Plant Variety Protection (PVP) Board Meeting Minutes – December 5-6, 2016

USDA Plant Variety Protection Office (PVPO)
Randolph 1A / 1B Room of the Hyatt Regency Chicago Hotel
151 East Wacker Drive
Chicago, IL

Board Members attending (with affiliation):

Charles Brown; Brownseed Genetics, LLC
Jianli Chen; University of Idaho
Joon Cho; University of North Carolina at Chapel Hill
Danielle Conway; University of Maine
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 (ASTA)
Katherine White; Wayne State University
Alternate: James Sutton, Georgia Department of Agriculture

Absent:

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:

Fred Achard, Monsanto
Marymar Butruille, Monsanto
Peter Button, International Union for the Protection of New Varieties of Plants (UPOV)
Amy Curtis, Monsanto
Kees van Ettekoven, Naktuinbouw Variety Testing Department
Mark Massoudi, AgBiotech
Minna Moezie, US Patent and Trademark Office (PTO)
Barry Nelson, DuPont Pioneer
Paul Nelson, Monsanto

Call to Order, Introductions, and Opening Remarks

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

Electronic PVP (ePVP) application system update

The PVPO's ePVP system is now capable of receiving and examining 47 crops including soybean, peanut, pepper, and potato. The system has 2 components – the outside facing Portal for applicant data entry and Microsoft Customer Relationship Management (CRM) which in the internal Office only application for examination. The system has been enhanced so that breeders can now enter non-PVP reference varieties with their applications. The PVPO can now complete distinctness searches against both PVP and non-PVP varieties. The Board asked what percent of information has been transferred to the new system – it is more than half.

Over the next 6 months the ePVP capabilities will be expanded with the addition of 8 more crops (corn, wheat, barley, oat, tomato, triticale, rapeseed and rice). The issue of multiple reoccurrences of the same variety will also be corrected. Enhancements will include updated dropdown lists, additional field instructions and smoother operation of forms in the Portal for data entry. The system will also have the ability to save a template application which would ease data entry from the same applicant and will provide for the bulk upload of 20+ applications at one time. The Board ask if an external user would get an immediate distinctness pass/fail from the system after they enter their application variety information - not under the current system, but this might be possible in the future.

The PVPO is looking for applicants who would need to be e-authenticated to test the system with either test or live data. It would also be useful to do more testing with potatoes and the grasses – the Board suggested looking at the ASTA Farm and Lawn seed division for the grasses and that it could help identify ePVP testers if a list of crops needing testing was provided.

The longer term plan for the ePVP system includes 1) a training by Webinar in July 2017, 2) a rollout plan with GovDelivery notices in August 2017, 3) the official ePVP launch with GovDelivery notice in October 2017, and 4) decommissioning the STAR database by October 2017.

The office provided a live demonstration of the ePVP portal and CRM. The portal side provides an electronic screen that follows the PVPO's paper forms. The Board asked if the entire application will be un-fragmented once the certificate is issued – it would. It was asked if electronic applications will replace paper before October 2017 –paper or

emailed application will be needed up until the October 2017 launch unless some of the ready-to-go crop (soybean, pepper) applicants choose exclusive electronic filing.

The PTO congratulated the PVPO on its electronic system and mentioned that currently plant patents are filed using paper only since there are concerns about getting true color rendition in an electronic system. The ePVP system would accept scanned photos and PVP applicants usually provide a color reference number such as the Royal Horticulture society value for color representation.

Joint ASTA/PVP Board Molecular Marker Working Group

The joint ASTA/PVP Board Molecular Marker Working Group (WG) is made up of 27 scientists from 18 public and private institutions. A history of the WG was presented focusing on prior work with the Reference Variety Model (presented to the December 2014 Board) and the current work on Single Nucleotide Polymorphism (SNP) for soybean pairwise comparison model. An explanation of the basics of DNA and molecular markers and the use of isozymes to distinguish varieties was also discussed.

Molecular markers (MM) have been used as proxies for morphology (for example with single gene traits which have markers somewhere in the genome - however these are rare). MM associated with specific genes are costly to identify and aren't very simple since most traits are the results of multiple gene complex interactions. Another means to use MM is augmented morphology which identifies patterns; these are informative for distinguishing among individuals but aren't associated with a specific trait. UPOV recognized this use of MM for the management of reference collections. MM have been used to calculate how different two varieties are based on the similarity of their DNA.

MM have been used in a criminal cases recently – for example to match stolen corn seeds to proprietary germplasm. It was noted during the 2016 UPOV Biomolecular Technique (BMT) meeting 9 of the 25 topics involved DNA markers. It was also noted that both the European Union's Community Plant Variety Office (CPVO) and the Seed Association of the Americas (SAA) have active MM working groups.

The use of SNP markers to determine differences between 2 varieties compared to the use of isozymes in barley for distinctness by the CPVO was discussed. The CPVO document explained that the barley isozymes are not routinely used to determine distinctness, but they can be used as a complement to other characteristics. The WG approach is similar to the CPVO method in that it wouldn't be used routinely, only in those cases where distinctness was in question. The SNP WG approach would complement other differences and would only be used as needed (similar to the CPVO

approach) but using SNP markers instead of isozymes. It would only be called upon when morphological evidence is not adequate to determine distinctness.

The WG has made progress in 1) it defining the marker technology used - SNP, and 2) defining what public marker sets should be used - 6K set for soybean and 3072 set for maize. Currently the WG is working on determining the maximum similarity threshold for soybean distinctness. In 2017 the WG plans to have technical recommendations for the threshold along with guidelines, methods, and standard operating procedures. A SNP subgroup of the WG was formed and has 8-10 active participants using 4-5 analytical approaches– they are now working now toward scientific consensus and a preliminary write-up of results and conclusions.

The Board asked what the thought process in determining thresholds. The WG genotyped 320 public soybean varieties and did pairwise comparisons between all 320 varieties. They focused on investigating those varieties that approached a similarity of 1.0. It was also explained that there has extensive essential derived variety (EDV) work in maize and this would help establish thresholds.

The WG will provide a recommendation to the Board and formulate results of the threshold study for publication in a peer reviewed publication. The WG needs to be clear how they got to the threshold recommendation to provide the Board with a good basis for a recommendation to the PVPO. The Board asked if the thresholds will be different for different crops – yes it would be crop specific due to the genomic and marker specificity of different crops. The Board asked if a threshold goes both ways i.e., if a variety is above the threshold – does that prevent it from obtaining PVP. No, a variety above the threshold could obtain PVP if other morphological characteristics could distinguish it from other varieties.

The Board asked what did the office need from the WG and the Board to use the threshold in the case of a tie. The PVPO would need it shown that this approach is scientifically valid by undergoing a peer review process and also an explanation of the threshold concept in non-technical terms. SOPs and guidance would be developed based on the peer reviewed publication. The Board stressed that the threshold approach will need scientific validation through the peer review process.

The history of the threshold concept was further explain based on a previous Board recommending that it is reasonable to use background MM in the case of a tie. Also the previous Board recommended a team to study the threshold idea and what level of similarity/difference is enough.

The Board asked how many ties does the PVPO encounter – it's very low, less than 1%. Currently in the case of ties – the PVPO works with applicant to find other characteristics (morphological or disease tolerance/resistance characteristics) that applicants can use to distinguish a variety. The Board asked were there any considerations of using MM exclusively – no the PVPO will rely on morphology as the primary determination of distinctness.

The Board summarized that the use of SNP MM would be rare and would not be used exclusively – only to break ties. The Board also recommended that an independent validation set be developed to demonstrate the utility of breaking ties and that there is enough genetic variation in background markers to distinguish varieties.

The Board commented that there could be some unintended consequences of setting a threshold such as enforcement issues, verification, error rates, etc. It would be important to review these and other factors before establishing thresholds. The Board asked what if the pairwise problem occurred between 2 different companies' varieties – it was explained that in the CPVO both parties would need to agree to run a MM comparison.

Presentation of the UPOV EAS, ISC, and current topics

Peter Button (Vice Secretary-General of UPOV) provided an overview of the UPOV, use of biomolecular techniques, the planned Electronic Application Form (EAF), an update on discussion for an International System of Cooperation, and other relevant topics.

UPOV members can cooperate with other countries by using existing distinct, uniform, and stable (DUS) test reports that are produced by a different UPOV member which can eliminate the need for a separate DUS test in that country. Under the UPOV Model administrative agreement it is recommended that the receiving country pay 350 Swiss francs (CHF) for taking over the DUS report from the producing country. Other arrangements that UPOV members have developed are 1) bilateral arrangements that remove the duplication of DUS Tests and 2) centralized DUS testing at regional or global level that encompass several countries. UPOV has guidance on what the DUS report should include in document TGP/5 including a model DUS report and variety description. UPOV also has a model DUS test agreement that assists the cooperation of UPOV members. It's recommends that DUS examinations follow UPOV Test Guidelines so that the examination and resulting DUS report will be the same from country to country.

UPOV has a network of cooperative agreements that can be found in the UPOV GENIE database. For example Switzerland will take over any UPOV members' DUS report and Slovakia has an agreement to accept DUS reports from the Czech Republic. UPOV is also conducting a survey to investigate obstacles to cooperation in examination.

The concept of using molecular techniques within UPOV for DUS was discussed. UPOV has worked on the FAQ "Is it possible to obtain protection of a variety on the basis of its DNA-profile - with the response: "For a variety to be protected, it needs to be clearly distinguishable from all existing varieties on the basis of characteristics that are physically expressed, e.g. plant height, time of flowering, fruit color, disease resistance etc. The DNA-profile is not the basis for obtaining the protection of a variety, although this information may be used as supporting information." The Board asked if isozymes are included as a DNA-profile – no isozymes are considered as a part of the variety's phenotype and closer to morphology. The use of specifically isozymes is covered UPOV document TGP/12 "Guidance on Certain Physiological Characteristics", which explains as follows:

> *"[…]*
> *2. With regard to protein characteristics derived by using electrophoresis, UPOV has decided to place these characteristics in an annex to the Test Guidelines, thereby creating a special category of characteristic, because the majority of the members of the Union is of the view that it is not possible to establish distinctness solely on the basis of a difference found in a characteristic derived by using electrophoresis. Such characteristics should therefore only be used as a complement to other differences in morphological or physiological characteristics. UPOV reconfirms that these characteristics are considered useful but that they might not be sufficient on their own to establish distinctness. They should not be used as a routine characteristic but at the request or with the agreement of the applicant of the candidate variety.*
>
> *3. For protein characteristics derived by using electrophoresis to be included in an annex to the Test Guidelines, it is necessary:*
>
> *(a) to establish the genetic control of the protein(s) concerned; and*
> *(b) to specify an appropriate method for the examination.*
>
> *4. Examples of protein characteristics derived by using electrophoresis can be found in the Test Guidelines for Barley (document TG/19/10), for Maize (document TG/2/7) and for Wheat (document TG/3/11 + Corr.)."*

Another more specific FAQ was “Does UPOV allow molecular techniques (DNA profiles) in the DUS examination?” with the responses “It is important to note that, in some cases, varieties may have a different DNA profile but be phenotypically identical, whilst, in other cases, varieties which have a large phenotypic difference may have the same DNA profile for a particular set of molecular markers (e.g. some mutations).
In relation to the use of molecular markers that are not related to phenotypic differences, the concern is that it might be possible to use a limitless number of markers to find differences between varieties at the genetic level that are not reflected in phenotypic characteristics.”

On this basis UPOV has agreed to the following uses of molecular techniques in relation to DUS examination:

> Molecular markers can be used as a method of examining DUS characteristics that satisfy the criteria for characteristics set out in the General Introduction if there is a reliable link between the marker and the characteristic.

A combination of phenotypic differences and molecular distances can be used to improve the selection of varieties to be compared in the growing trial if the molecular distances are sufficiently related to phenotypic differences. This method does not create an increased risk of not selecting a variety in the variety collection to compare to candidate varieties in the DUS growing trial and would reduce the cost of growing the DUS trial. This model was used for maize and is being considered by UPOV members in other crops.

It was explained that varieties may be seen as phenotypically identical but have different DNA profiles and conversely two varieties may have a large phenotypic difference but have an identical DNA profile. It was also discussed that there was a concern that changes could be made in the non-coding part of the DNA that would show a different DNA profile but be identical phenotypically.

UPOV also has the PLUTO database to assist UPOV members in using the same variety denomination for that variety worldwide.

The Electronic Application Form (EAF) project was developed to help breeders file PVP applications in any of the participating members using questions in any of the 4 UPOV languages and potentially other languages of participating UPOV members. EAF data can be automatically re-used in subsequent applications. The EAF is planned for launch on January 9, 2017 for apple, lettuce, potato, rose, and soybean with 12 UPOV members participating. In 2017 the EAF will have further enhancements including additional UPOV member participation, more crops, and languages.

The EAF process uses the UPOV website as a type of postbox permitting direct data transfer and email application filing. Breeders would have the opportunity to upload data directly from their file server to the UPOV server without manual entry.

The EAF would not affect the fees that breeders pay to UPOV members for PVP filing, but there would be a UPOV processing fee (initially 150 CHF and then increasing to 250 CHF) to cover costs. UPOV anticipates about 180 applications filed by EAF in 2017 and increasing to approximately 1,700 applications by 2022. The Board asked if all UPOV1991 members participated in EAF - any UPOV member (1978 or 1991) was free to participate with the only requirements being that a UPOV member provide their application forms and technical questionnaires.

The possible International System of Cooperation (ISC) was discussed based on the proposal of the International Seed Federation, the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Varieties (CIOPORA), and Crop Life. UPOV has reviewed this proposal and is looking to build on existing voluntary cooperation instead of building a new centralized filing system.

A UPOV cooperation system could involve: 1) a breeder making an application via EAF, 2) bilateral arrangements for examination between UPOV members, 3) cooperation on novelty and variety denomination. Ultimately it would be each UPOV member's final decision on granting PVP.
UPOV has set up a working group to look at the purpose: 1) responsibilities remain with each UPOV member, 2) participation and cooperation would be voluntary, 3) it would be inclusive and applicable to all UPOV members, and 4) it must be efficient and based on existing UPOV initiatives and materials. The first meeting of the ISC working group identified the needs of UPOV members and, in the next step, will review how the issues raised by breeders correspond to those needs. The key aspect of an ISC is that it would be cooperation from bottom up – cooperation between members that feeds to the international level.

The Board asked if the ISC-WG has been constituted – yes and the U.S. is a member of the WG.

Presentation on the Netherlands PVP process and the use of molecular technology from the UPOV-BMT perspective

Kees van Ettekoven provided an overview of the Netherlands PVP system and the usage of molecular technology within UPOV.

The program for PVP and DUS testing in the Netherlands was described. The Netherlands in a world market leader for vegetables, ornamentals, and potatoes with approximately 24% of global export of seeds/propagating material and 47% of European seeds/propagating material. There are approximately 2,200 applications filed annually for new varieties that are split between the Netherlands and the Community Plant Variety Office (CPVO). The Netherlands has about 350 breeding companies that have about $3 billion annual sales and with about 15-20% of sales spent in research.

The Netherlands lead Plant Breeder's Rights (PBR) office is located in Naktuinbouw with a staff of 286. Since 1960 over 62,000 variety applications have been filed for 663 different species – with vegetables, ornamentals, and agricultural species topping the list. The Netherlands has obligatory national lists for agricultural, fruit and vegetable species – where that variety can only be marketed if it is officially listed/registered. Agricultural species also require value for culture and use (VCU) where the variety must show better traits than the existing varieties. The Netherlands works with the CPVO to translate UPOV test guidelines into protocols that provide stricter adherence on which DUS characteristics to examine.

The Netherlands PBR is self-financed. The cost of filing PV in the Netherlands is 434 EU per application, with a 1,855 to 2,530 EU charge for each DUS testing per cycle – with most species requiring 2 growing cycles. There is no annual maintenance fee. Total costs are approximately $6,000 for a tomato variety.

In 2015 2,482 applications were received. The Netherlands has bilateral cooperation with other EU offices – for example maize gets tested by France, Germany – fruit, wheat – Czech Republic, etc.

The structure of the regional European (CPVO) system was also discussed - it co-exists with the national systems of 24 EU member states. It is the applicant's choice on where to file either at the national or CPVO level. In the EU the farmer's saved seed exemption is limited to fodder plants, cereals, potatoes, oil and fiber plants; farmers are required to pay the seed company for saved seed at a price that's lower than the amount charged for the licensed seed. Small farmers are exempt from this rule.

The CPVO is self-financed with application fees of 450-650 EU, examination fee of 1,430-3,210 EU/cycle, 240 EU take over fee, and 250 EU annual fee. The Board asked about the CPVO's online application process and the decision process for the 200 EU fee reduction with electronic filing. The CPVO found that the application quality was better with electronic filing and they saved money which both justified a fee reduction.

The Board also asked what effect the British exit from the EU would have – it's undetermined for now.

The top species filed in the CPVO are ornamentals, agricultural, vegetable, and fruit varieties. The top 4 CPVO filing countries are Netherlands, France, Germany, and United States. In summary the CPVO provides an efficient system for applicants, less administration for national authorities, and protection at reasonable prices.

The possible cooperation between the U.S. and Netherlands / EU was discussed and is open to further consideration. The PVPO discussed its pilot test with lettuce and that the EU data didn't provide enough characteristics for the PVPO to distinguish a variety from others it the database. It was discussed that there will be further pilot tests looking at potato for possible cooperation.

The Board asked if a variety becomes public in the Netherlands when the protection expires – seeds of the variety are not released to the public upon expiration. The Netherlands will however send the germplasm of open pollinated varieties to the public gene bank upon expiration. The Board asked if there has been consolidation of seed companies in the Netherlands and its impact on PVP – there has been some consolidation with the Netherlands PBR office experiencing a temporary reduction in applications for 2-3 years following a consolidation. It was explained that following consolidations small niche breeding companies often fill the breeding voids.

The role of DNA in plant breeding, supporting DUS testing, management of variety collections was discussed. It was explained that electrophoresis data was one of the first non-morphological characteristics to be used as a supporting evidence in DUS testing. The two most common use of molecular markers by the EU were discussed:

> Option 1 - Characteristic-specific molecular markers – this is straight forward with example of specific disease resistance markers in tomato and cytoplasmic male sterility in Brassicaceae;
>
> Option 2: Combining phenotypic and molecular distances in the management of variety collections. This option is more complicated and includes the management of variety collections in potato to reduce the number of reference varieties in DUS trials, decreases the field trial duration time, and cost. Its advantages include 1) having a huge collection of varieties in common knowledge in a DNA database, 2) increased reliability for a candidate variety to be (or not to be) distinct from all that is known, 3) possible exclusion or inclusion of reference varieties based on their DNA profiles, and 4) in some cases the

duration of DUS trial can be reduced (cost reduction). The use of DNA databases as source for genetic first selection of close varieties from common knowledge has advantages for reducing the size and cost of DUS trials. The advantages include greater certainty that no identical varieties are missed, less confusion with breeder provided technical questionnaire data, and the independence of DNA databases from climate and other physical facors. DNA database challenges include the selection of the marker set and the cost of building the database.

New potential UPOV molecular models might include 1) the use of DNA data in combination with a morphological description as basis for DUS decision and 2) the use of genetic distance relative to standard varieties as a UPOV characteristic. For the U.S. "tie-breaking" approach– it was explained that this would not be in line with UPOV since the determination would not be based on expressed characteristics. However the U.S. approach might be considered valid if molecular data is used in connection with non-UPOV differences such as yield, lodging, or performance. (Yield is not an acceptable DUS characteristic because it is unreliable and it is very difficult to get statistically robust data between 2 varieties.)

The Board discussed that it may not be good to use the term "tie" - it was suggested to use "morphologically indistinguishable" instead.

The reference variety model as first proposed by the U.S. at the 2015 BMT meeting was discussed. The idea of converting genetic distance between an application and standard reference varieties into a 'normal' UPOV characteristic was also discussed. (The reference variety model is essential the same as the genetic distance model described below.) It may be possible to have the reference variety model adapted to be included in a variety description as an additional characteristic. This idea did not have much support at the Moscow 2016 BMT meeting. It was proposed that at the 2017 BMT La Rochelle meeting it may be possible to create genetic distance characteristics in an annex to a crop's test guidelines as a special characteristic category. Such characteristics would be only be used as a complement to other morphological or physiological differences.

Genetic distance characteristics would be useful but that they might not be sufficient on their own to establish distinctness. The genetic distance concept has advantages in that there is no need to develop databases and it would be very cost effective. Its challenges include the selection of the best marker set, identification of the standard varieties, and the DNA platform that would be used.

Other UPOV related DNA developments include the creation of a joint tomato DNA database (between the Netherlands, France, and China based on a sequence based SNP array) partly financed by CPVO. The database would contain tomato varieties of common knowledge and be used for the genetic selection of varieties for DUS trials as well as enforcement and certification. The use of this database would be available for all DUS authorities against a fee through one of the three participants. Similarly a DNA database for rose varieties between The Netherlands, United Kingdom and possibly Germany is being considered based on a sequence based SNP array.

The Board commented that a variety's phenotype will vary based on the environment where it is grown. Breeders will take a variety from one geographic region and grow it in another place where it shows a different phenotype and then apply for PVP based on that new phenotype. Molecular data would show that the variety is identical but this data cannot be used to challenge since it is based on DNA data.

The Board discussed China's intellectual property (IP) activity for new variety development. It was discussed that China has advanced in the PVP world, having one of the largest mechanisms for IP protection and wanting to modernize their seed industry with a robust IP system. China is very interested in enforcement – and the use of molecular markers. The central government has the power to control germplasm, but the provinces may have problems with germplasm theft.

Overview of the December 2015 PVP Board Brainstorming Ideas, PVPO Actions, and New Brainstorming Ideas

The PVPO provided an overview of the 11 brainstorming ideas that were developed by the Board at the December 2015 meeting. The molecular marker topic and ePVP deployment were not discussed any further at this session since they were discussed in detail during the earlier session.

Develop better FAQs on the benefits and differences between PVP and Patents
The PVPO developed a chart highlighting the benefits and differences between PVP and Patents by focusing on the topics presented in the chart below

Question: What are the differences between PVP and Utility Patents for new plant varieties?

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

TOPIC	**PVP**	**Utility Patent**
Requirements	New, Distinct, Uniform, and Stable	New, Non-Obvious, Useful
Novelty (New)	1 year of sale in U.S. / 4 years sales outside the U.S.	Up to 1 year - only for the applicants from disclosure (e.g. sale, public use, publication)
Years of Protection	20 years after issuance - for most plants; 25 years for trees or vines	20 years after issuance (can be modified under certain circumstances; e.g. regulatory review)
Protection after Filing	Yes, full protection while the application is pending	Yes, some protection after filing and before issue (see 35 USC 154(d) for more information)
Estimated Filing Costs	$5,150 – No maintenance fee	Varies depending on the patentee corporate size - can range from $8,000-$20,000. Maintenance fees required
Essentially Derived Varieties (EDV)	Provides for EDV	No EDV Provision, but claims can protect certain derivative products
International Acceptance	Can be accepted to speed PVP filing in 70+ (UPOV) countries and PVP can be used to establish priority.	Not accepted worldwide
Research for plant breeding	Research is allowed unless excluded by other agreements or patents	No research allowed, depending on issued claims
Farmer Saved Seed	Allowed to use on own farm unless excluded by other agreements or patents	Not allowed, depending on issued claims
Public Usage in a Crisis	Secretary may declare a variety open for public use	No provision. Bayh–Dole Act may provide public usage for varieties developed through federal government-funded research
Germplasm deposit requirement	Seed or tuber deposit (including any propagating material necessary for propagation of a variety) required - which only	Seed or propagating material deposit may be required to fulfill a patent's enablement requirement – this material may

	becomes publicly available upon PVP expiration	be available to the public after patent issuance.
Time to Grant	Approximately 1-1.5 years	Approximately 1-3 years
Who may file	Anyone can file a PVP application including breeders, farmers, and legal representatives	Usually requires a legal representative that is registered to practice before the Patent Office

The Board suggested that data analytics be used for this FAQ and response using a "click through" approach and to consider presenting this topic to a variety of users. It was also suggested PVP's benefits be highlighted and show that neither PVP nor Patents are mutually exclusive since dual protection can be obtained in the U.S. It was also suggested that plant patents be mentioned.

An infringement litigation category might also be another topic to add to the table from the PVP standpoint (PVP stops others from selling/marketing the variety; PVP has a proven track record in the courts; and PVP provides a litigation advantage while not "risking" the broader protection of the patent) and the Patent standpoint (Patents can stop others from saving seed / using the variety for further variety development; litigating may put an entire trait (disease resistance, herbicide resistance, etc.) at risk; and patent litigation may involve a team of lawyers and is tried in the federal district court system).

The Board suggested that this FAQ would be best done as a digital infographic poster presentation perhaps by creating a competition among law students to prepare an infographic. Students could be awarded prizes and present their final product at ASTA events or the PVP Board meeting. The Board commented that it would be important to know the audience since a potential user of the PVP system may be more interested in understanding the PVP's benefits than the differences with patents. Also a poster could be used at outreach events that the PVPO cannot attend.

The Board asked if the PVPO uses social media – PVPO's social media coverage is coordinated by AMS public affairs. The Board commented that both the legal wording of the FAQ response as well as the user friendliness of the response needs to be considered. The Board recommended not putting this together as a narrative paper since it would bury what it trying to be conveyed with an infographic.

<u>Exploring creative ways to mitigate the effects of PVP exemptions (breeder's exemption and the right to save seed exemption)</u>

Based on the PVP Act and UPOV 1991 convention – both the breeder's and right to save seed exemptions are permitted however variety owners can restrict exemptions through contracts. The Right to Save Seed exemption is described in section 113 of the PVP Act – and in Article 15 of the UPOV convention. The breeder's exemption is described in section 114 of the PVP Act and in article 15 of the UPOV 1991 convention. There is no provision under U.S. PVP that can limit or mitigate these exemptions however both of these may be limited through contractual agreements.

Establish a quality management system

The goal in establishing a PVP Quality Management System would be to show that the U.S. PVP system is verifiable, accountable, and that both the PVPO and its applicants follow defined procedures. The PVPO presented a proposed Quality Manual as an example of what the system would encompass from both the applicant's and the PVPO's perspective. In this example the PVPO processes would provide guidelines for applicant activities and would document the SOPs, guidelines, and instructions for the PVPO activities. Under this approach the PVPO would have guidelines that help applicants with topics such as choosing/completing the correct forms to selecting the correct reference varieties.

The Board commented that this may be more a user guide than Quality Management. The PVPO explained that the outline is preliminary and that the intent is to would document processes and provide advice to applicants. Developing the breeder's interface would require input from both the Board and breeders to look at their quality systems in place. Also interfacing with breeders would be done so as not to add any burdens. The PVPO plan is to first produce the Quality Management system and to extract a User's guide afterward. The Board recommended that the ePVP system provides a well-documented user's guide. It was mentioned that discussion of quality management usually involves records to measure quality that can be audited and which implies processes that are verifiable and auditable especially in the seed sector (UPOV does not set a standard for every member and PVP office).

The PVPO plan is to create a quality manual to show how it conducts its operations which cannot be measured against an external standard. It was explained that the intent is to develop a quality management manual that covers the quality of the entire PVPO system showing how it's verifiable and can be audited. The Board explained that each company will have its own quality management system for plant breeding and recommended the PVPO quality system not impinge upon the breeder's system. The Board suggested looking at the ASTA website for the seed quality management manual as an example.

The Board asked what were the steps and timelines to develop the quality management system. The PVPO will look at other quality systems to see if other outlines are more appropriate and readjust the plan it as needed. The Board asked if the Quality system could benefit by having interaction with the Board or other groups. The plan is to have a more defined outline of a Quality Management system by next year.

Enhance the enforcement of PVP

It was explained that the PVPO has no enforcement authority and that it's the responsibility of a variety owner to enforce their PVP right. In order to help breeders with enforcement – the PVPO plans to develop a webpage with tips on infringement and enforcement including:1) providing information on remedies for infringement; 2) recommend language for seed-bag labels to give notice about a variety's PVP status; and 3) providing links to other websites regarding infringement/enforcement. Examples of infringement findings and settlements from the Farmer's Yield Initiative website (www.farmersyieldinitiative.com) were provided to the Board.

The Board suggested reaching out to the Seed Innovation and Protection Alliance (SIPA) for help on communicating transparency of enforcement/infringement. The Board also suggested not posting infringement settlements on the PVPO website – but use third party website links instead. The PVPO should discuss what guidance tips for infringement it can provide with the USDA Office of General Counsel.

It was mentioned that SIPA has an infringement tip line. The Board commented that the variety owner does not need to spend effort on infringement discovery but needs help on what to do when infringement is suspected. The Board suggested that the PVPO not offer advice on infringement but instead direct inquiries to others using resources such as SIPA. It was asked if there any organizations to offer guidance on PVP rights – SIPA, agricultural law policy centers and legal reviews fulfill this role (Illinois, Iowa, Arkansas, George Mason law schools may provide resources on enforcement). It was suggested that the American Bar association and the American Intellectual Property Lawyers Association would be other resources.

Using Board members for PVP outreach

The PVPO has developed a basic PVP outreach presentation that has been reviewed by AMS Public Affairs and was provided to the Board members. The PVPO will assist Board members in modifying the basic presentation to best fit their audience. The PVPO would like to hear back from any Board member who has made a PVP presentation to get feedback, were there any questions, and any other issues.

PVP Factsheets are also available for Board members to use during any PVP outreach activity and can be downloaded/reprinted (a Spanish version will be available by February 2017). The Board suggested using the fact sheet as the first line information to educate small breeding programs about PVP. It would be useful to show breeders a pathway for intellectual property decisions and to elaborate the PVP route versus the patent route which could help a breeder or their legal counsel choose the best path to pursue

Surveying Universities about PVP

During the December 2015 Board meeting it was suggested that the University/Public Sector should be targeted for outreach. In response the PVPO communicated with 12 universities by phone asking question about their use of PVP. The PVPO and a Board member also made outreach presentations at 3 university venues to increase understanding and elicit questions about PVP.

Based on these conversations it was found that universities release about 7 varieties each year and apply for about 3 variety-PVPs per year on average. The PVPO also learned that some institutions don't obtain any intellectual property protection at all. The lack of any protection was particularly true for forage species (alfalfa and many of the grasses) – these developers sometimes choose the Association of Official Seed Certifying Agencies (AOSCA) variety review board route instead. Based on the variety review board recommendations these varieties can be selected to be sold only as certified seed and as such the developer can control the seed necessary to produce the variety as part of the certification process.

The PVPO also found that one of the largest barriers for university breeders obtaining PVP was the lack of commercial sponsors and low market interest for some new varieties. University breeders might be more interested in obtaining PVP if PVP forms were simplified, asexual varieties were added to U.S. PVP, electronic filing was available, and commercial partners could be found. Even though the PVPO was not able to find a pool of prospective applicants through this survey process it is now able to better communicate with the university community using phone, email, and GovDelivery.

The Board commented that the university sector is also a good outreach target for SIPA and that it would be beneficial to ask universities "what is your IP policy?" and "who makes the IP decisions at your institution". IP is handled very differently at each university. It was mentioned that SIPA is looking to reach universities using AUTM and the PVPO could leverage what other organizations are doing to reach the universities.

The Board mentioned that the university industry partner problem is large and that without licensing partners no further actions are taken for IP protection. .

Using a different venue for university outreach - the PVPO will provide a webinar to AUTM on January 24, 2017 in conjunction with USDA-ARS Office of Technology Transfer “Insights into Plant Variety Protection and Variety Licensing”. The PVPO may also participate in March 2017annual AUTM meeting. The Board suggested looking at the Agronomy society annual meeting to organize a session with technology transfer and breeders to discuss the U.S. framework for the IP. It might also be beneficial to work with SIPA on identifying breeders/technology transfer for university outreach. Two other possible venues for outreach are the University Industry Consortium meeting (Baltimore, April 2017 and the ASTA farm and lawn seed conference held every fall.

Exploring an annual maintenance fee

The PVPO explained that an annual fee could be added by changing PVP regulations based on Section 31 of the PVP Act. However, the PVP Act doesn’t provide a means to take action or to cancel a certificate for the non-payment of this fee. The Attorney General may bring action for the recovery of charges, but this is unlikely. It does not appear that the PVPO can recover enough annual fee payments to cover its cost (the CPVO PVP owner pay this fee for 4.4 years and Canadian PBR holders pay for 5.4 years on average)

It would not appear to be worthwhile for the PVPO to add a regulation for annual fees due to 1) the complexity of regulation change, 2) determining appropriate fee structure change – i.e. reduce the filing examination fee while instituting an annual fee and 3) the longevity of an annual fee is relatively short based on the experiences of other counties.

The Board commented that if the PVPO put an annual fee in place that it would need to recover most of its costs in the first 5 years to recoup its current revenue.

Exploring adding asexually propagated varieties to US PVP

During the December 2015 PVP Board meeting it was suggested that the PVPO explore adding asexually propagated plants to PVP by looking at the PVP law and regulations. Two sections of the law as detailed below would prevent asexually propagated plants from obtaining PVP.

> Sec. 42. Right to Plant Variety Protection; Plant Varieties Protectable, (a) IN GENERAL.-The breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety, or the

> successor in interest of the breeder, shall be entitled to plant variety protection for the variety, subject to the conditions and requirements of this Act;
>
> Sec. 52. Content of Application (4) a declaration that a viable sample of basic seed (including any propagating material) necessary for propagation of the variety will be deposited and replenished periodically in a public repository in accordance with regulations to be established hereunder.

The PVP Act requirement for the deposit of seed necessary for propagation of the variety cannot be fulfilled even with regulation change therefore adding asexual varieties would require changes to the PVP Act.

The two relevant points regarding PVP and asexually propagated plants are: 1) asexually propagated variety developers are looking for help on essentially derived varieties (EDV) – since it's possible to develop an EDV from one that is protected by a plant patent however the patent law has no provision for EDV and 2) variety developers from outside the U.S. are barred from obtaining a plant patent if their variety has been disclosed for 1 year or more (all other UPOV country PVP Offices provide for 4 years for breeders from outside that country). This section of the patent law has prevented foreign plant breeders from protecting or marketing their varieties in the U.S.

The Board commented that if asexually propagated plants were added to PVP cryopreservation of these varieties may be an option for the germplasm deposit. The deposit serves as a voucher specimen that is used as the official representation of the variety. It was mentioned that in the Netherlands only the DNA is stored for the representation of the variety and not the germplasm. The Board discussed the importance of the deposit and the public availability of the germplasm as a social contract between the variety developer and the public.

ASTA is reviewing if changes to the PVP Act could be made to protect asexually propagated varieties and may come back to the Board with a recommendation. ASTA is looking into the options of the Plant Patent Act and the PVP Act in conjunction with the PTO and expects to have a report in early February.

<u>Develop guidance on conducting DUS tests for US PVP</u>

Historically some guidelines for conducting U.S. DUS field test were part of the exhibit C form and other guidance was on the PVPO website resulting in PVP guidance that was often confusing. In the past the PVPO provided in-person training on conducting DUS tests and selecting reference varieties however the training was discontinued due to budgetary reasons, as a result more guidelines were added to the Exhibit C forms.

The PVPO made changes to remove the guidelines from all exhibit C forms as well as removing suggested reference varieties from the forms (some listed reference varieties were so old that they were difficult for breeders to obtain and no longer relevant). The PVPO will develop test guidelines for all crops with a draft of the Soybean test guideline to be completed by March 2017. These guidelines will be a type of instruction manual on how to conduct a field test and collect data for a PVP application. The guidelines will follow the same format as those established by UPOV. Both plant breeders and the PVPO examiners will review the test guidelines before these are publicly available.

The overall purpose is to show that the U.S. PVP Office has guidelines that applicants follow and which are very similar to UPOV's but which allow some flexibility for the breeder DUS testing system. The PVPO will recommend that breeders follow the UPOV test guidelines for any crop without a PVPO established guideline.

The Board agreed that alignment with UPOV and providing U.S. guidelines that are consistent with other countries was important. It would help other countries to accept U.S. DUS reports if these test were comparable to the DUS tests done by other countries. It was mentioned that the UPOV soybean test guidelines were last changed in 1998. The UPOV process for updating the soybean guidelines would occur after a member's proposal to revise the guideline along with participation in UPOV 2017 Technical Working Party for Agricultural Crop meeting.

The Board asked if there were other UPOV members who have a hybrid of breeder testing / government testing. In UPOV there is a continuum range of testing systems from breeder based to government based testing. The Board mentioned that in some countries the government does not have good DUS facilities so that the phenotype of a variety is flawed and different from what the farmer or breeder observes. In UPOV it is important to have consistency of testing so that all of a crop's varieties can be compared under conditions that express their characteristics in a reasonable way.

<u>New Idea for 2016 – Host the UPOV BMT meeting</u>

The UPOV Biomolecular Technique (BMT) Working Group discusses and evaluates approaches for using molecular markers in the PVP examination process. The last time the U.S. hosted the BMT was in 2005. The U.S. has been actively involved in the BMT for the past several years. The PVPO asked the Board if the U.S. should host the BMT meeting in 2019 with possible venues in Washington DC, Iowa, or Davis, CA. Possible funding could be provided by the USDA, PTO, and the seed industry for a reception or tour of molecular facilities.

The Board asked how large would the group be – 40-50 attendees is typical. UPOV indicated that several countries are also interested in hosting the 2019 meeting. The Board discussed that it may be difficult to have international visitors travel to Iowa compared to Davis or Washington. However Iowa would be a very good venue to highlight the U.S. seed industry and molecular marker facilities. The BMT meeting is usually a 3 day session with an additional explanatory workshop. With the faster developments in molecular marker research it may be necessary for UPOV to have more frequent meetings instead of every 18 months. The UPOV Technical Working Party for Computers and Automation meeting may also be important for the consideration of bioinformatics, statistics, and database issues. The Board endorsed and supported the concept of the U.S. hosting the 2019 BMT meeting.

PVP Incoming Application Issue

The number of PVP applications that were filed peaked in fiscal year 2010 at 598, in FY16 - 413 applications were received, (over the past 10 years the PVPO received 491 applications on average per year). Incoming corn applications was at an all-time low in FY16 - 9 were received. Also only 9 applications were received in October and 3 in November, over the last 10 years the PVPO received 50 applications on average for those combined 2 months. The PVPO presented these numbers as evidence that there may be a decreased incoming application trend.

There may be many factors contributing to the drop of incoming applications including increased protection options with both utility patents and plant variety review boards for seed certification; ever decreasing applicant pool due to industry consolidation; the high initial cost of PVP; and inadequate benefits of PVP compared to other IP options.

The PVPO asked the Board: Has PVP's usefulness to the plant breeding community decreased? Is there less need for PVP? How can we determine if PVP is relevant in the current IP landscape with other options available to variety developers? Should we accept this and let the market decide? Is reduction of incoming PVP's the new normal? What 1-2 factors would enhance PVP's usefulness? What can we do to counter the trend? What are possible "low hanging fruit" to improve PVP's significance?

The Board discussed the merger of seed companies and policy shifts on PVP filing. The Board wanted to know what crops didn't file applications in the first 2 months of this year – in FY17 the filing was a mix of potatoes, lettuce, beans and other crops; for prior years the crops expected in the first 2 months is highly variable. Seed industry representatives indicated that they will be filing their corn applications during January through March 2017.

The Board commented that it can't be assumed that seed industry consolidation would cause decreased incoming applications. Also there is a lack of understanding on how a breeder can enforce PVP. The PVPO commented that in the U.S. there are other IP options that plant breeders might be selecting over PVP. The PVPO is not at a crisis state yet, the current application inventory is in the low 200's. When the ePVP is fully implemented examination will be faster and the inventory will continue to decrease.

The Board asked if there are opportunities to collaborate with Canada for harmonization or mutual recognition for increased PVP filings. The PVP has had conversations with Canada but there is no concrete conclusion. The Board commented that the U.S. does not have obligatory royalties under PVP and farm saved seed is not a big problem except for wheat and cereals.

It was commented that innovation is the life blood of variety development and newer breeding methods will need IP protection. It was mentioned that there is more integrated soybean variety development between North and South America with interchangeable technologies. The Board commented that it will be increasingly difficult for PVP applicants to work the old way especially for soybean. It was suggested that the PVPO needs to find reasonable ways to find acceptable differences in soybean since there are a limited number of morphological traits and that soybean breeders don't want to measure more traits that have no effect on performance.

The Board suggested that he U.S. could develop UPOV sanctioned data collection / examination centers so that other countries would accept the U.S. DUS reports. Ideally these would be PVPO certified testing facilities. (For example the phytosanitary system recognizes third party testers/certifiers.) It was stated that in Asian countries there are 3 options for PVP DUS testing – 1) the applicant can collect the data, 2) government collects the data, or 3) the third party collects the data.

It was suggested that if an applicant wants their data exported to another country they should work within the UPOV guidelines and ask for an official audit of their trial to insure that the required number of plants and varieties are in the trial and that the data collection is accurate. Breeders are very good variety testers – because they know their variety best. It's important to know how other UPOV members would view this approach and if it would address their concerns. These type of discussions would be best to occur within the UPOV-ISC working group. The PVPO suggested a pilot program with the EU for one crop and work on acceptable standards and methods to satisfy both the U.S. and EU. The Board suggested starting off with a system that has a great chance of success and such as Canada.

PVP Board and the Next Meeting

The next potential Board meeting would be a teleconference that would occur before May 2017 if needed depending on outcomes of the Molecular Marker working group or other issues that need the Board's recommendations. The Board's Charter was renewed on January 11, 2017 and is active for 2 years. The term of the 2015-2017 Board expires on May 26, 2017. The PVPO is currently soliciting nominations for 2017-2019 Board using the PVPO website and a planned Federal Register notice – nominations are due by March 20, 2017.

The PVPO asked the Board their opinion about the next physical Board meeting. The Board suggested having the meeting again in Chicago in conjunction with the ASTA meeting but only for 1 day instead of 2 – most likely on the Monday.

A motion was made to adjourn the meeting and was approved.

Board Recommendations

1) The PVPO should enlist volunteers to study the consequences/implications of establishing molecular marker thresholds.
2) Use the term "morphologically indistinguishable" instead of "tie" for the SNP pairwise project.
3) Work with law students to develop an infographic on the differences and benefits of PVP and Patents.
4) Work on establishing a Quality management system in conjunction with the Board and seed industry.
5) Work with SIPA to develop PVP website guidance on where breeders can turn for suspected PVP infringement and PVP enforcement assistance.
6) Review the concept of adding asexually propagated plants to PVP after the ASTA winter conference.
7) Develop a PVP user guide and test guidelines that follow UPOV guidelines that assist PVP applicants in conducting field trials.
8) The U.S. should offer to hold the 2019 BMT meeting.
9) Hold the next physical Board meeting 1 day instead of 1-1/2 days.