

Minutes
Plant Variety Protection Board Meeting
March 4-5, 2003

George Washington Carver Center
Beltsville, Maryland 20705 USA

Board Members attending (with affiliation):

Peter Bretting, USDA, Agricultural Research Service
Leticia Cabrera, University of Texas at Brownsville
Harry Collins, Delta and Pine Land Company
Bruce Hunter, Syngenta Seeds (retired) and American Seed Trade Association
Sharan Lanini, Consultant
Virginia Lehman, Blue Moon Farm, LLC
Salomon Montano, New Mexico farmer
Bruce Morrissey, Dupont de Nemours Co.
Hector Quemada, Crop Technology Consulting, Inc.
Renee Rockwell, Pioneer Hi-Bred International, Inc.
Gary Whiteaker, Sakata Seed America, Inc.
Walter Wiles, Southern University

USDA and AMS staff:

William Hawks, Under Secretary for Marketing and Regulatory Programs
Robert Epstein, Deputy Administrator, USDA/AMS/Science and Technology
Alan Post, Associate Deputy Administrator, USDA/AMS/Science and Technology
Robert Ertman, USDA/Office of the General Counsel
Annette White, USDA/AMS/Budget Office
Marian Minnifield, USDA/AMS/Office of the Director
Ann Marie Thro, National Program Leader Plant Genetics, USDA/CSREES
Yvette Waul, Program Assistant

PVP¹ staff:

Paul Zankowski, Commissioner
Alan Atchley, Senior Examiner
Thomas Salt, Senior Examiner
Janice Strachan, Senior Examiner
Jeffrey Strachan, Senior Examiner
Mark Hermeling, Examiner
James Mantooh, Associate Examiner
Beretha Thornton, Associate Examiner
Bernadette Thomas, Computer Specialist
Bridget Thomas, Contract Clerk

¹PVP = Plant Variety Protection Office; PVPA = Plant Variety Protection Act

Visitors:

June Blalock, USDA, ARS, Office of Technology Transfer
Richard Stoll, attorney for Simplot
Joel Barker, Vice President and General Manager Simplot
Dunn, Simplot
Sign Language Interpreters : Cathy Rader and Yvonne Robinson

Opening remarks were made by Paul Zankowski, Robert Epstein, and Bill Hawks. The meeting agenda was adopted. The Board approved the minutes of the November 2001 meeting.

Reports:

Overview of the PVP Act and PVP Office. Thomas Salt. A PVP Certificate is personal property. The PVP Act follows the UPOV² treaty, in that the variety must be new, distinct, uniform, and stable. There are no other conditions for granting of rights under UPOV. The variety must be uniform for all traits, therefore unimproved germplasm is not eligible. The variety must be stable for the length of protection, which is 20 years. The PVP Office is tasked to collect data, to communicate with applicants, and to examine and make final decisions concerning applications.

The US PVP Office does not do grow out trials. Therefore, the applicant must gather and report all data needed to perform the examination. Section 61 of the Act and 97.100(b) of the Regulations task the PVP Office with performing examinations. Section 8 states that PVP Office will maintain a reference library. Sections 22, 52 and 97.5 ' describes the form and contents of an application. When communicating with an applicant, we try to be helpful by sharing data we have gathered and suggesting improvements to the application. We continue dialog with applicants until all issues are resolved and a final decision can be made. Our decisions are based on good science and therefore are legally strong. If the applicant has not established DUS³, then the application is denied.

Appeal to the Secretary. Simplot protested the final abandonment of a turfgrass application. The application was originally filed by ABT, which went bankrupt. The abandonment happened during the bankruptcy proceedings, when Simplot was in the process of purchasing the variety from the bankruptcy court. Simplot alleged that they were misled about the application's status during the purchase and were subsequently not given the opportunity to take action to revive the application prior to its permanent. The Board voted 10-1 (with 1 abstention) that the PVP Office had followed proper procedures, that the actions of the PVP Office were consistent with the PVP Office guidelines for the handling of applications, and that the final abandonment should not be overturned.

² UPOV is the French acronym for the International Union for the Protection of New Varieties of Plants., an international treaty which was first drafted in 1961. Currently, there are 51 members of UPOV. The US PVP Act complies with the 1991 UPOV Convention.

³DUS is an abbreviation for new, distinct, uniform, and stable.

PVP Accomplishments from November 2001 to March 2003. Paul Zankowski. The PVP Office has 13 positions, two of which are currently vacant and one is filled by a contractor. The size of the Office is relatively small compared to other UPOV offices. Since November 2001, two associate examiners were promoted to full examiners, one associate and program assistant resigned. One examiner is working only part time. There are plans to modify one examiner slot to be a Quality Assurance/Examiner position.

Zankowski provided a breakdown of which examiner handles each of the major crops, and what their current workload is. Since November 2001, the PVP Office has reduced the backlog of undecided applications from 1043 to 824 as of January 29, 2003. We continue to make progress in decreasing application review time and the total time to issuance of a certificate.

We have implemented a Quality Assurance program, based on the ISO9000 example. Our main goal is to harmonize the processing of applications among the examiners, and to ensure that all questions regarding DUS are addressed in a similar fashion.

In Fiscal Year 2002, we had budgeted expenditures of \$1,197, 563 but actually spent \$1,286,000. This means that we needed to take money from our trust fund to operate. On February 10, 2003, a 35% fee increase went into effect. This should help to balance the Fiscal Year 2003 budget.

We attempted to bring in additional funds by pursuing new business opportunities. We proposed using PVP crop-specific databases to do searches for the Patent Office. As a trial of this, we did searches for live patents of 3 corns, 2 soybeans, and 2 canolas. Despite our databases having evidence of prior art in some cases, the Patent Office rejected the results and this plan for outsourcing has been abandoned. The American Nursery & Landscape Association inquired whether the PVP Act could be amended to include asexually propagated crops. This was in an effort to provide intellectual property rights to those crops which could not meet the time requirements of 102B of the Patent Act. To implement this, the PVP Act would need to be amended in seven places to include the words *or asexually*. This could potentially bring in up to 600 new applications per year. Because they are separate laws and regulations, this change probably would not affect the relationship between PVP and PTO. And not all patent applicants would move their business. (Lehman suggested there may be precedent from apomictic grasses.)

The PVP has contracted with the Foreign Agricultural Service to provide training in the US form of plant breeders rights. Training has been done in China, Thailand, Yugoslavia, and in Beltsville for China's PVP examiners. Many countries are interested in establishing plant breeders=rights offices and using the US as a model for their system. By providing them with information, we hope to open emerging markets to facilitate international trade.

We are in the process of converting our database to a MS SQL Server 2000 platform. This is expected to provide ease of access and improve PVP effectiveness.

The PVP Office used a contractor to scan the expired certificates and convert them to pdf format with optical character recognition so they are searchable. This will allow PVP to archive the originals and still make them available to interested persons.

To this end, we are also pursuing electronic payment of fees by credit card. We are working with Verisign and the AMS budget office and the bank to work out the details of implementing this.

We met with the Commissioner of Patents to discuss their e-business system. Currently at PTO, 2000 out of 300,000 annual patent applications are filed electronically. Patent lawyers prefer to use their own software.

PVP Accomplishments: Application review and Filing Statistics. Jeff Strachan. In fiscal year 2002, the PVP Office received 277 new applications, closed 490 applications, and ended with 828 undecided applications. So far in fiscal year 2003, the PVP Office has received 162 new applications, has closed 135 applications, and currently has 862 undecided applications. Our best predictions for this fiscal year indicate that we will receive a total of 260 applications and dispose of a total of 500 applications. We are currently ahead of the prediction for incoming applications due to the temporary increase in filings that were timed to come in before the new fees became effective on February 10th.

Update on Process Improvement Plan (Six Sigma). Janice Strachan. The Six Sigma project that was reported at the November 2001 meeting was summarized. At that time, the average processing time (from filing date to issuance date) was 849 days. An analysis of the work flow was done and suggestions for improvement to the work flow were made. Since November 2001, the PVP Office has implemented several improvements, including a quality assurance program performed by an examiner rather than the commissioner, more frequent progress reviews, and changes to the website. We are still working to implement electronic payment, electronic filing, direct seed deposits, and fees for additional customer services. For those applications processed since November 2001, the average processing time is 935 days.

Additional activities that impacted the work flow included an Office of the Inspector General inquiry about biotechnology and seed samples, phytosanitary requirements, scanning expired certificates, discussions about migrating to a new database structure, the Simplot protest, an attempt to extend the length of protection for an expiring application, biotechnology training class, MS Access training class, drafting and implementing the 35% fee increase, drafting the supplemental fee structure, discussions about remodeling versus relocating our office space, and administrative duties.

We have gone through one cycle of Six Sigma, which focused on the overall productivity of the PVP Office. The next step is to look at details of the processing cycle, on a per crop or per person level to see if there are ways of accommodating differences in crops and streamlining these processes.

PVP Quality Assurance Program. Mark Hermeling. Only one third of the applications are reviewed to spot check whether quality assurance is being met. We continue to refine the list of standards that the examiners (and applicants) must meet. On the application form, the standards include having a valid signature, evidence that the variety is new, and name clearance. The Exhibit A needs to trace the pedigree back to public or commercial lines, then describe the breeding methods and selection criteria used, finish by showing evidence that the variety is uniform and stable, and explicitly discuss variants. The Exhibit B must provide the names of comparison varieties, and establish and support clear differences. The Exhibit C must provide an adequate variety description. Data in the Exhibit D should not contradict information presented elsewhere in the application. The Exhibit E must properly establish who is the owner and their eligibility for PVP.

Variety name discussion: The Board members questioned whether the variety naming regulations in the US are similar to those in other UPOV countries. Variety names must be

unique worldwide and the same variety name must be used in all countries. After some discussion, the Board decided that the applicant is responsible for clearing the variety name with the proper naming authorities.

PVP Office Site Update. Alan Atchley. The administration in the NAL Building has informed us that they want to install sprinklers on our floor within the next two years. This has prompted another discussion of whether to leave the NAL Building or to temporarily relocate within the building. The reasons for leaving include the costs of renting; the on-going building remodeling and repairs with its associated noise and debris; the age of the building (40 yrs old) and associated inconveniences, and the implementation of additional security measures due to homeland security issues. The reasons for staying include access to the library collections, ease of access for visitors and USDA officials, access to experts located on the Beltsville campus, and costs involved with moving the office to another location. In order to compromise between access to resources and the desire for better accommodations, the PVP Office is looking at relocating options that include other buildings in Beltsville, and sites that are within reasonable commuting distance from Beltsville and the downtown administrative offices.

PVP Financial Summary. Annette White. In fiscal year 2002, the PVP Office had a \$115,000 deficit. This deficit would have been higher but PVP received additional revenue from a Biotechnology fund (\$352,000) and a Global Market fund (\$35,000). The majority of the money from the biotechnology fund (\$314,000) was used to fund the database conversion project, and \$25,000 of the Global Market money was used to attend Biodiversity Treaty meetings and to travel to UPOV meetings. At the end of the fiscal year, the PVP trust fund balance was \$1,197,672.

For fiscal year 2003, the estimated expenditures are \$1,243,918 and the estimated income from user fees is \$936,000. This revenue estimate assumes a total of 260 new applications will be filed and includes fees at the 35% increase level for applications received after February 10, 2003. Although it is not a permanent addition to their future budgets, the PVP will get money from Biotechnology fund (\$438,000) and Global Market (\$35,000) in FY 2003. The estimated budget shortfall for FY 2003 is \$210,000, which will bring the trust fund balance at the end of FY03 to \$988,000. White recommended that the Board consider raising fees an additional 20% to be effective at the start of FY05.

The Board discussed whether this fee increase was really necessary on top of the 35% fee increase that just went into effect on February 10, 2003. There is a point where the value of a PVP Certificate may be less than the costs of acquiring it. Epstein answered that it takes 18 months for a proposed fee increase to be processed and go into effect. The 35% fee increase made up for five years without fee increases. Over the next two years, the PVP Office will incur cost of living salary increases, increased rent and supply costs, and possible loss of biotechnology and global market monies. We are obligated to complete the processing of all applications that have already been filed. Although we try to anticipate future needs, we are always behind. In relation to research and development costs, PVP fees are small, but these costs are passed on to seed buyers. The Board stated that raising fees is not a magic bullet. PVP needs to promote itself to potential customers, and especially look outside the USA.

Following this discussion, the Board approved a 20% fee increase, which would become effective in fiscal year 2005. The Board noted that even a 20% fee increase will not cover all

costs of an office move, database migration, and other projects. Increased productivity is the only way to serve customers and show the strength of the PVP Office and its staff. Examiners need to focus on the job responsibilities for which they were trained (agriculture, botany, horticulture). If an activity does not lead to examination, then the Office should not do it. It may appease customers if they could see the list of services that they are getting for their money, and the standard operating procedures for their crop.

PVP E-Business and Database Migration Plans. Bernadette Thomas. PVP is pursuing five major projects related to computer technology and databases. The first project is the database migration, which will occur in five phases. We are in the first phase of writing a requirements analysis and finding a contractor to do the work plan. The money from the biotechnology fund will pay for this phase. Once the work plan is complete, the next phases are to migrate the data, train the staff, maintain the system, and determine any system enhancements.

The next project is to allow payment of some fees by credit card. We will start by accepting payments for new applications, issuance fees, and copy fees. We are making good progress on this project and hope to be able to implement it by October 1, 2003.

We have started scanning expired certificates. We contracted with a company to scan the certificate inserts only (not the correspondence or the examiner reports). We plan to make these files searchable and post them on the web.

We are rebuilding old forms in MS Word and Adobe (pdf) formats. The modified forms will need to be reviewed and given form numbers before they can be posted to the website. We are also investigating the acceptability of electronic signatures.

Currently, the text of our web page is all on one page and you scroll down to see the entire text. We have drafted a version which breaks the information into separate pages, with links to take users to the desired pages more quickly. The text of the web page is updated when new information is available. The application status data is downloaded once per month within the first week of the month.

With the exception of the database migration project, each of these projects is funded from PVP user fees.

Discussion on the US PVP. Paul Zankowski. One of the recommendations from the Six Sigma review was to deposit seed directly at Ft. Collins, Colorado. This would streamline PVP work flow and prepare for paperless filing in the future. Some crops use the seed sample during examination, so a small seed sample will still be needed for those crops. How can we best reflect these changes in the regulations?

The Board wanted to know how this change will affect the filing date of the application; what will serve as verification; and whether foreign applicants will have an advantage over US applicants. They were insistent that seeds be deposited prior to or at the same time as filing the application so that processing and issuance would not be delayed. After some discussion, the Board voted to make the following change to Section 97.6(1):

At the applicant will submit with the application:

- (1) (a) for certain crops, a sample of 25 seeds of the variety to verify the statements in the application;
- (1) (b) verification from the seed depository that at least 2,500 seeds of the viable basic seed required to reproduce the variety have been deposited in a public depository approved by the Commissioner and will be maintained

for the duration of the certificate;@

As part of homeland security, the APHIS has become more strict with regards to the need for phytosanitary certificates, along with other inspection licenses for certain crops. Seed samples from foreign applicants must have these documents and will then be subject to an inspection in Beltsville. Without these documents and inspection, the samples will be refused by the NCGRP.

PVP has participated in UPOV administrative meetings. In the past year, there have been discussions at these meetings about patents versus plant breeders rights. We have been able to provide input into our interpretation of plant breeders rights and intellectual property rights.

PVP also participates in interagency meetings on biodiversity, access and benefit sharing, and related topics.

At the WIPO/UPOV meeting last fall, other people were referencing an article from the Houston Law Review, *U.S. Plant Variety Protection: Sound and Fury...?* and another article from Nature Biotechnology written by the same authors (a copy of this article was provided to the Board). These articles portray a negative image of the U.S. PVP system. The Board provided guidance in how to respond to these articles: correct any incorrect facts; keep responses short; let others (non-PVP staff) write the positive spin rebuttals.

PVP Role in International Training. Tom Salt. In 1991, there were 18 UPOV member countries. Now there are 51 UPOV member countries, with 150 more countries interested in developing laws similar to UPOV. This growth has been spurred by international treaties, such as NAFTA and the Convention on Biological Diversity. Although UPOV has a sample law that countries can use to fill in the blanks, the actual process of implementing the law can be overwhelming to those assigned this task. The PVP has been able to assist five countries as they develop their plant breeders rights system.

The Foreign Agricultural Service and ASTA⁴ get grants to do outreach for access and benefit sharing. These outreach efforts have three phases, which happen over a five year period. The first phase occurs when the new PBR⁵ director is trying to establish the office. At this point, they need help with drafting a budget, staffing, and writing their rules and regulations. The second phase starts after they hire staff, who need to be trained in how to examine an application. The third phase happens after applications start arriving and the examiners experience the actual work load, and start handling difficult situations.

The PVP has assisted at each of these levels by sharing our experiences, and encouraging them to establish and follow procedures. Our efforts help the international movement of seed under the OECD. If other countries understand the US PVP system, they may develop a similar system, which can harmonize the requirements for PVP applications between major trading partners. The cost to PVP is zero because our contracts with the FAS cover salary, benefits, travel, and lost productivity. When eight Chinese examiners spent a week here, the cost to FAS was \$18,000 for two examiners=time.

⁴American Seed Trade Association

⁵PBR = plant breeders=rights

Proposed Supplemental Fees. Janice Strachan. Currently we are drafting the language for the proposed supplemental fees that were approved at the November 2001 Board meeting. These fees will apply to optional administrative services that customers may request. Based on the requests for these services during fiscal year 2001, the projected income from the supplemental fee schedule is estimated to be \$143,000.00. This figure will vary depending on the number of requests for these services that are requested by users.

Only one fee will apply to all applicants and that is the Paperwork Reduction Act fee of \$250 per application. This fee will be used to scan certificate papers into electronic format, and to maintain the software and hardware needed to archive documents, make them searchable, and make them available to PVP staff and customers. Based on 260 new applications being received, this fee will generate \$65,000.00 per year.

The new fee schedule will include fees for providing training to interested people. As was stated earlier, the Foreign Agricultural Service is primary user of this service at this time. They have already stated that the proposed fees are excessive and will cause them to find another source for this service, such as the programs currently available from Cornell or Michigan State.

The Board recommended that the Commissioner check with the government training institute to further investigate and right-size these fees.

PVP Comparisons to Patents. Tom Salt. Because PVP and patents are separate laws with separate rules and regulations, there are differences in the requirements, claims, enforcement, duration, and costs. In order to compare the two laws, Salt listed some concepts that are similar and pointed out the differences in the two statutes. He also emphasized the differences between patents, PVP and the UPOV Convention.

The Patent and Trademark Office has made at least three changes in the last two years. Although patents are exclusionary, plant breeders rights were drafted in 1961 to allowed for non-exclusionary use for the purpose of advancing breeding work. Many people in Europe and elsewhere perceive US patents as allowing for short term capital gains and that in 10 years all germplasm will be locked up, thus making more money for lawyers who handle the licensing agreements. There are five countries which grant patents on plants, but 51 who have implemented a plant breeders rights system.

Future Program Activities of the PVP. Paul Zankowski. The on-going activities of the office were summarized: supplemental fee docket, e-business issues, Six Sigma, new business opportunities, and international training. The productivity goals for the PVP are to finish 500 applications per year, either by issuance of the certificate, denial of the application, or by applicant abandonments or withdrawals. At this rate, the number of undecided applications will be reduced to under 400 by fiscal year 2005.

We also have the goal of attending more seed trade and variety review board meetings to promote PVP and answer customer questions. There is the possibility that we will be able to accept applications for asexually propagated plants in the future, if certain lobbying groups can modify the PVP Act. Although we performed eight searches for the Patent Office to locate prior art, the Patent Office examiners did not find the results acceptable. Several UPOV countries have expressed interest in obtaining our crop databases. If this is done, a reasonable fee will be charged for them.

We will continue to offer training as long as we can afford to free up examiner time. By training applicants how to prepare better applications, we can eliminate time-consuming requests

for additional information and supplemental data. By increasing our productivity, we show our customers that we provide a valuable service.

New Business.

Dr. Cabrera asked whether the PVP could save money on office space by allowing employees to work from home. Dr. Epstein answered that this has been tried for employees with health concerns for a short time. The security of the data was a major concern.

Dr. Whiteaker provided information from the California Seed Association (CSA) Newsletter that indicated the CSA has introduced AB 1080 (Assembly Agriculture Committee) within California. The purpose of this amendment would be to enable the California Department of Food and Agriculture and county agricultural commissioner to take enforcement actions related to violations of the PVPA in California.

Meeting adjourned.

Summary List of Recommendations by the Board:

1. The Board voted 10:1 to uphold the decision of the PVP Office for permanent abandonment of the 'L-93' bentgrass application.
2. The Board recommends that the applicant do the variety name clearance themselves and that PVP guide them in how to do this.
3. The Board recommends that PVPO increase fees by 20%.
4. The Board recommends that applicants ship seed directly to NCGRP, that NCGRP verifies receipt of the seeds within 10 days, and that 25 seeds of certain crops be sent to PVP with the application when it is filed.
5. The Board recommends that short articles be drafted to clear up factual errors in articles about PVP, for example the Sound & Fury article, but that rebuttals or opinions of the benefits of PVP not be written by USDA.
6. The Board recommends that the training fees in the supplemental fee proposal be investigated to right-size them.