

USDA Plant Variety Protection Office (PVPO)
Room 3543
USDA South Building
1400 Independence Ave. S.W.
Washington, DC 20250

Board Members attending (with affiliation):

Charles Brown; Brownseed Genetics, LLC
Jianli Chen; University of Idaho
Joonhyung Cho; University of North Carolina at Chapel Hill
Danielle Conway; University of Maine
Eloy Corona; Bayer Crop Science LP
Jose Costa; USDA/ARS
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: David Burns, Burns' Farms, Inc.
Alternate: James Sutton, Georgia Department of Agriculture

USDA and AMS staff:

Ruihong Guo, Deputy Administrator, USDA/AMS/Science and Technology
Douglas Keeler, Associate Deputy Administrator, USDA/AMS/Science and
Technology
Sharlene Deskins, Attorney, Office of General Counsel (OGC)
Paul Zankowski; Commissioner PVPO
Jeff Haynes, Deputy Commissioner, PVPO

Others Attending:

June Blalock, USDA Consultant
Marymar Butruille, Monsanto
Harry Collins, Farmer
Rob Griesbach, USDA Office of Technology Transfer
Paul Nelson, Monsanto
Frank Michiels, Bayer
Rachel Pilloff, Lowe Hauptman & Ham, LLP

Call to Order, Opening Remarks, and Introductions

Opening welcoming remarks were made by Paul Zankowski and Ruihong Guo. The meeting agenda was adopted. The 2015-2017 Board consists of 14 members and 2 alternates with 4 members continuing from the 2013-2015 Board and 2 who were members of earlier Boards. The three main functions of the Board were discussed – 1) advising the Secretary regarding the Plant Variety Protection Office's (PVPO) Rules and Regulations, 2) making advisory decisions on all appeals to the Secretary, and 3) advising the Secretary on all questions regarding public usage of the varieties. The PVPO has also leveraged the Board by asking for their advice on PVPO procedural matters.

Key Points about US PVP and the PVPO

A briefing report was provided to the Board prior to the teleconference that described the US PVP system, intellectual property (IP) protection in the US, and the basics of the US Patent system. PVP encourages the development of new varieties of seed and tuber reproduced plants. Plant breeders provide information to the PVPO to show that their variety is new, distinct, uniform, and stable (DUS). The PVPO completes an examination to confirm the breeder's results and makes a recommendation for issuing a PVP certificate.

The PVPO is composed of 11 staff members – with 3 Examiners, 3 Associate Examiners, 2 Program Analyst, 1 Information Technology Specialist, 1 Deputy Commissioner, and 1 Commissioner – each having a specific role in PVP application processing.

The Board was also provided with a report on the accomplishments of the PVPO for the first 9 months of fiscal year (FY) 2015. During this time the PVPO received 352 new applications, processed 367, and reduced processing time from 2.43 years in FY14 to 1.8 years in FY15. The PVPO had \$2.5 million in revenue with expenses of \$2.2 million with the trust fund balance growing to \$4.3 million (which is equivalent to 24 months operating reserve). The PVPO is required to be above 5 months of operating reserve. The Board asked if the operating reserve had improved from the past – it did since FY14 had a \$3.9 million reserve. The Board also inquired if there were rules about how the PVPO's budget is allocated and if there was an upper limit to the reserve – the PVPO's budget allocation is flexible, the reserve didn't have a limit, and 24 months of reserve is considered healthy. The PVPO discussed reducing its application inventory and staff reduction as major factors to the PVPO's financial health. It was also mentioned that the PVPO is solely dependent on incoming applications for revenue

since it does not collect an annual maintenance fee that most other countries PVP offices do.

The PVPO was active in 8 international outreach activities and 4 domestic events, in addition to traveling to 3 DUS trials to better understand plant breeders PVP challenges. The Board considered the PVPO's participation in these events as very important to enhance the PVPO staff's understanding of plant breeder issues as well allowing breeders to better comprehend the PVPO's current perspective.

ePVP Update

The goal of the electronic PVP (ePVP) system is to completely replace the current STAR database system with Microsoft's Customer Relationship Management (CRM) software system. This would provide PVP stakeholders with an efficient electronic filing system and PVP staff with an effective electronic examination system. The basic ePVP system has been built but some fixes and enhancements to the external portal and internal CRM are needed. Also the data needs to be re-migrated from the legacy STAR database to the CRM system. The Board asked what does this mean for PVP applicants – the PVPO indicated applicants could submit their applications electronically, bulk upload applications, pay fees electronically, and receive certificates electronically too.

The Board asked if this system would be compatible with International Union for the Protection of New Varieties of Plants (UPOV) electronic application system (EAS) – the PVPO responded that it was active in the UPOV EAS development using lettuce as a trial species and that the PVPO would submit soybean information to UPOV next. The UPOV EAS is compatible with the PVPO's CRM and would allow the PVPO to accept UPOV EAS data but the UPOV electronic payment issue needs to be resolved. The Board asked if the UPOV EAS would allow bulk upload of many applications – the PVPO responded that UPOV was working on that issue. The Board also asked about the security of ePVP – the PVPO responded that the USDA's e-authentication process provides a very secure system.

PVP Forms Subcommittee Summary

The PVPO provided a background on the Forms issue which arose because PVP applicants need to provide germplasm (seed or in vitro material for potato) to the USDA National Center for Genetic Resources Preservation (NCGRP) when submitting a PVP application. When PVP expires the germplasm stored at NCGRP is made available to the public. This germplasm maybe be genetically engineered (GE) and may produce plant incorporated protectants (PIP) that would be regulated by the Environmental Protection Agency (EPA). NCGRP needs a better means of informing public seed

recipients about expired PVP germplasm from the information that is collected by the PVPO. NCGRP has asked the PVPO to help gather accurate information about the PVP seed that is stored for 20+ years and eventually distributed to the public using the PVP application and seed deposit forms. The Board's Forms Subcommittee was started in 2014 to address PVP questions about IP and biotechnology events. NCGRP resolved the IP issue and this subcommittee made recommendation about the GE issue.

The chair of the Forms Subcommittee provided an update and the recommendations. The current PVP forms did not provide adequate GE information to NCGRP and responses were optional. For the IP issue - NCGRP's current resolution is to recommend that germplasm recipients contact the variety owner to inquire if any IP issues are outstanding. The two main issues for the PVP forms involved block 18 of the PVP application form (ST-470) and block 4 of the PVP seed deposit form (ST-472).

The Subcommittee recommended that

- The word "optional" should be deleted from both block 18 and 4
- The GE wording of the two forms should be consistent
- The recommended wording for the GE question in Blocks 18 and 4 is:

Does the variety contain any biotechnology events?"

A biotechnology event is defined as a single insertion of a nucleic acid construct into a specific site in a plant's chromosome, that is regulated under the U.S. Coordinated Framework for the Regulation of Biotechnology.

- Block 5 of Form ST-472 should be deleted since it is no longer needed by NCGRP.
- The contact information on Form ST-472 should be updated to be generic.

The Board approved these recommendations.

The PVPO indicated that these form changes will need to go through the Office of Management and Budget (OMB) forms approval process. The American Seed Trade Association (ASTA) also has voluntary forms for the PVP deposited germplasm on the ASTA website to guide PVP applicants about biotechnology event information needed by NCGRP prior to PVP expiration, and also guidance on providing IP information to NCGRP. The Board asked if PVPO forms would be retroactive – these forms would not be retroactive, however the ASTA forms may provide voluntary guidance and information for expiring PVP varieties that NCGRP would release.

The Board asked if the revised form questions would cover future biotechnology events (genome editing, knockouts, etc.) that may not be regulated under the current system – future biotechnology events may be beyond the scope of the current questions. It was commented that biotechnology events were defined to capture what is currently regulated under the Coordinated Framework and these forms don't make assumptions regarding biotechnology event. The Board asked about the timeframe for the changes with OMB – this will need to go through a justification, work plan, approval, and public notice/comments period which may require years.

This completes the mission of the Board's Forms Subcommittee and it is hereby closed.

Molecular Marker (MM) Subcommittee/Working Group Update

The PVPO provided a brief update on the MM Joint Working Group. Plant breeders use MMs to accelerate variety development and for variety identification purposes. The PVPO sometimes receives applications with MM data that applicants use to distinguish their variety from other varieties and as such the PVPO has become an informal repository for MM data. In July 2013 the Board recommended that a Subcommittee be formed to explore MMs for PVP. In 2013-2014 MM subcommittee identified corn, soybean, and lettuce as priority crops.

In 2014 the PVPO provided maize phenotype data for 89 varieties to the subcommittee for a proof of concept study to determine if MM correlates with phenotype data – this showed some significance but with low correlation between phenotype and MM. The Maize Reference Model arose as an alternative to phenotype-MM direct correlation, additionally the PVPO provided soybean phenotype data as another attempt to correlate MM and morphology.

In August 2014 the PVP Subcommittee merged with the ASTA Corn Variety Identification Subcommittee to form the ASTA/PVP Joint Working Group since both groups were working on complementary issues that could be synergized through this merger.

Currently the PVPO has not used MM differences to distinguish any crops. During the December 2014 Board meeting it was recommended that MM could be used to break ties in cases where the new variety is facing a phenotypic tie with existing PVP varieties. The PVPO will work with applicants to suggest other morphological / physiological (phenotypic) traits that could distinguish their variety in these ties. If no other phenotypic characteristics can be found then the MM difference must be clear and scientifically/statistically valid, and would only be used to distinguish between new varieties from an applicant's existing PVP variety.

Overall the PVPO will continue to explore MMs through the MM Working Group's findings as it provides information to the Board. The PVPO will provide a more detailed briefing on MM topics prior to the December Board meeting during which a more in depth MM discussion will occur.

The Board asked if the ePVP system will have the ability to store MM data - the current system is capable of storing the MM data that has been received previously, but it would be impractical to store all MM analysis data for each application. The better approach would be to concentrate on finding a solution for the Maize and Soybean reference models for variety comparison and only saving the reference data in the PVPO database. Currently, the PVPO does not have plans to save molecular profile data for each variety.

Outreach Subcommittee plan

Expanding the use of PVP and increasing the number of incoming PVP applications has been a major PVPO challenge since incoming applications are the PVPO's only revenue source. Over the past 10 years the average number of incoming applications is 430, with a range of 304 to 598. The top incoming crops are corn, soybean, wheat, potato, and cotton.

During the December 2014 Board meeting it was suggested that the Board form an Outreach Subcommittee composed of Board members and outreach experts. The goals would include increasing the awareness of PVP's benefits and ultimately increasing the number of incoming PVP applications. Conceptually this Subcommittee would develop outreach ideas, identify target audiences, and identify training/outreach materials needed.

The Board suggested that the PVPO could establish outreach benchmarks through higher education with opportunities for synergy. It was also commented that there are many goals for outreach, not just maximizing new PVP applicants, but also maximizing the benefits for current PVP applicants. It would also be useful to have outreach for underrepresented crop sectors and for international applicants. There would also be an element of capacity building that would enable new applicants to be successful at PVP. The Board wanted to know how awareness was identified as the most critical factor of why not to PVP. It was mentioned that universities often look for industry partners before they decide to file PVP – if a partner isn't found – they won't file.

The Board commented that it may not be reasonable to try to increase the number of PVP applications each year – since there has been consolidation and other methods of

IP protection. The Board also asked if there has been any trend in public versus the private sector growth. It was mentioned that it may be possible to have a PVP survey through the National Wheat Improvement Committee.

The PVPO is at a point where strategic visioning is necessary and with the Board's help the PVPO can better align its vision with the needs of plant breeders. The outcome of an Outreach Subcommittee may be different than expanding the use of PVP; instead it may provide a broader vision of where the PVPO should focus. The Board suggested a broader analysis and visioning to describe a future state and to be more strategic such as how to increase the intrinsic value of PVP to variety developers. Overall this will help the PVPO develop a strategic plan.

The PVPO asked anyone who is interested in participating in this Subcommittee to email the PVPO.

Miscellaneous, Plan for December 2015 Board Meeting, and Adjourn

Marshall Ryegrass Issue

The PVPO has received communications that a third 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 Board meeting – the Board unanimously voted for this recommendation.

The Plant Variety Protection Advisory Board expresses its grave concern over the Marshall Ryegrass issue regarding the legislated private reissuance of a Plant Variety Protection certificate, for the second time in approximately ten years. The Board believes this practice is contrary to Section 131 of the Plant Variety Protection Act and creates significant risk to innovation by undermining encouragement for research and investment

by creating uncertainty of future commercial opportunities. This legislation is also counter to the purpose and spirit of the PVP Act. The Board believes such a practice will greatly reduce the volume and diversity of available certified crop varieties, and unfairly increase the cost of seed to society. The Board proposes the PVP Office and the Secretary of Agriculture communicate these concerns to the appropriate Congressional authorities.

It was discussed that similar language may be inserted into the Agriculture Appropriation bill in November 2015. The Board also commented that this recommendation may be beyond the scope of the three functions of the Board established by the PVP Act. The Board commented that they believe a recommendation was necessary since this type of legislation would undermine the integrity of the PVP system and the US IP system; and that other countries could follow the U.S. and selectively extend IP protection. Ultimately, it was discussed; the farmers will be harmed if this language is allowed.

The Board discussed this issue and recommended that the same recommendation from 2014 be placed before the PVP Board again.

The Board unanimously approved this recommendation. The PVPO indicated that they could forward this language to the White House Liaison Office for forwarding to the Secretary.

December 2015 PVP Board Meeting

The December 2015 PVP Board meeting will occur at ASTA's Corn, Sorghum, and Soybean Research Conference at the Hyatt Hotel on East Wacker Dr., Chicago, IL. The meeting will occur over 2 days December 7, 2015 - 1:00-5:00 PM and December 8, 2015 - 8:00 AM - 5:00 PM. The meeting agenda will include updates on PVPO accomplishments, Outreach Subcommittee, MM Working Group, UPOV / SAA meetings, ePVP and activities on PVP cooperation with other countries. It was suggested that the Outreach Subcommittee update and the agenda item on cooperation with other countries be adjacent to each other.

The Board meeting was adjourned.