



BMT/9/14

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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS
GENEVA

**WORKING GROUP ON BIOCHEMICAL AND MOLECULAR
TECHNIQUES AND DNA PROFILING IN PARTICULAR**

Ninth Session
Washington, D.C., June 21 to 23, 2005

REPORT

*adopted by the Working Group on Biochemical and Molecular Techniques, and
DNA Profiling in Particular*

1. The Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT) held its ninth session in Washington, D.C., United States of America, from June 21 to 23, 2005, under the chairmanship of Mr. Gerhard Denecken, Denmark. The list of participants is reproduced in Annex I to this report.

Adoption of the Agenda

2. The BMT adopted the revised Agenda as reproduced in document BMT/9/1 Rev., with the addition of an item for a presentation on the systems for plant variety protection available in the United States of America.

Plant Variety Protection Systems in the United States of America

3. The BMT was welcomed by Mrs. Karen Hauda, Attorney-Advisor, Office of International Relations, United States Patent & Trademark Office (USPTO), who provided an overview of the plant variety protection systems available in the United States of America. A copy of the presentation is reproduced as Annex II. Mrs. Anne Marie Grunberg, Patent Examiner, United States Patent and Trademark Office, made a presentation on the utilization of molecular markers in the applications for plant patents and in plant utility patents,

reproduced as Annex III, and Mr. Paul M. Zankowsky, Commissioner, Plant Variety Protection Office, United States Department of Agriculture (USDA), made a presentation on the Plant Variety Protection Office (USDA), as reproduced in Annex IV.

Report on Development in UPOV Concerning Biochemical and Molecular Techniques

4. The Office of the Union (the Office) provided a report on developments in UPOV concerning Biochemical and Molecular Techniques, on the basis of document BMT/9/2.

5. A representative of the Community Plant Variety Office (CPVO) welcomed the decision of the Technical Committee (TC) and the Administrative and Legal Committee (CAJ) to invite the BMT Review Group to examine the possible use of molecular tools for variety identification in relation to the enforcement of plant breeders' rights and technical verification, and wished to know when it would meet. The Office explained that no date had been fixed, but given the need to involve experts from both the TC and the CAJ, it was likely that it would meet in conjunction with the sessions of the TC and CAJ to be held in April, 2006.

Reports on the work of the Crop Subgroups

6. Mr. Luis Salaices (Spain), Chairman of the *Ad hoc* Crop Subgroup on Molecular Techniques for Sugarcane (Crop Subgroup for Sugarcane) reported that the Crop Subgroup for Sugarcane had held its second session in Poznań, Poland, on the afternoon of June 28, 2004, after the meetings of the Wheat and Potato Crop Subgroups and in conjunction with the thirty-third session of the Technical Working Party for Agricultural Crops (TWA). The Crop Subgroup for Sugarcane had agreed with the proposals of the Crop Subgroup for Wheat (all participants having attended both meetings) for the future development of the BMT Guidelines (proj.2). The Crop Subgroup for Sugarcane noted that the developments presented in document BMT-TWA/Sugarcane/2/2 "Draft Guidelines for Harmonizing Protocols on the Development of Molecular Markers for Use in DUS Testing with a Specific Emphasis on Sugarcane" already followed the BMT Guidelines (proj.2) and that, as presented in document BMT-TWA/Sugarcane/2/3 "Progress report on the Crop Subgroup for Sugarcane", work for the development of specific BMT Guidelines for sugarcane would continue, with new results and information from a "ring test" involving Australia, Brazil, Colombia, France, Mauritius and South Africa, expected in 2005. Mr. Salaices noted that it might be appropriate to hold the next meeting of the Crop Subgroup for Sugarcane in conjunction with the TWA, which would hold its thirty-fourth session in Christchurch, New Zealand, from October 31 to November 4, 2005.

7. The BMT heard from Mrs. Beate Rücker (Germany), Chairperson of the Crop Subgroup for Potato that it had held its first session in Poznań, Poland, on June 28, 2004, in conjunction with the TWA Meeting and the Crop Subgroup sessions for Wheat and Sugarcane. The Crop Subgroup for Potato agreed with the proposals on the "BMT Guidelines", made by the Crop Subgroup for Wheat, which had met immediately prior to the session. It noted the developments presented in five documents by experts from France, Germany and United Kingdom. The following main issues were raised: (a) the importance and potential power of molecular techniques for variety identification; (b) benefit from work on issues not related to distinctness, uniformity and stability for consideration of molecular techniques in DUS relevant areas; and (c) harmonization of methods and exchange of data.

The Crop Subgroup for Potato had considered that work on variety identification could be useful, but suggested that the TC, the CAJ and the BMT Review Group would need to develop guidance on how specific techniques could be used for variety identification if those techniques differed from the methods used for testing distinctness, uniformity and stability. It agreed that work could continue with the aim of improving and harmonizing methodologies and the construction of databases.

8. Mr. Robert J. Cooke (United Kingdom), Chairman of the Crop Subgroup for Wheat, reported that it had held its second session in Poznań, Poland, on the afternoon of June 28, 2004. A report had been made on research in the United Kingdom which explored the possibility of an option 2 approach using the PREDIP software developed by experts from France. The document BMT Guidelines (proj.2) was discussed. The Crop Subgroup for Wheat had considered that the document should be redrafted by an expert/experts with suitable knowledge of, and experience in, the use of molecular techniques. On that basis, it had agreed that Mr. Cooke should undertake the redrafting, with the assistance of Mrs. Françoise Blouet (France), in connection with section 5 “Constructing the database”, for molecular techniques. Mr. Cooke noted that, if sufficient papers were available, the next meeting could be held in conjunction with the thirty-fourth session of the TWA. However, he considered that it was more likely that it would be 2006 before sufficient papers would be available.

9. Mr. Michael Camlin (United Kingdom), Chairman of the Crop Subgroup for Ryegrass, explained that the first meeting was planned to take place in 2005, possibly in conjunction with the thirty-fourth session of the TWA. He noted that the International Seed Federation (ISF) had held a workshop on essential derivation in ryegrass in February 2005. The information provided at that workshop had indicated a good agreement between morphological and molecular differences, suggesting that an option 2 approach might be possible.

10. The representative of ISF explained that the objective of the workshop on essential derivation in ryegrass had been to harmonize the approach of breeders in respect of the code of conduct on essential derivation in relation to the thresholds for essential derivation which the ISF had identified in 2002. A meeting would be held in October 2005, in order to finalize the arrangements for a ring-test, which would take place between December 2005 and June 2006.

Short Presentations on new Developments in Biochemical and Molecular Techniques by DUS experts, Biochemical and Molecular Specialists, and Plant Breeders

11. The BMT agreed that, where agreed by the relevant experts, the presentations made at the meeting should be made available in the BMT document section of the UPOV website, as addenda to the relevant documents.

12. An expert from the Ministry of Agriculture (MOA) of China reported that the list of species covered by the plant breeder's right system has been extended to a total of 62 species at that time. They also reported that the number of applications for plant breeder's right filed at the MOA had been increasing every year. In 2004, 735 applications had been filed, representing an increase of 30% compared to 2003. At the end of 2004, the total number of applications filed was 2046 and 503 plant breeder's rights had been granted. They reported that during 2004 the Ministry of Agriculture, the State Forestry Administration and the State

Intellectual Property Office, in cooperation with the Office of the Union, had organized a “Seminar on the Advantages of the 1991 Act of the UPOV Convention” and a “Workshop on Data Handling”. With regard to the use of molecular markers, China was following the approach agreed within UPOV.

13. The BMT heard from an expert from Canada that there had been a two-day seminar on UPOV plant variety protection and the use of molecular techniques. The first day of the seminar had considered the national situation and the second day had taken an international perspective. Thanks were given to the international participants with special thanks to the international speakers at the seminar. The seminar had proved to be very informative. It was explained that Canada was very interested in the potential for molecular techniques and considered that those techniques might be of benefit in the examination of distinctness, uniformity and stability, particularly in some species.

14. The expert from France reported that there was a lot of work on microsatellite markers in France, mainly in maize and oilseed rape, but also in other crops such as rose and ryegrass. In respect of an option 1 approach, work would be done to try to develop markers for disease resistance in sunflower and tomato. France was involved in work for the Community Plant Variety Office (CPVO) and also welcomed other forms of international cooperation.

15. The representative of ISF reported that ISF considered that molecular markers could be very effective for variety identification. He also explained that ISF was very active in studies on essential derivation, with projects concerning ryegrass, tomato, oilseed rape, cotton and maize. With respect to the project on tomato, he clarified that that was, strictly speaking, not a project on essential derivation, but more to check on the presence of parent lines in hybrid varieties. The latest project concerning maize was seeking to consolidate three earlier studies on that crop conducted by breeders from France and Germany from and by breeders and public laboratories from the United States of America. A meeting was scheduled for October 2005, the aim of which was to develop a common approach on ryegrass and one in December 2005, to develop a common approach in maize.

16. An expert from the United States of America explained that the National Science Laboratory of the U.S. Department of Agriculture (NSL) offered molecular testing services on a fee-paying basis and noted that applicants for plant variety protection would be able to request their services. He also expressed the interest of NSL to participate in ring tests concerning molecular techniques and database construction and proposed that NSL be included in the membership of the existing Crop Subgroups in order to participate in those matters.

17. The representative of the International Community of Breeders of Asexually Reproduced Ornamental and Fruit-tree Varieties (CIOPORA) noted the value of molecular markers as tools for variety identification in relation to the enforcement of plant breeders' rights and for use in relation to the investigation of essential derivation. He reported on a project involving carnation breeders in Spain, where a database of molecular marker information was being constructed in order to help to combat unauthorized variety propagation.

18. An expert from the United Kingdom explained that he would be presenting papers on the work in the United Kingdom concerning SNPs in barley and SSRs in oilseed rape. He then reported on a CPVO co-funded project, involving Germany, the Netherlands and the United Kingdom, concerning a European reference collection of rose varieties. That project

involved a pilot experiment to construct a database integrating key morphological information, based on Technical Questionnaire characteristics, standardized photographs and molecular marker profiles, obtained from microsatellite markers. The principle aim of the project was to examine how the database could be used for the management of reference collections and for technical verification.

19. An expert from Spain reported that work on molecular markers was being pursued for grapevine, peach, olive and other fruit tree species. The identification of molecular markers linked to disease resistance was underway in relation to *Phaseolus vulgaris* (in relation to BCMV virus), watermelon, melon, tomato and some other species.

20. The BMT heard from an expert that work in Argentina was looking at statistical approaches for the identification of soybean varieties in the context of enforcement of plant breeders' rights. Work was also starting on sunflower. Work on developing protein profile information for varieties of wheat and ryegrass was also in progress.

21. A representative of the CPVO reported that, up to that time, it had decided to co-finance six research and development projects, including the project on rose previously reported by the expert from the United Kingdom. He clarified that some of the work was in relation to molecular techniques, in the framework of the management of reference collections in an option 1 or 2 approach. It was also reported that the CPVO intended to facilitate, for titleholders, enforcement of their plant breeders' rights and, as a first step, was holding a seminar in Brussels on October 4 and 5, 2005, and may hold further seminars in 2006. The possible use of molecular markers in relation to the presentation of evidence would be covered in the seminar.

22. An expert from the Republic of Korea reported that there was work on molecular markers in a number of species. In particular, work on a possible option 2 approach for the management of the reference collection of hot pepper varieties, using microsatellite markers, was being investigated. Another expert from the Republic of Korea reported on work to use microsatellite markers to screen 250 varieties of *Castanea* (Chestnut). Data would be collected on both molecular and morphological information. He noted that there had been an exchange of germplasm of *Castanea* over more than 1,000 years between China, Japan and the Republic of Korea and observed the potential benefits of cooperation between those countries in such work.

23. The BMT heard that, in Japan, a draft law to amend the Seeds and Seedlings Law, which would extend the coverage of protection to products made directly from harvested material of the protected variety, was under consideration by the Diet. A list of different kinds of products to be covered by the plant breeder's right would be established by a Government Order. The maximum duration of the breeder's right would be also prolonged from 25 years to 30 years for woody plants and from 20 years to 25 years for the other plants.

24. An expert from the Netherlands reported that, since the meeting of the Crop Subgroup for Potato, the Scottish Agricultural Science Agency (United Kingdom), CGN (Netherlands) and the Bundessortenamt (Germany) had cooperated and had identified nine suitable microsatellite markers to characterize 300 varieties. The results would now be cross-checked. A proposal for a project to extend the number of varieties and to develop a searchable database had been submitted to the CPVO. Germany and Poland would also be involved in that project. The aim would be to characterize all the varieties in the Common Catalogue of the European Union by 2007.

25. The expert from the Food and Agriculture Organization of the United Nations (FAO) recalled the close collaboration with UPOV and thanked UPOV for extending the invitation to FAO to participate in the BMT session. She noted that it would be helpful to know whether the use of molecular techniques could “jump-start” the DUS testing systems in developing countries, in particular where there were limited resources. She also presented a brief report on the recent developments concerning the International Treaty on Plant Genetic Resources for Food and Agriculture and thanked the United States of America for sponsoring the First Meeting of the Contact Group on the Terms of the Standard Material Transfer Agreement which would be held in Hammamet, Tunisia, from July 18 to 22, 2005.

26. The Chairman reported on developments in Denmark. He informed the BMT that a project using microsatellite markers to characterize varieties of ryegrass was in progress and that initial results would be available at the end of 2005. Denmark was participating in the CPVO project on oilseed rape. In addition, a project was under development to demonstrate an Option 1 approach in barley, based on molecular markers linked to mildew resistance and hordein proteins.

Reports of Work on Molecular Techniques on a Crop-by-crop Basis

Repeatability and discrimination power of SSR data in the vegetatively reproduced potato varieties: impact of “weak alleles”

27. The BMT considered document BMT/9/4 and a presentation made by Mr. Eric Bonnel (France).

28. An expert from the Netherlands noted that occurrence of “weak alleles” had been found in the project it had conducted jointly with the United Kingdom. In their case, repeating the run had been found to overcome the problem in some cases. An expert from Canada noted that the primer sites could have evolved during the breeding process. An expert from the United Kingdom informed the BMT that the Scottish Crop Research Institute, which had been a source of markers used in their project, was re-sequencing to improve their primer sites.

29. The representative of ISF expressed surprise that no varieties were found to have SSR variability in the range between 5 and 15%. An expert from the United Kingdom considered that the absence of variability in that range was a matter of chance, and he had found varieties within that range. It was considered that the level of variability below 5% was probably due to artifacts.

Assessment of the uniformity of Chinese maize varieties by a set of SSR markers

30. The BMT received a presentation by Ms. Fengge Wang (China), based on document BMT/9/5.

31. The representative from ISF noted some difficulty in working on hybrid varieties, because of the possibility of plants resulting from outcrossing. The expert from Germany suggested that it would be worthwhile to investigate the uniformity of the varieties using morphological characteristics and to examine the uniformity of the parent lines. In response to a question by an expert from the United States of America, it was clarified that the primers

used in the project were not generally available; however, once they were published as a standard they would become available for use in other countries.

32. Another expert from China clarified that the work on molecular data in relation to distinctness was in the form of research in relation to a possible Option 3 type approach for which its suitability/value for the assessment of distinctness had not yet been established. He further clarified that it was not being used in the examination of DUS at that time. However, molecular data was being used in relation to variety identification.

Identification of quince varieties using SSR markers developed from pear and apple

33. The BMT received a presentation by Mr. Tetsuya Kimura (Japan), based on document BMT/9/6.

34. It was noted that the presentation contained a suggestion to consider a variety as non-distinct if it had the same banding pattern as another variety. In that respect, it was noted that varieties might be distinguishable using morphological characteristics even if they had the same banding pattern, since their genotypes would not necessarily be identical; i.e. a banding pattern does not represent a complete genotype.

35. An expert from the United Kingdom noted that molecular techniques might offer a particular advantage in fruit trees because of the long time required to establish trees for the examination of morphological characteristics.

Research project co-financed by the Community Plant Variety Office (CPVO): “Management of Winter Oilseed Rape Reference Collections”

36. The BMT received a presentation from Mr. Robert Cooke (United Kingdom), based on document BMT/9/8.

SNPs in barley: a potential “Option 1” approach

37. Mr. Robert Cooke (United Kingdom) made a presentation, based on document BMT/9/9.

38. The expert from Germany suggested that it would be useful to investigate the status of “alternative” type varieties in barley.

39. In response to a question by a representative of the CPVO, Mr. Cooke indicated that the results of the study would probably be made generally available.

A microsatellite-based system for the protection of grapevine varieties

40. The BMT received a presentation by Mr. Javier Ibañez, based on document BMT/9/11. Mr. Ibañez clarified that, in paragraph 17 of document BMT/9/11, it should read “minimum distance of two alleles” instead of “minimum distance of 1 allele”.

41. Mr. Ibañez reported that the technique had been used in a court case in the United Kingdom in relation to variety identification.

42. A representative from the CPVO noted the use of only two plants to examine uniformity and wondered if such an approach could be followed for the DUS growing trials and could reduce the number of plants to be examined in vegetatively propagated species.

43. The BMT discussed, in particular, the proposal made in the document for a difference of two alleles to be used as a basis for distinctness. An expert from the United Kingdom noted that the proposal followed the same basis as that considered by the BMT Review Group under Option 3 for Rose. An expert from France suggested that the approach proposed in the document might be worthy of further consideration in relation to other vegetatively propagated varieties, notably potato. A representative of the CPVO clarified that, under the CPVO regulations, distinctness had to be based on phenotypic differences. It was considered that the proposal concerning grapevine should be considered further by the interested parties, including in particular the breeders, in the form of a specific crop subgroup or jointly with other vegetatively propagated species.

44. The expert from Germany suggested that the information collected on grapevine would be a good example for the BMT Review Group to consider in relation to matters concerning variety identification.

Analysis of a database of DNA profiles of 734 hybrid tea rose (Rosa hybrida) varieties

45. The BMT received a presentation from Mrs. Lysbeth Hof (Netherlands), based on document BMT/9/12, which had been prepared by Mr. Ben Vosman (Netherlands).

46. On the basis of the results presented, several experts considered that an Option 2 approach was unlikely to be successful in rose.

The potential of SNP markers in expressed genes for identification of potato varieties and determination of distinctness

47. The BMT received a presentation from Mr. Robert Cooke (United Kingdom), based on document BMT/9/13, which had been prepared by Mr. Ben Vosman (Netherlands).

48. An expert from Spain commented that it would be difficult to develop an option 2 approach for microsatellite markers when using only a small number of markers.

49. In relation to whether markers detecting polymorphisms in expressed genes would be considered acceptable, it was recalled that the BMT Review Group were asked to assess possible application models in relation to:

(a) conformity with the UPOV Convention; and

(b) potential impact on the strength of protection compared to that provided by current examination methods and advise if this could undermine the effectiveness of protection offered under the UPOV system.

50. In that context, a question was raised as to whether Option 3 could also include a mixture of morphological characteristics and molecular techniques. It was clarified that Option 3 did not exclude any possibility.

51. The BMT discussed whether proposals concerning vegetatively propagated varieties should be considered by the TC and the BMT Review Group after review in the relevant Crop Subgroups. The representative of CIOFORA supported the establishment of a Crop Subgroup covering vegetatively propagated varieties. It was noted that it might be appropriate to avoid consideration of whether the proposals fell under any, or none, of the existing options considered by the BMT Review Group and to consider individual proposals on their own merits.

52. The BMT expressed interest in the development of these techniques for future consideration under Option 1.

Guidelines for Molecular Marker Selection and Database Construction “BMT Guidelines”

53. The BMT considered document BMT Guidelines (proj.3), presented by Mr. Robert Cooke (United Kingdom). Mr. Cooke acknowledged the contribution of Mr. Ben Vosman in the drafting of the document. In relation to section 5 of the BMT Guidelines, the BMT received a presentation by Mr. Sylvain Grégoire (France) based on document TWC/23/7-BMT/9/3.

54. The BMT made the following proposals:

Title	to read “Guidelines for DNA-Profiling: molecular marker selection and database construction (“BMT Guidelines”)
A INTRO.	First sentence to read “The purpose of this document (BMT Guidelines) is to provide guidance for developing harmonized methodologies in the generation of molecular data in order to ensure that the quality of the data produced can be universally accepted for database construction.”
1.3	to be revised to avoid an implication that the document restricts the techniques which might be used and to consider adding examples of other techniques e.g. SCARs, CAPs.
2.1	to clarify that this section identifies criteria which are appropriate for molecular markers, irrespective of the use of the markers and to explain that specific uses may impose certain additional criteria.
2.1(a)	subparagraph (a) after (c) to be corrected to (d)
2.2	title to read “Criteria for specific types of molecular markers”
2.2.1	to consider moving the explanation of microsatellite markers to a glossary
2.2.1.3	to add a recommendation that the markers should not be linked
2.2.2	to explain SNPs in a glossary, in a similar style to that used to explain microsatellites. To explain that, whilst there would be only two allelic states, the dosage could vary for polyploid plants. Last sentence to read “...to allow the efficient and effective profiling...”
2.2.3	to be deleted
2.3	to become a new Chapter 3. Second sentence to read “UPOV has developed guidance for the use of products or methodologies which are the subject of intellectual property rights (see document TGP/7/1 Annex 3, GN 14) and this guidance should be followed for the purposes of these guidelines.
3.1	to be revised to address the different arrangements for DUS testing, e.g. official testing and breeder testing approaches.

3.3	to introduce a section for hybrids indicating that method of sampling for hybrid varieties depends on the type of hybrid.
3.3.1	to read "...except for mutants which are not usually..."
3.3.2	final sentence to be deleted
3.4	final sentence to be deleted
4.1	to replace reference to "ISTA-type" with a reference to an internationally recognized method of validation.
4.2.2	to read "The detailed methodology should be set out in a protocol".
4.3.1	to replace "an agreed set" with "a set"
4.3.2	to replace "...within the varieties concerned..." with "...within the species and type of variety..."
4.3.3	to replace reference to a "blind ring test" with a reference to an internationally recognized method of validation.
4.4.1 (b)	to replace "normal gene" with "PCR"
4.4.2	to read "... Also, in cases where a gel-based system is used for visualizing marker bands, a suitable size (molecular weight) 'ladder' is recommended, to simplify the interpretation of results within and between laboratories. However, that should not be considered as a replacement for an allele reference collection."
5.	see below
Glossary	glossary of terms e.g. PIC, SNPs, pigtail etc. to be provided

55. In relation to section 5 "Databases", the BMT agreed with the conclusions of the Technical Working Party on Automation and Computer Programs (TWC), as reported by the Chairman of the BMT, that the six core logic objects identified in Figure 1 of document TWC/23/7-BMT/9/3 be included in an addition item and made reference to document TWC/23/7-BMT/9/3 when relevant. As proposed by the TWC, it was agreed that the TWC and, in particular, Mr. Sylvain Grégoire (France) should contribute to the drafting of section 5 on that basis.

56. It was agreed that codification of the logical objects was of crucial importance for the development of an exchangeable database. In that respect, it was recalled that the species codification was addressed by the UPOV code and, apart from some exceptions such as candidate varieties, the variety denomination provided codification for varieties. It was also thought that the identification of the marker technique (e.g. SSR, SNPs etc) was straightforward. However, it was noted that the codification of the loci and the alleles was an area which would require further development by the relevant experts.

57. Mr. Grégoire suggested that it would be useful to move forward with a pilot project, involving a small number of crops, in the development of an exchangeable database. He noted that from an IT perspective such an exercise would be straightforward, but that it would require all participating partners to identify the markers to be used and to clarify and agree on the status of the information to be included in the database and the accessibility of that data, e.g. to contributing partners or to all interested experts from members of the Union. The representative of ISF considered that UPOV was the appropriate body to take the matter forward.

58. Mr. Michael Sussman, National Science Laboratory (NSL), United States Department of Agriculture, explained that NSL would be able to participate in ring tests and a pilot

database project involving any crops of interest. The relevant experts from the Netherlands and the United Kingdom, involved in the projects presented in documents BMT/9/8 “Research project co-financed by the Community Plant Variety Office (CPVO): Management of winter oilseed rape reference collections”, BMT/9/12 “Analysis of a database of DNA profiles of 734 hybrid tea rose (*Rosa hybrida*) varieties” and involved in the project to characterize all the varieties in the Common Catalogue of the European Union by 2007 (see paragraph 24), indicated their willingness to participate in a pilot database project. It was agreed that the matter should be considered by the relevant Crop Subgroups and the TC.

The Use of Molecular Techniques in Examining Essential Derivation

International Seed Federation (ISF) Oilseed Rape Essentially Derived Varieties (EDV) Study

59. Mr. Bernard Le Buanec (ISF) introduced document BMT/9/7. The BMT noted that the study was continuing.

Essential derivation and diversity issues in winter wheat

60. The BMT noted the presentation, made by Mr. John Law (United Kingdom), based on document BMT/9/10.

Proposals for the Future Work of the Existing Crop Subgroups and for the Establishment of new Crop Subgroups

61. The BMT invited the relevant Technical Working Parties and the TC to consider:

(a) *Crop Subgroup for Vegetatively Propagated Varieties*

The establishment of a crop subgroup for a range of vegetatively propagated crops which, in conjunction with all interested parties and breeders in particular, could formulate proposals for consideration by the TC and BMT Review Group.

(b) *Crop Subgroup for Wheat and Barley*

The extension of the Crop Subgroup for Wheat to cover both wheat and barley.

(c) *Crop Subgroup for Grapevine*

In relation to proposal (a), consideration should be given to the establishment of a specific crop subgroup for grapevine.

Future Program, Date and Place of the Next Session

62. In response to the invitation received from the Republic of Korea, the BMT agreed to hold its tenth session in Seoul, Republic of Korea, at the beginning of 2007.

63. During its tenth session, the BMT planned to discuss the following items:
1. Opening of the Session
 2. Adoption of the agenda
 3. Short presentations on new developments in biochemical and molecular techniques by DUS experts, biochemical and molecular specialists, and plant breeders
 4. Reports from the BMT Review Group, Technical Committee and Crop Subgroups
 5. Report of work on molecular techniques on a crop-by crop-basis
 6. BMT Guidelines
 7. Construction and standardization of databases of molecular characteristics of plant varieties
 8. Statistical methods for data produced by biochemical and molecular techniques
 9. The use of molecular techniques in examining essential derivation
 10. Recommendations on the establishment of new crop specific subgroups
 11. Date and place of next session
 12. Future program
 13. Report of the session (if time permits)
 14. Closing of the session

UPOV Medal

64. Mr. Gerhard Deneken (Denmark) was awarded a UPOV bronze medal in recognition of his chairmanship of the BMT from 2003 to 2005.

Technical Visit

65. The participants of the BMT were invited to participate in a technical visit to the laboratory of Dr. Perry Cregan (USDA, ARS, Beltsville) on the afternoon of Thursday, June 23, 2005 and to the National Center for Biotechnology Information on the morning of Friday, June 24, 2005.

66. *The BMT adopted this report at the close of its session.*

[Annexes follow]

LIST OF PARTICIPANTS

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[Annex II follows]

Presentation made by

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Plant Variety Protection in the United States

Karen M. Hauda
Attorney-Advisor
Office of International Relations
United States Patent & Trademark Office

1

Types of Protection

- * Plant Patent Act
– 35 U.S.C. §§ 161-164
- * Plant Variety Protection Act
– 7 U.S.C. §§ 2321 et seq.
- * Utility Patent to a Plant
– 35 U.S.C. §§ 101 et. seq. (102, 103, 112)

2

Plant Patent Act

- * First protection of its kind worldwide
- * Enacted in 1930
- * Plant must be New and Non-obvious
- * Applies to asexually reproduced plants and plant parts (not including edible tuber propagated plants)
- * 20 year term from date of filing
- * Right to exclude others from making, using, selling, offering for sale and importing the plant in the U.S.
- * Protects a single variety having a common characteristic

3

Plant Variety Protection Act

- * Complies with the 1991 UPOV Convention
- * Enacted in 1970, Amended in 1980 & 1994
- * Plant must be New, Distinct, Uniform and Stable
- * In U.S. applies only to sexually reproduced plants and tuber propagated plants
- * 20 year protection from date of grant
- * Exclude others from selling, offering for sale, multiplying, conditioning, importing, exporting and stocking the variety in the U.S.
- * Protects a single variety having a common trait

4

Plant Variety Protection Act

- * Provides for Breeder's Exemption
 - Private acts for non-commercial purposes
 - Acts done for experimental purposes
 - Acts done for breeding other varieties
- * Provides for Farmer's Exception under limited circumstances

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Utility Patents: History

- * Diamond v. Chakrabarty, 447 U.S. 303 (1980)
 - Held living things were indeed patentable
- * Ex Parte Hibberd, 227 USPQ 443 (PTO Bd. Pat. App. & Int. 1985)
 - Ruled that seeds, plant tissue cultures, and the plant itself are patentable subject matter under the utility patent statute
- * J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124 (2001)
 - Held newly developed plant varieties fall within the scope of §101, and neither the PPA or PVPA limits this coverage

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Utility Patent

- * Technology neutral
- * 20 year protection from date of filing
- * Right to exclude others from making, using, selling, offering for sale, and importing the patented plant in the U.S.
- * Possible to protect a class of varieties with a novel trait, plant parts and methods of producing or using plant varieties

7

Basic Patentability Standards

- * 35 USC 101, Utility
- * 35 USC 102, Anticipation (Novelty)
- * 35 USC 103, Obviousness
- * 35 USC 112, 1st Paragraph, Written Description
- * 35 USC 112, 1st Paragraph, Enablement
- * 35 USC 112, 2nd Paragraph, Claim Clarity

8

Patentability May Be Negated By:

- * Lack of novelty
- * Sale or public use of the plant in the U.S. more than 1 year prior to filing for U.S. patent

9

Patentability May Be Negated By:

- * Description of the plant in a printed publication, combined with public availability (anywhere) more than 1 year prior to filing for U.S. patent
 - (Ex Parte Thompson, 24 USPQ2d 1618 (Bd. Pat. App. & Int. 1992); In re Elsner 381 F.3d 1125)
- * Obviousness in view of the prior art

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Ex Parte Thompson

- * If the plant in question was publicly available, then the granted PBR certificate, combined with knowledge in the prior art, would enable one of ordinary skill in the art to reproduce the claimed plant, and would therefore constitute an enabling disclosure under 35 USC § 102(b)

11

In Re Elsner

381 F.3d 1125

- * CAFC held: Because the published applications, combined with the foreign sales of the **plants**, placed the claimed inventions in the possession of the public, we therefore hold that they are proper § 102(b) anticipatory references that may bar patentability
- * The foreign sale must not be an obscure, solitary occurrence that would go unnoticed by those skilled in the art. Its availability must have been known in the art, just as a printed publication must be publicly available.

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Plant Protection

- * As of December 31, 2003 approximately:
- * >14,000 Plant Patents
- * >5500 Plant Variety Certificates (~170 Crops)
- * >4200 Utility Patents claiming a Plant Variety
- * >1700 Utility Patents to Plant Varieties that have not been genetically modified

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PAIR

- * Patent Application Information Retrieval
 - Displays information regarding patent application status
 - Both public and private PAIR
 - * Public PAIR: only published applications and issued patents displayed
 - * Private PAIR: secure real-time access to pending application status and history

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PAIR

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16

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[Annex III follows]

Presentation made by

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Diapositiva resumen

- Utilization of Molecular Marker Data in Examination of PLT and Plant utility applications

Utilization of Molecular Marker Data in Examination of PLT and Plant utility applications

Anne Marie Grunberg with special thanks to David Kruse and Keith Robinson

Types of Molecular Markers commonly encountered

- AFLP (Amplified Fragment Length Polymorphism)
- SSR (Simple Sequence Repeats) or microsatellites
- RFLP (Restriction Fragment Length Polymorphism)
- RAPD (Random Amplified Polymorphic DNA)
- Isozymes
- SNPs (Single Nucleotide Polymorphism)
- Codominant/dominant, environment dependence, tissue dependence, population dependent

Plant Patents

- No enablement requirement (how to make and use)
 - No deposit requirement
- New matter and amendments
 - Molecular marker information can be added or deleted
- Sequence compliance

Plant Patents (PLTs)

- One claim drawn to the new and distinct variety of plant as shown and described
 - 1. A new and distinct variety of hybrid tea rose plant, substantially as illustrated and described herein.

Molecular Marker Presentation in PLTs

- Technology identified
- Primer sequence information
- Method steps such as reaction mixture, annealing temperature, type of gel, etc.
- Gel photo showing polymorphism
- Dendrogram information and analysis

Summary of PLT Utilization of Molecular Markers

- Distinctness
- Possession of a trait closely linked to the marker

Plant Utility Patents

- Number of claims
- Product or process
- Claim often refers to molecular markers
 - distinctness
 - Commonly used to identify or follow a trait with tight linkage to the marker
 - MAS
 - Biofactory (oils, phenols, sterols, proteins, etc)

Plant Utility Issues

- Utility requirement (specific, substantial, credible use)
- Enablement requirement (how to make and use)
- Written description requirement (fully described)
- Prior Art (anticipation, obviousness)
- New matter issues (claims must be supported upon filing of amendment)

Utility Guidelines

- 35 U.S.C. 101
 - Substantial, specific and credible use of marker
- Distinguish from a product of nature –
 - plants produced from the method
 - Isolated (claim language)

Enablement

- Deposit (37 CFR §1.802)
- Sequence listing
- Known and readily available
- Can be made or isolated without undue experimentation

Marker Breeding Claims - Deposit

- 1. A method for producing a recombinant pre-harvest sprouting resistant red wheat plant line, comprising: identifying one or more markers in a pre-harvest sprouting resistant donor plant line selected from PHSP01 deposited as ATCC accession No. 123456 and pre-harvest sprouting resistant progeny therefrom by restriction fragment length polymorphism analysis; the one or more molecular markers being linked to one or more quantitative trait loci associated with pre-harvest sprouting resistance; and

Marker Breeding Claims - Sequence

What is claimed is:

1. A method of selecting a first plant by marker assisted selection of a quantitative trait locus (QTL) associated with pre-harvest sprouting resistance, the method comprising the steps of:

(i) detecting a first nucleic acid from the first plant which is genetically linked to a locus corresponding to a marker selected from the group consisting of phsp01 (SEQ ID No. 1), phsp02 SEQ ID No. 2), and phsp03 (SEQ ID No. 3); and,

(ii) selecting the first plant comprising the first nucleic acid, thereby selecting the QTL.

Marker Breeding Claims – Known Molecular markers

• A method for the maintenance of a pre-harvest sprouting resistant parental line of wheat for use in the production of hybrid wheat, said method comprising:

(a) Crossing a female parent with a male parent, said female parent being a pre-harvest sprouting resistant plant homozygous both for any one of the recessive phsp-B1 pre-harvest sprouting resistant alleles on the short arm of chromosome 4B (4BS), and for the dominant sudden death Sd-B1 allele on the long arm of chromosome 6B (6BL), said male parent being the maintainer line and being isogenic to the female parent and homozygous for the same phsp-B1 and Sd-B1 alleles as the female parent, and...

Written Description

- *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997)
 - Sequence information
 - Structure
 - Formula
 - Chemical name
 - Physical properties

Prior Art

- *Integra Life Sciences I LTD. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC SCalif 1999) and *Ex Parte Novitski*, 26 USPQ2d 1389 (BPAI, 1993)
 - Method claims
 - Usefulness of prior art not disclosed, preamble
 - Inherency
 - Not read into claims limitations from the specification

Inherency

- *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999)
 - Discovery of previously unappreciated property of prior art composition, or scientific explanation of functioning does not render old composition new.
 - Inherency not necessarily coterminous with the knowledge of those of ordinary skill in the art
 - Single prior art species anticipates generic claim.

Summary

- Molecular markers in PLT and Plant Utility cases
 - Utility
 - Enablement and written description
 - Prior art
 - New matter

[Annex IV follows]

Presentation made by

Mr. Paul M. Zankowsky
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United States Department of Agriculture (USDA)

USDA PVPO Overview

- History
 - Formed in 1971 after the passage of the Plant Variety Protection Act (passed December 24, 1970) with 3 staff members
 - First PVP certificate issued in 1973
- Location
 - Located on the 4th floor of the National Agricultural Library on the grounds of the Beltsville Agricultural Research Center (ARS facility) in Beltsville, Maryland.



Plant Variety Protection Office (PVPO)



- The Staff
 - 1 Commissioner
 - 6 PVP Examiners
 - 2 Associate PVP Examiners
 - 1 Information Technology Specialist
 - 1 PVP Program Analyst
 - 1 PVP Program Assistant
 - 1 Contract Secretary
- Total: 13 Full Time

PVP Application Visual Information Provided by PVP Applicants



King Henry (PV#9500323) - Top; Tall Guzmanne - Below

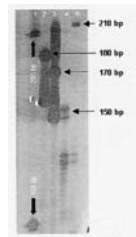


Beall's Gourmet (PV#8700189)

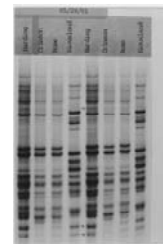


Tropicana Bright Eye Vinca (PV#9200109) vs. Tropicana Blush

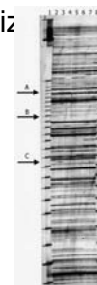
Examples of PVP Biochemical & Molecular Information Utiliz



Microsatellite marker (170 bp) present for the subject variety in lane #3 vs. absent in most similar variety (lane 4)



PAGE banding pattern difference



AFLP Markers

PVPO Use of Molecular Data

- Help to differentiate a new variety from a few older varieties.
 - Often faster than doing grow-out trials to establish morphological differences.
- PVP applicants use molecular or DNA data to establish that the application variety is different from the most similar comparison varieties.
 - Often done when a gene has been inserted in the new variety and its presence or absence makes the variety distinct from other varieties.

Issues on Using Molecular Data

- Use of molecular data must be treated the same as other methods used to establish distinctness.
- Tests - Need to use published procedures and reagents that are available to everyone who wants to perform the tests.
- Distinct Difference - Must be uniform and stable
 - Show that the tests were done on more than one individual
 - Two or more generations.

**Potential Problems with Using Molecular or
DNA Data**

- Repeated tests
 - Show differences exist between all individuals of the varieties
 - Differences do not change over time.
- Issue of the sole basis for distinctness
- Ability to distinguish a new variety from all previously existing varieties.
 - Older varieties
 - No molecular profiles
 - Not sufficiently uniform and stable
 - Morphological data will continue to be necessary to differentiate older varieties in our databases from newer varieties.
 - If all older varieties are profiled and that profile is made available to the PVP Office, it is possible that a way can be found to use this data to differentiate all older varieties from new application varieties.

[End of Annex IV and of document]