPO asked the Board members to forward any presentations that it had on benefits and value of PVP.

It was suggested that the PVPO keep track of presentations made, get feedback, and tune-up as needed. It was also suggested that the PVPO survey applicants on what improvements they would like to see from the PVPO especially from universities and decision makers who file PVP. The Board also recommended that the PVPO include testimonials about applicant's experience. Furthermore regarding presentations, the PVPO should look at UPOV train the trainer prepared material to explain the benefits/importance of PVP to breeders, farmers, and consumers – then tailor the presentation to US needs.

The Board advised caution about approaching and targeting universities about breeding / PVP effort since many staff are called "plant breeders" even though they don't have an active plant breeding program; universities continue to phase out breeding programs therefore it was suggested to reach out to university members of the Board for guidance.

The PVPO asked about a proposed tiered fee structure – the Board responded that it is difficult to identify a small entity but it might be acceptable to have a different fee for non-profits. The PTO's tiered fee approach for patents was mandated by Congress. The Board commented that a tiered PVP fee structure is not necessarily an incentive to getting PVP, but instead focus on educating about value provided from PVP. Some applicants have a choice – PVP versus Patents – what gives the best value added and how can PVP's value be strengthened. It was stated that PVP DUS field trial costs are a major expense when taking into account the staff, growing ground, and data analysis. The Board suggested that the PVPO consider giving new/starting PVP applicants an incentive – 50% price reduction for their first 3-5 applications.

It was commented that university plant breeders sometime avoid intellectual property protection due to its complexity and apparent restrictive stigma therefore it may be better to sell PVP as innovation protection. The Board commented that there may also be a problem reaching out to state commissioners rather than university technology transfer offices because the commissioners don't want intellectual property protection for profit, but instead want varieties freely available. There is balance between the political (wheat commissioner, soy commissioner, etc.) and the plant breeders. Universities may have a separate marketing agreement with that state's marketing commission.

PVP Board asked how often does the U.S. receive PVP applications requesting priority based on another countries filing and likewise how often does a U.S. PVP (test report) used for filing in another country – the PVPO rarely receives priority requests and Canada has been the most frequent requester (2-7 requests per year) for the U.S. DUS reports.

The issue of the farmer's exemption was discussed – Canada indicated that as producers and the seed industry become more interested in sustainable sources of revenue/investment for plant breeding in specific crops (e.g. cereals), there may be pressure to develop a farm saved seed or end-point royalty system. It was also mentioned that the breeder's exemption may be set through essential derived thresholds set by molecular markers. The Board asked if UPOV would recognize the concept of thresholds for EDV and if it would recognize a marker based threshold. Potentially the Americas could set a soybean marker EDV threshold.

Following this discussion Board members voted on the 14 PVPO priorities and ranked them as below:

1. Manage the rollout of the molecular marker system to break PVP ties
2. Develop better FAQs on the benefits and difference between PVP and Patents
3. Fully deploy electronic PVP filing though UPOV and/or the U.S. ePVP system
4. Explore creative ways to address and mitigate the effect of PVP exemptions (breeder's exemption and farmer's exemption – possible royalty to the breeder)
5. Establish a quality management system and investigate/publicize third party DUS contract testers
6. Enhance the enforcement of PVP
7. Use Board member contacts for outreach
8. Explore an annual maintenance fee
9. Explore adding asexually propagated varieties to US PVP
10. Develop guidance on conducting DUS tests for US PVP
11. Capitalize on best practices and expand on them
12. Build stronger alliances and define universities to target
13. Accept DUS reports from other countries
14. Consider regulations to allow virtual labeling/marketing of seed bags

#### Other Topics

##### PVPO Direct Wire Transfer or Deposit Account Options

The PVPO can provide a deposit account if its user need it. The Board commented that direct wire transfer looked better to them and that a deposit

account might be useful for quick transfer, but it was unsure if it was needed. This question might be asked on a PVP survey.

#### PVPO Variety Name Verification/Clearance

The PVPO is verifying that there is no conflict for an applicant's variety name within UPOV or at the CPVO. If a conflict does occur the PVPO notifies the applicant and the UPOV country. The Board asked if there was a need to check the PTO or Trademark database for conflicts – the PVPO does complete this checking when the PTO initiates a request.

#### Marshall Ryegrass Update

The PVPO received communications that an extension for the PVP of 'Marshall' ryegrass might be forthcoming. The PVPO presented a summary of the PVP activity for this variety – this variety originally received PVP (certificate# 8200179) on June 29, 1984 after the office's examination and finding that the variety was new, distinct, uniform, and stable; the PVP certificate expired on June 29, 2002 (PVP was granted for an 18 year term under the PVP Act in place at the time of certification).

PVP certificate 200400094 for the 'Marshall' ryegrass variety was granted again on February 6, 2004 based on the Consolidated Appropriations Act of 2004.

The ten year term for the second PVP grant expired on February 6, 2014. This was the only variety ever granted a second certificate and in effect a term extension by the PVPO. At the May 2014 and August 2015 Board meetings – the Board unanimously voted for a recommendation against this extension.

It was estimated that about 500,000 pounds of Marshall ryegrass was currently available on the market, with another 600,000 pounds to be harvested and ready for sale in the spring. The Board asked if there was a process to challenge the issuance of this certificate. The PVPO indicated that the certificate could be challenged under the PVP protest process as specified in section 91 of the PVP Act and also that section 44 of the law "Public Interest in Wide Usage".

The Board discussed the Marshall Ryegrass issue further and recommended the following statements:

*Plant Variety Protection Board Issues Strong Objection to Extension of  
Marshall Ryegrass Plant Variety Protection*

*The Plant Variety Protection Advisory Board is extremely disappointed and gravely concerned about the proposed legislative reissuance of the Marshall Ryegrass Plant Variety Protection certificate, for the second time in ten years. The variety was initially protected in 1984 for 18 years. Upon expiration in 2002, it should have become available to the public; however, the certificate of protection was legislatively extended in 2004 for 10 years. The extended certificate expired in 2014, becoming freely available for public use.*

*Since 2014, more than a dozen entities including growers, seed companies, brokers and distributors have grown and distributed this variety legally. There are hundreds of thousands of pounds of Marshall Ryegrass available on the open market now and in the ground waiting to be harvested in late spring. The potential legal jeopardy and financial losses for these businesses are compelling arguments against another extension.*

*More fundamentally, the proposed extension violates the purpose and spirit of the Plant Variety Protection Act and seriously harms the U.S. intellectual property system. The Board strongly believes such an action will reduce the volume and diversity of available crop varieties, unfairly increase the cost of seed, and create an unsustainable precedent to damage intellectual property protection in America for many years to come.*

*The Board requests that the Secretary of Agriculture communicate these concerns to the appropriate Congressional authorities.*

The Board recommended that a formal protest be submitted to the PVPO if the Marshall Ryegrass certificate were extended. *Note: Based on a review of the Consolidated Appropriations Act of 2016 – no language was included in this law that extended Marshall's PVP.*

#### Meeting Wrap-up and Discussion

The Board liked the broad strategic advice as well as specific recommendations. The Board appreciated the participation of Canada and SAA at this meeting. It was commented that not many countries have a formal Board meeting in order to get advice from stakeholders. The Board appreciated the diversity of topics – including the 2015 accomplishments and the 2016 outlook. The Board suggested that Peter Button make

a presentation to the December 2016 PVP Board meeting and that Mexico and/or Argentina participate too.

The Board suggested bringing forth an important topic prior to the next meeting such as “requests for PVP deposited seed when that seed goes off PVP” – a preprint of this article would be sent to the Board. The Board also suggested that the Joint Marker WG – provide clear technical proposals on the marker work. The PVPO plans to have full presentation on the molecular marker accomplishments for the next meeting.

The next Board meeting will be held in July or August via teleconference – with the plan to have the meeting via Adobe Connect or WebEx.

The Board meeting was adjourned.

### Board Recommendations

- 1) The U.S. delegation to UPOV should continue to support the ISC proposal and that the U.S. should be part of the ISC Working Group
- 2) Manage the rollout of the molecular marker system to break PVP ties
- 3) Develop better FAQs on the benefits and difference between PVP and Patents
- 4) Fully deploy electronic PVP filing through UPOV and/or the U.S. ePVP system
- 5) Explore creative ways to address and mitigate the effect of PVP exemptions (breeder’s exemption and farmer’s exemption – with possible royalties to the breeder)
- 6) Establish a quality management system and investigate/publicize third party DUS contract testers
- 7) Issue a strong objection to Extension of Marshall Ryegrass Plant Variety Protection