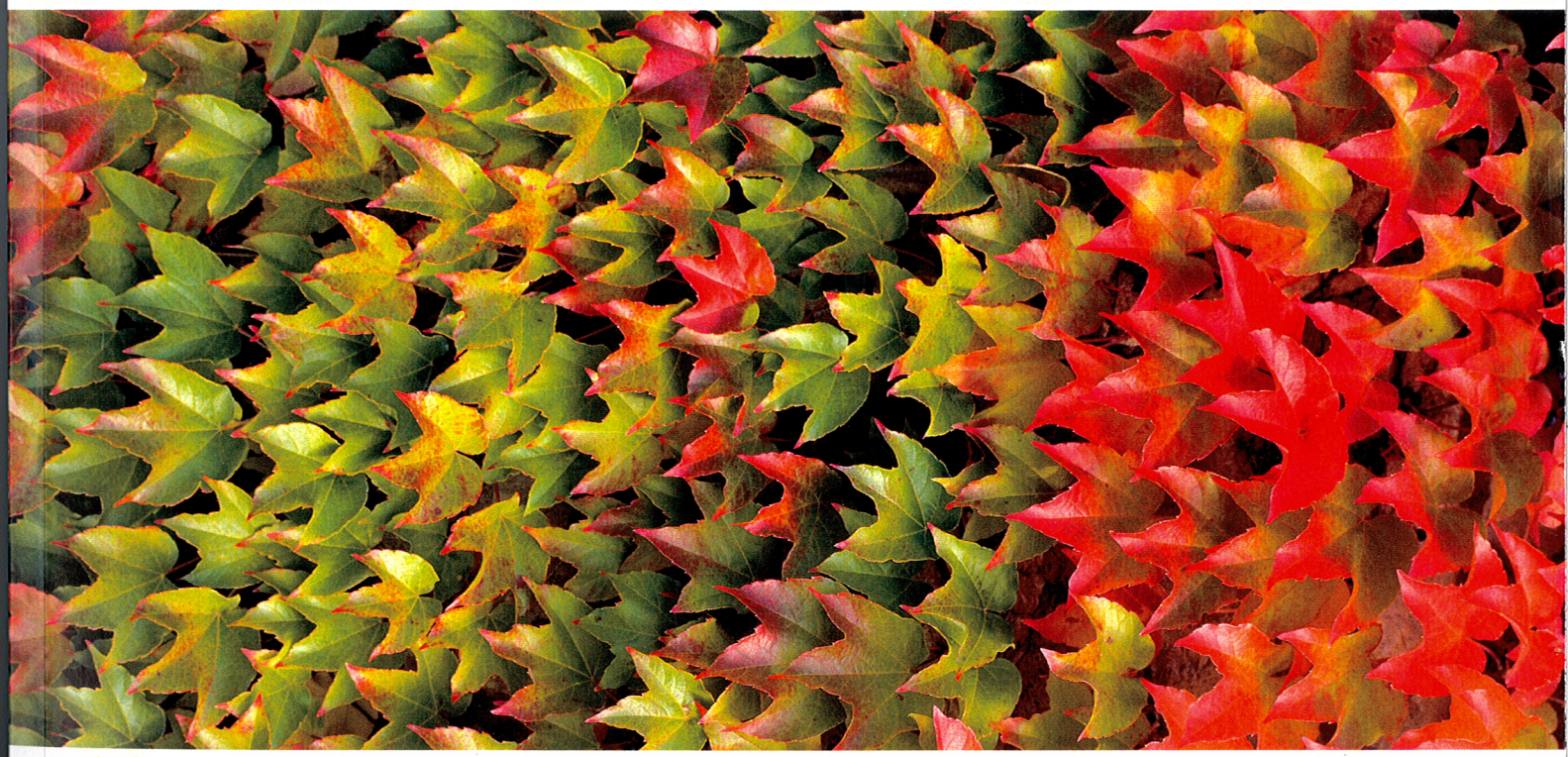
PART I: THE CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS IN THE PROMOTION OF BIOTECHNOLOGICAL DEVELOPMENTS

PART II: INTELLECTUAL PROPERTY RIGHTS IN PLANT BIOTECHNOLOGY



COMPILATION OF THE 2002 & 2003 JOINT SYMPOSIA DOCUMENTS OF THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) AND THE INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS (UPOV)

PART I: THE CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS IN THE PROMOTION OF BIOTECHNOLOGICAL DEVELOPMENTS

PART II: INTELLECTUAL PROPERTY RIGHTS IN PLANT BIOTECHNOLOGY

COMPILATION OF THE 2002 & 2003 JOINT SYMPOSIA DOCUMENTS OF THE WOLRD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) AND THE INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS (UPOV)

UPOV PUBLICATION
No. 792 (E)

ISBN 92-905-1484-9

PREFACE

The World Intellectual Property Organization (WIPO) and the International Union for the Protection of New Varieties of Plants (UPOV) jointly convened two symposia on the topic of biotechnology, in 2002 and 2003.

The first symposium was entitled, "The Co-existence of Patents and Plant Breeders' Rights in the Promotion of Biotechnological Developments", and the second, "Intellectual Property Rights in Plant Biotechnology". The focus of these symposia addressed the challenges facing inventors and plant breeders in light of developments in biotechnology on the one hand, and examined the role of intellectual property in the field of plant biotechnology on the other.

Biotechnology is a rapidly growing sector in the world economy, for both developed and developing countries and concerns society as a whole. Plant biotechnology, in particular, seeks to respond to the challenges posed by pests and diseases, limited resources such as land, water, and fertilizer, and to improve productivity and quality. This requires effective use and management of intellectual property rights such as patents and plant breeders' rights and an understanding of how complex legal frameworks interact at the international, regional and national levels. For these reasons, experts and participants from governments, international organizations, academia, legal fields, and companies active in biotechnology and plant breeding were brought together to discuss the various aspects of the issues concerning plant biotechnology.

In response to the interest and demand, this publication reproduces the documents of the two symposia. It is hoped that the information contained herein will be useful in furthering the knowledge and discussion in the area of plant biotechnology.

Kamil Idris
Director General, WIPO
Secretary-General, UPOV

CONTENTS*

PART I:

WIPO-UPOV SYMPOSIUM ON THE CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS IN THE PROMOTION OF BIOTECHNOLOGICAL DEVELOPMENTS

October 25, 2002

* ***Disclaimer:*** The views expressed in the papers and discussions of the WIPO-UPOV Symposia 2002 and 2003 are those of the speakers and/or participants and not necessarily those of UPOV or WIPO.

PART II:

WIPO-UPOV SYMPOSIUM ON INTELLECTUAL PROPERTY RIGHTS IN PLANT BIOTECHNOLOGY

October 24, 2003

Session III: Intellectual Property in Plant Biotechnology: National/Regional Experiences

Session IV: Management of Intellectual Property Rights

* * *

WIPO-UPOV SYMPOSIUM ON THE CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS IN THE PROMOTION OF BIOTECHNOLOGICAL DEVELOPMENTS

October 25, 2002

Biographies of Speakers

FRANCIS GURRY

Assistant Director General and Legal Counsel of the World Intellectual Property Organization (WIPO)

Francis Gurry, a national of Australia, is Assistant Director General and the Legal Counsel of the World Intellectual Property Organization (WIPO) in Geneva. He is responsible for WIPO's activities in the area of patents, which include patent policy questions and the administration of the Patent Cooperation Treaty (PCT), under which over 100,000 international patent applications were filed in 2001; biotechnology and genetic resource policy questions; traditional knowledge; electronic commerce; and the WIPO Arbitration and Mediation Center, which administered nearly 3,000 disputes over Internet domain names in 2001.

Dr. Gurry holds law degrees from the University of Melbourne and a Doctor of Philosophy from the University of Cambridge in the United Kingdom. He is a Vice President of the International Federation of Commercial Arbitration Institutions (IFCAI).

Before joining WIPO in 1985, he practiced as an attorney in Melbourne and Sydney and also taught law at the University of Melbourne. He is the author of a textbook on the law of trade secrets and confidential information, entitled ***Breach of Confidence***, published by Oxford University Press in the United Kingdom in 1984 and re-printed in 1990, and co-author, with Frederick Abbott and Thomas Cottier, of ***The International Intellectual Property System: Commentary and Materials***, published by Kluwer in July 1999.

ROLF JÖRDENS

Born in 1946, in Celle, Germany

A Diploma in Agricultural Economics, University of Stuttgart-Hohenheim, Germany, followed by a Doctor's degree at the same Institute, two-year research position at the ***Institut National Agronomique*** in Paris, France

Vice Secretary-General,
International Union for the Protection of New Varieties of Plants (UPOV)
(July 2000 – present)

President, German Federal Office of Plant Varieties (Bundessortenamt), Hanover, Germany
(July 1997 – June 2000)
Overall responsibility of the Office: variety testing, plant breeders' rights, listing of varieties

Head of Division, Federal Ministry of Food, Agriculture and Forestry, Bonn
Alternatives to Food Production; Energy, Renewable Resources (March 1994 - July 1997)
Agriculture and Environment (March 1993 – February 1994)

Deputy Head/Head of Division, Federal Chancellor's Office, Bonn
(October 1987 - February 1993)
Food, Agriculture and Forestry

Federal Ministry of Food, Agriculture and Forestry, Bonn (May 1976 - October 1987)
Fisheries Policy
Research Planning and Research Coordination

European Commission (Cabinet level), Brussels (March 1980 – August 1980)
Research and Energy

Memberships

Royal Swedish Academy of Agriculture and Forestry

German Society of Agriculture (DLG)

QIAO DEXI

Qiao Dexi, who was born in 1944, now serves as Director General, International Cooperation Department, the State Intellectual Property Office (SIPO) of the People's Republic of China.

In 1968, he finished his college education at the Eastern China Normal University. In 1981, he graduated from the Graduate School of the China Science & Technology University with a Master of Science Degree in Machine Translation.

He was a visiting scholar at the United States Patent and Trademark Office (USPTO) in 1979 and at the Law School of the University of Washington in 1990.

Working at the SIPO (note: Chinese Patent Office before 1998) from 1980, he was engaged in patent legislative and legal affairs extensively, including drafting and revising the Chinese Patent Law, regulations on the protection of the new varieties of plants and semi-conductor chips.

As a legal expert, he attended various WIPO meetings from 1983 including meetings for the Patent Cooperation Treaty and the Patent Law Treaty. He is also a Director of the Board of the AIPPI China Group and the China Intellectual Property Society. His main publications include:

"Revision of the Chinese Patent Law"
"Protection of the New Varieties of Plants in China"
"Protection of the Layout-design of Integrated Circuits in China"
"A Survey of the Intellectual Property Issues in Chinese-US Trade Negotiations under the Special 301 Provisions."

TIM W. ROBERTS

Tim Roberts read Chemistry at Oxford. He joined the international chemical company ICI in 1960, and from then until 1996 worked for ICI, and then its successor company Zeneca, on intellectual property matters, primarily patents. He is a Master of Arts of the University of Oxford, a British Chartered Patent Agent and a European Patent Attorney.

He qualified as a patent agent in 1964. From 1967 to 1986, he worked as Patents Manager for ICI's Agrochemicals Division at Jealott's Hill Research Station in Berkshire, UK. This involved patent filing and prosecution in many countries of the world, US Interference practice, and extensive patent litigation. In 1987, he transferred to ICI Seeds (now Zeneca Seeds) as Intellectual Property Manager. Zeneca Seeds worked on the application of biotechnology to crops such as maize, sugar beet, oilseed rape, sunflower and barley, in many countries of the world, including Europe, North and South America, Australia, India and Thailand. He resigned from Zeneca on 31 December 1995 to become an independent intellectual property consultant.

He serves on several bodies concerned with the impact of intellectual property law on biotechnology (or ***vice versa***). These include committees of:

Chartered Institute of Patent Agents (CIPA) [Council member: Chairman of Biotechnology Committee and of Textbooks Committee]; Federation of Trademarks, Patents and Designs (TMPDF); Green Industry Biotechnology Platform (GIBiP); British Society of Plant Breeders (BSPB); ASSINSEL, the international society of plant breeders; International Chamber of Commerce (ICC, Paris).

He also represented ICC in discussions (1987-1991) on the 1991 revision of the International Convention for the Protection of Plant Varieties (UPOV). He took part in the Keystone Dialogue on Plant Genetic Resources (Final Consensus Report, 1991), and is a member of the Crucible Group ("People, Plants and Patents", IDRC, 1994). He is a Panel Member of the Board of Appeals of the European Plant Variety Rights Office.

He was appointed in September 1997 to chair an international expert Panel on Proprietary Science and Technology, set up under the auspices of the World Bank to advise the Consultative Group on International Agricultural Research (CGIAR) on its intellectual property policy. The Panel's report was delivered in May 1998.

Recent articles include "Broad Claims" (European Intellectual Property Review [EIPR], August 1994) ; "The Former Biotech Patents Directive" (Patents World, May 1995), "Patenting Plants around the World" (EIPR, October 1996) and "Paper, Scissors, Stone" (EIPR, March 1998). He is Biotech News Corespondent for the EIPR, General Editor of the European Patents Handbook, on the Editorial Board of the Bio-Science Law Review and on the Supervisory Board of the University of Sheffield Institute of Biotechnological Law and Ethics (SIBLE).

VICTORIA HENSON-APOLLONIO

Victoria Henson-Apollonio, an ISNAR Senior Research Officer for Intellectual Property (IP) since February 2002, has been the Manager of the CGIAR Central Advisory Service on Intellectual Property (CAS), since January 2002. During her educational and professional career she has been associated with three U.S.-land grant universities –the University of Florida, Auburn University and Purdue University and three non-profit institutions –the Argonne National Laboratory, The Jackson Laboratory, and the McLaughlin Biomedical Research Institute.

Victoria has over 20 years of biotechnology research experience and 10 years of intellectual property evaluation and assistance in patent application and prosecution procedures and technology transfer activities. She has authored over fifty publications, presentations, and abstracts in the areas of intellectual property/technology transfer, immunology, bioinformatics, and studies involving wetlands plants. And she has prepared over one hundred invention reports, patent application reviews, and technology evaluation/assessment reports. In her capacity with CAS, she has made presentations at both national and international fora.

She is a registered U.S. Patent Agent, licensed to practice before the U.S. Patent and Trademark Office (USPTO), with a Ph.D. in Molecular Biology/Pathology from the University of Florida, Gainesville, Florida. Victoria has an undergraduate degree in Animal Science from the University of Florida, College of Agriculture and two years of post-baccalaureate courses from the College of Veterinary Medicine at Auburn University, Auburn, Alabama. She has participated in molecular biology courses at the European Molecular Biology Laboratory (EMBL) in Heidelberg, Germany and at the Cold Spring Harbor Laboratory in Cold Spring Harbor, NY. In addition, she has attended courses in Patent Law and Biotechnology Licensing at the American Type Culture Collection (ATCC) Fora in Washington, D.C. and Patent Law courses in Chicago, IL.

Victoria was an IP consultant at the Argonne National Laboratory (ANL), from 1992 to 1998, and a full-time Invention Evaluator/Patent Agent employee, during 1999. In her work at Argonne, she served as a liaison between ANL inventors and IP attorneys in the preparation and prosecution of patent applications, and she was involved in the management of a 15 Million (US) Dollar Biotechnology Patent portfolio. She also worked with the Industrial Technology Division (ITD), at ANL on patent, technology transfer and licensing issues. While at ISNAR, Dr. Henson-Apollonio has helped to raise awareness of IP and IP rights (IPR) issues associated with agricultural research, both within and outside of, --the CGIAR system. She has written a distance learning course for WIPO, entitled, "Biotechnology and Intellectual Property".

While at Purdue, Dr. Henson-Apollonio was tenured as an Associate Professor of Biology at Purdue University, where she taught courses in genetics, molecular biology, cell biology, immunobiology, and computer applications in biology. She carried out research in the areas of fish immunology and in population genetics of wetland plants.

BERNARD LE BUANEC

Bernard Le Buanec is the Secretary General of the International Seed Federation (ISF), newly formed from the merger in May 2002 of the previous FIS and ASSINSEL.

A graduate from the French Institut National Paris-Grignon (Ingénieur Agronome), he had a Master's in Soil Science at ORSTOM Paris.

He then joined the public research and spent 10 years in Africa on agronomy projects. During that period, he presented his Doctor-Engineer's thesis on Plant Biology.

In 1975, he joined Groupe Limagrain as Chief of the Agronomy Department, then CEO of the company Mennesson and finally member of the strategic committee of the Group, as Senior Vice-President in charge of research. At that time, he was also Chairman of the Board and CEO of the BIOCEM Company, biotech company with laboratories in France, United Kingdom and Australia, member of the Board then Chairman of the Board of Gene Shears, a joint-venture between Groupe Limagrain, Johnson & Johnson and the CSIRO.

In 1993, he left Groupe Limagrain to join FIS and ASSINSEL Secretariats, as Secretary General.

In addition to his professional activities, Bernard Le Buanec has served in several elected or nominated positions in France or at international levels, mainly:
1982-1986: Chairman of the Beet Section of FIS/ASSINSEL and member of the FIS Executive Committee;
1986-1990: Chairman of the Maize Section and Chairman of the Intellectual Property Group of ASSINSEL;
1987-1992: Founding member, member of the steering committee and then Chairman of GIBiP, the European Green Industry Biotechnology Platform; member of the group on biotechnology then on life science of the Industrial Research and Development Advisory Committee of the European Community;
1990-1992: ASSINSEL Vice-President;
1992-1993: ASSINSEL President;
1997-1998: member of the CGIAR expert panel on Proprietary Science and Technology.

At the moment, B. Le Buanec is member of the Genetic Resources Policy Committee of the CGIAR, member of the Scientific Council of the French National Agricultural Research Institute (INRA), member of the French Académie des Technologies and corresponding member of the French Académie d'Agriculture.

He has authored/co-authored several articles in scientific and professional journals.

FRANÇOIS DESPREZ

Né le 6 août 1957 à Lille,

Ingénieur Agronome de l'INA de Paris (1976)

Président Directeur Général de la S.A. Maison FLORIMOND DESPREZ à Cappelle en Pévèle

Président de la Société Coopérative d'Intérêt Collectif Agricole Anonyme à Capital Variable (S.I.C.A.S.O.V.)
Past-Président de l'Association Internationale des Sélectionneurs pour la Protection des Obtentions Végétales (A.S.S.I.N.S.E.L.)
Membre du Board of Directors de l'International Seed Federation (I.S.F.)
Vice-Président du Groupement National Interprofessionnel des Semences (G.N.I.S.)
Président de la section Céréales et Protéagineux de l'Association Européenne des Semences (E.S.A.)
Administrateur de la Confédération Française des Semences (C.F.S.)
Membre du Conseil Central de l'Office National Interprofessionnel des Céréales (O.N.I.C.)
Membre du Comité pour la Protection des Obtentions Végétales (C.P.O.V.)

LUIZ ANTONIO BARRETO DE CASTRO

Education

B.S. (Agronomy)
Federal Rural University of Rio de Janeiro
Period: March 1959 – December 1962

M.Sc. (Agronomy)
Mississippi State University
Period: January 1968 – January 1970

Ph.D (Plant Physiology)
University of California Davis
Period: September 1973 – December 1977

Pos. Doctor. (Molecular Biology)*
University of California Los Angeles
Period: September/December 1986-1988

Visiting Schollar. (Molecular Biology)*
University of California Los Angeles
January/March 1989-1992
*Reference: Robert B. Goldberg

Professional Experience

Twenty-six years of experience as university teacher in areas such as Agronomy, Seed Technology, Plant Breeding, Plant Physiology and Plant Biochemistry at the Federal Rural University of Rio de Janeiro.

Thirty-five years experience in scientific research in areas such as Plant Breeding Seed Technology, Plant Physiology, Plant Molecular Biology and Plant Genetic Engineering at the Federal Rural University of Rio de Janeiro and EMBRAPA/National Center of Genetic Resources and Biotechnology.

Eight years of experience in the area of Science and Technology Management at the Ministry of Science and Technology.

Chief of the Intellectual Property Secretariat of EMBRAPA since June 1999.

Wards, Fellowships and Expert Activities
Order of Judiciary Merit by the Supreme Labour Court, National Order of Scientific Merit – By The Presidence of the Republic of Brazil, President of the Brazilian Society of Biotechnology, President of the Brazilian Society for the Advancement of Agriculture.

Scolarships and Fellowships granted by USAID, Rockfeller Foundation, National Research Council and Ministry of Education of Brazil.

Consultant for IICA, World Bank, UNCED Conference, Member of the BAC of the Stockholm Environment Institute, Coordinator of the National Research Program of Biotechnology for Agriculture at EMBRAPA/CENARGEN (Brasília). Executive Secretary of the Federal Program for the Financing of Science and Technology (Brasil) – PADCT/Ministry of Science and Technology, President of the Biosafety National Technical Commission in Brazil during the last three years.

Publications and Patents

More than forty scientific papers published in Journals with referees and three patents granted in foreign countries in the area of genetic engineering.

WALTER SMOLDERS

European Patent Attorney and Lic.organic chemistry at the University of Gent (BE). Started his professional career at the Institut International des Brevets (The Hague). Joined the Sandoz Patent Department in 1969, was there Head of the patent Section Crop Protection, Seeds and Nutrition from 1979, till creation of Novartis in 1997. Became then Head of i.a. Biotech/Seeds of Novartis Services and is presently Global Head of IP-Seeds and New Technology at Syngenta. Being an active member of the International Seed Federation's Intellectual Property Committee since 1995.

CHARLES R. MCMANIS

Charles R. McManis is a scholar who is active nationally and internationally in the area of intellectual property law. Professor McManis earned an undergraduate degree from Birmingham-Southern College in 1964, and both his MA and JD degrees from Duke University in 1972, where he was a Duke Scholar.

Professor McManis has taught and done research in universities throughout the United States and Asia. In 1997, he was Exchange Professor at Yonsei University in Seoul and in 1989 at Sichuan University in Chengdu, China. For over ten years he has been a Visiting Lecturer at Nihon University College of Law and Economics and the Japan Institute for International Business Law. During 1993 and 1994, Professor McManis made his Fulbright Fellowship visits to Korea to lecture and do research at the International Intellectual Property Training Institute in Taejon. As a consultant for the World Intellectual Property Organization he has taught seminars in India, Korea and China, and was member of the Asia Pacific Legal Institute delegation to the 68th Biennial Conference of the International Law Association in Taipei, Taiwan in 1998.

Professor McManis' book, Intellectual Property & Unfair Competition in a Nutshell, is now in its 4th edition. He is also co-author of Licensing of the Intellectual Property in the Digital Age. His forthcoming book, Cases and Materials on the International Aspects of Intellectual Property Law (with Marshall Leaffer, Kenneth Port and others) will be published by
Carolina Academic Press.

In 2001 he was honored by the School of Law Alumni Association with its Distinguished Teaching Award and was named by law students as Teacher of the Year. In April 2002, he co-chaired the Conference on Patenting Genetic Products presented by the Center for Interdisciplinary Studies at the School of Law and the Genome Sequencing Center, School of Medicine which was part of the Washington University's Law and the Human Genome project. In September, 2002, he was installed as the Thomas & Karole Green Professor of Law.

PROFESSOR JOSEPH STRAUS

Joseph Straus, Professor of Law (Universities of Munich and Ljubljana) and Managing Director of the Max-Planck-Institute for Foreign and International Patent-, Copyright and Competition Law, Munich. Visiting Professor of Law, Cornell Law School, Ithaca, N.Y. (between 1989 and 1998); Distinguished Visiting Professor of Law, George Washington University School of Law (Spring, 2002).

Author or co-author of numerous publications in the field of intellectual property law, especially in the field of the protection of biotechnological inventions. Consultant to OECD, WIPO, UNCTAD, UNIDO, EC-Commission, World Bank, Scientific Services of the German Bundestag and the German Government, as well as the European Parliament and the European Patent Organisation. Active in many international associations, e.g. Chair Intellectual Property Rights Committee of the Human Genome Organisation (HUGO), Chair Programme Committee, International Association for the Protection of Intellectual Property (AIPPI).

DR. JUR. PETER LANGE

Born 31.12.40, in Northeim, Lower Saxony, Germany.
Married, 3 children.

Study of chemistry and law. PhD in law, University of Göttingen.
Lawyer (Private law firm)

Working for KWS SAAT AG, Einbeck, Germany, since 01.07.1974. Since 1978 Head of Legal Department of KWS SAAT AG and since 1993 Administrative Director of PLANTA, Angewandte Pflanzengenetik und Biotechnologie GmbH, Einbeck (research company of the KWS-Group).

Since 1988 Member of the Executive Committee of ASSINSEL and between 1991 - 1997 Chairman of the IPG (Intellectual Property Group) of ASSINSEL.

Since its foundation (1999) Member of PBU (Plant Biotech Unit) of EuropaBio.

Since 2000 Chairman of the CIPR (Committee of Intellectual Property Rights) of ESA (European Seed Association) and Member of the Board of ESA. Member of the Board of ISF (International Seed Federation). Chairman of the Department of Biotechnology and Genetechnology of the German Breeders Association (BDP).

Member of several Committees and Associations on the national, european and world wide level within the area of plant breeding and biotechnology representing KWS SAAT AG and/or BDP.

Several publications in the field of Intellectual Property Rights, Seed Laws, Gene technology Laws and related Regulatory issues in the area of Plant Breeding and Biotechnology.

WIPO-UPOV SYMPOSIUM ON THE CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS IN THE PROMOTION OF BIOTECHNOLOGICAL DEVELOPMENTS

Geneva, October 25, 2002

Opening Address

Mr. Karl Olov Öster
President of the UPOV Council

on behalf of

Dr. Kamil Idris
Director General
World Intellectual Property Organization
Secretary-General
International Union for the Protection of New Varieties of Plants

Ladies and gentlemen,
Friends and colleagues,

It is a pleasure and an honor for me to address such a distinguished assembly at this Symposium on the co-existence of patents and plant breeders' rights in the promotion of biotechnological developments.

WIPO and UPOV are convening this important gathering to address the challenges facing inventors and plant breeders in light of developments in the world of plant biotechnology and, in particular, genetic engineering.

Biotechnology is likely to play an increasingly important role in improving every day life. Biotechnology is a fast growing area of the world economy, for both developed and developing countries. The biotechnology industry has more than tripled in size since 1992. The use of biotechnology concerns society as a whole.

Plant biotechnology, in particular, seeks to respond to the challenges posed by pests and diseases, limited resources (land, fertilizer, water, chemicals), the need to improve productivity and quality, and meeting more sophisticated consumer preferences. In short, it seeks to meet the current demands of society. During the 1990s, the growth rate of biotechnology patents (10%) was double that of total patent applications (5%).

Biotechnology is one of the most research-intensive industries in the world. In the field of genetic engineering, research and development require considerable high-risk investment and adequate protection in order to promote developments in this field.
In the international context, the objective of both WIPO and UPOV to protect and promote intellectual property is essential in encouraging the development of plant biotechnology for the benefit of society.

The international agreements on intellectual property rights provide a flexible framework within which intergovernmental organizations, individual States and stakeholders in intellectual property can and have addressed various policy issues. The Paris Convention, for instance, sets out

general principles for obtaining patents that have accommodated and fostered the growth of new industries. This is precisely the case of the industrial sector often referred to with the broad label "biotechnology" that did not exist when the early treaties were first adopted. Further, the Patent Cooperation Treaty has been an exemplary tool that has facilitated access to patent systems around the world by innovators from all regions of the globe.

The objective of the UPOV Convention is the protection of plant breeders' rights. The conditions for protection, as well as the scope of protection and related exceptions, are designed specifically for plant varieties. Of particular interest is the extent to which important elements of the UPOV Convention, namely the concept of the breeder's exemption and essentially derived varieties are relevant for plant breeders' rights in relation to the rights provided by patents.

Recent technological developments, for example the rising number of gene-related patents and rapid progress in the field of genetic engineering, may have considerable effects on plant breeding and, as a consequence, have repercussions on the co-existence of the two systems.

The sessions of today's Symposium will identify the areas of interface between the two systems, current practices, and possible problems and solutions. The Symposium will focus on:

- recent developments affecting intellectual property protection systems related to plants and plant varieties;
- accessibility of protected inventions and plant varieties for further innovation and breeding;
- case studies of private sector experience concerning intellectual property strategies and licensing in the field of biotechnology.

I should like to express from the outset, our gratitude to our distinguished speakers who have kindly accepted the invitation of WIPO and UPOV to participate in this event. Their knowledge and experience on the topics of the Symposium will no doubt enlighten our discussions.

I thank you for your attention and I wish you all a successful Symposium.

I herewith declare the WIPO-UPOV Symposium open.

SESSION I

LEGAL AND TECHNOLOGICAL DEVELOPMENTS LEADING TO THIS SYMPOSIUM

UPOV'S PERSPECTIVE

MR. ROLF JÖRDENS

Vice Secretary-General, International Union for the Protection of New Varieties of Plants (UPOV)

I. INTRODUCTION

1. Plant breeding has always benefited from technological developments. One of the most important recent developments in biotechnology is genetic modification which is a major factor leading to this Symposium. Genetic modification might, in simple terms, be explained as the process by which genes are introduced into organisms in a different way to that found in nature. It is increasingly becoming an important new tool for breeders in their quest to improve plant varieties.

2. As it was mentioned during the opening, plant biotechnology seeks to respond to the challenges posed by pests and diseases, limited resources (land, fertilizer, water, chemicals), the need to improve productivity and quality, and meeting more sophisticated consumer preferences. One way to identify the importance of modern biotechnology in plant breeding is to see the increase in the global area planted with transgenic crops. In 1996, this area was 1.7 million hectares reaching 39.9 million hectares in 1999, corresponding to a twenty-fold increase between 1996 and 1999.[1]

3. It is important to clarify from the beginning that protection of the intellectual property assets associated with biotechnology developments is not related to the required approval mechanisms to commercialize products resulting from those intellectual property assets. Protection and commercialization procedures are separated and independent from each other. In this regard, a parallel could be drawn with protection and commercialization of pharmaceutical products. The necessary assessments and controls on environmental effects before releasing genetically modified organisms belong to the applicable biosafety rules that have been or are in the process of being adopted at the national level. Biosafety concerns fall outside the scope of this Symposium.

4. The common objective of plant breeders' rights and patents is to provide an incentive for the development of innovative and useful products or processes. The patent system covers inventions in all fields of technology, whereas the system of plant variety protection, based on the International Convention for the Protection of New Varieties of Plants (UPOV Convention)[2], has been specifically developed to cover plant varieties.

---

1 Zarrilli, Simonetta, International Trade in Genetically Modified Organisms and Multilateral Negotiations" United Nations Conference for Trade and Development, July 5, 2000, p.5.

2 As of October 24, 2002, there were 51 members of the Union. Their dates of joining UPOV and the Acts of the Convention by which they are bound are given in Table 1 in Annex I. Table 2 in Annex II lists the States or organizations which have initiated with the Council of UPOV the procedure for becoming members of the Union (18) and other States who have been in contact with the Office of the Union with a view to developing legislation in line with the UPOV Convention (39).

Table 3 below gives an outline comparison between protection of an invention by patent and protection of a variety by plant variety protection.

	Patent Protection	***Breeder's right based on the UPOV Convention***
I. Object of protection	invention	plant variety
II. Requirements for protection		
1. documentary examination	required	required
2. field examination	not required	required
3. plant material for testing	deposit of material may be required only in certain cases	required
4. conditions for protection	(a) novelty (b) industrial applicability (c) unobviousness (inventive step) (d) an enabling disclosure	(a) commercial novelty (b) distinctness (c) uniformity (d) stability (e) an appropriate denomination
III. Scope of Protection		
1. determination of scope of protection	determined by the claims of the patent	fixed by the national legislation in accordance with the UPOV Convention
2. use of a protected variety for breeding further varieties	may require the authorization of the patentee	does not require authorization of the right holder (breeder's exemption)
3. use of propagating material of the protected variety grown by a farmer for subsequent planting on the same farm	may require the authority of the patentee	often does not require authorization of the right holder
IV. Variety Denomination	not required	required
V. Term of Protection	20 years from date of application	18 years for trees and vines, 15 years for other species, from date of grant (increased respectively to 25 years and 20 years in the 1991 Act)

5. In some circumstances, the subject matter of protection covered by patents and plant breeders' rights might be the same, namely a plant variety. However, this is a situation which has existed for many years. The 1991 Act of the UPOV Convention, in contrast to the 1978 Act, no longer excludes protection of new plant varieties by the grant of a special title or a patent for the same botanical genus or species and thereby recognizes that both systems may even be applied to the same variety. This may raise questions in particular cases. They are, however, not in the focus of today's Symposium.

6. The Symposium centers around the scope of protection offered under the patent system and the UPOV system. In particular, this is explored in relation to the situation where, for example, a genetic engineering development can result in a plant variety which will be protected as a plant variety, by a plant breeder's right, but will also contain an invention protected by a patent (e.g. patented genetic element). The issues which arise from such protection are a result of differences in the scope and exceptions under the two systems. These differences and the relevant issues are explored in the following section.

An indication of the progressive development of plant variety protection in terms of the number of titles of protection is provided by Fig. 1 in Annex III.

II. ISSUES ARISING FROM THE GRANTING OF PROTECTION

Rights Conferred by the Protection

7. The rights provided by the UPOV system and the patent system are similar, as can be seen from the following table which compares the scope of protection in the UPOV Convention and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). This Agreement as part of the Agreement Establishing the World Trade Organization (WTO) sets international minimum standards on intellectual property protection and binds all Members of WTO (as of October 24, 2002, 144 Members).

TRIPS Agreement (Article 28)	UPOV (1991 Act – Article 14)
"1. A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of:	"(1) [***Acts in respect of the propagating material***] ***(a)*** Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:
making, using,	(i) production or reproduction (multiplication), (ii) conditioning for the purpose of propagation,
offering for sale,	(iii) offering for sale,
selling, or	(iv) selling or other marketing,
importing[3]	(v) exporting, (vi) importing,
for these purposes that product;"	(vii) stocking for any of the purposes mentioned in (i) to (vi), above."

8. It can be seen that the rights provided by the two systems are similar. Therefore, in general, those acts requiring the authorization of the breeder would also require the authorization of the patent holder and vice versa. One issue for a protected variety containing a patented invention(s) might be that authorization is required from both the breeder and patent holder(s). However, in practice, authorization is likely to be administered by one of the parties for each variety.

Exceptions to the Rights Conferred

9. In contrast to the close correspondence between the two systems in terms of the rights conferred, there is a fundamental difference in the scope of the exceptions to the rights conferred. This is explained below:

Exceptions to the breeder's right

10. Article 15(1) of the 1991 Act of the UPOV Convention states that:

"(1) [***Compulsory exceptions***] The breeder's right shall not extend to

(i) acts done privately and for non-commercial purposes,

[3] This right, like all other rights conferred under the TRIPS Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

(ii) acts done for experimental purposes and

(iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties."

11. The exception for the purpose of breeding other varieties, contained in Article 15(1)(iii), is a fundamental aspect of the UPOV system of plant variety protection. This exception is known as the "breeder's exemption." It recognizes that real progress in breeding—which must be the goal of intellectual property rights in this field—relies on access to the latest improvements and new variation. Access is needed to all breeding materials in the form of modern varieties, as well as landraces and wild species, to achieve the greatest progress and is only possible if protected varieties are available for breeding.

12. The breeder's exemption optimizes variety improvement by ensuring that germplasm sources remain accessible to all the community of breeders. However, it also helps to ensure that the genetic basis for plant improvement is broadened and is actively conserved, thereby ensuring an overall approach to plant breeding which is sustainable and productive in the long term. In short, it is an essential aspect of an effective system of plant variety protection which has the aim of encouraging the development of new varieties of plants, for the benefit of society.

Exceptions to the rights conferred by patent

13. Article 30 of the TRIPS Agreement states that:

"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

14. Open multilateral treaties in the field of patents do not provide for the extent to which those limited exceptions concerning the use of patented products or processes may be permitted.[4] It is, therefore, necessary to refer to national or regional patent legislation and to relevant jurisprudence.

15. Several laws establish that the rights conferred by the patent shall not extend to acts done for research or experimental purposes relating to the subject matter of the patented invention. Some national systems distinguish between experimental use for the purpose of obtaining additional scientific knowledge and uses aimed at obtaining marketing or other types of approval (e.g. approval for commercialization of generic drugs). Other systems consider that uses of the patent for selection and evaluation purposes may not be considered as falling within an acceptable exception.

16. National systems that provide a wide research exemption will require that the research or experiments are directed towards the generation of information and in these situations only "commercial use" would be prohibited.[5]

Issues Which May Arise from Inhibition of the Breeder's Exemption by the Granting of a Patent

17. Two main issues may arise if a patent inhibits the breeder's exemption. Firstly, there might be an imbalance between the UPOV system and patent system concerning the obligation to reward the right

[4] Article 5***ter*** of the Paris Convention for the Protection of Industrial Property of 1967 (Paris Convention) provides for limitations to the exclusive right conferred by the patent in certain cases of public interest in order to maintain the freedom of transport. These exceptions are not of direct relevance for the interface object of this document.

[5] Recent Japanese Supreme Court decision in 1999 and German Constitutional Court decision in 2000 favor a wide research exemption.

holder of the initial protected subject matter (i.e. patented invention or protected variety) as far as countries that are still bound by the 1961/72 and 1978 Acts of the UPOV Convention are concerned. This has been addressed by the provision for essentially derived varieties (EDV) in the 1991 Act of the UPOV Convention. Secondly, there is a need to consider how to maintain the ability to exercise the breeder's exemption in the case of varieties which contain patented inventions. These issues are explained below.

Balancing the reward to the respective rights holders (essentially derived varieties)

18. The potential imbalance between the exceptions under the patent system and the UPOV system was known at the time of the development of the 1991 Act of the Convention. In particular, it was recognized that, under the breeder's exemption, the holder of a patent on a genetic element (Gen-elem 1) was free to insert his genetic element into a protected variety (Variety A) to develop and protect a new variety (Variety B) without any obligation to reward the owner of Variety A. However, if the owner of Variety A wished to insert Gen-elem 1 into his variety to produce a new Variety C, he would be obliged to seek the permission of the Gen-elem 1 patent holder and would, in all likelihood, only be given permission to do so if the patent holder was satisfied that he would be adequately rewarded.

19. To address this imbalance, the 1991 Act of the UPOV Convention introduced a provision for essentially derived varieties. The essence of this provision (see Article 14(5) of the 1991 Act of the UPOV Convention) is that the scope of the breeder's rights for a variety extends to any varieties which are essentially derived from it. An essentially derived variety ("EDV") is one which is predominantly derived from an initial variety and retains the essential characteristics of the initial variety. The 1991 Act states in its Article 14(5)(c) that "Essentially derived varieties may be obtained for example by … transformation by genetic engineering." The introduction of this provision establishes a more equal balance between the patent and UPOV systems. Thus, in the example above, the patent holder of Gen-elem 1 would not be able to exploit his new Variety B without the authorization of the owner of Variety A, assuming that Variety B was considered to be essentially derived.

20. Having stated that the EDV concept establishes a more equal balance between the systems, it is important to note that there is still a significant and important difference between the EDV provision in the UPOV system and the right conferred under patent. The EDV provision does ***not*** prevent the breeding of new Variety B; it only requires that the authorization of the owner of Variety A is obtained to allow its exploitation. This means that the essence of the breeder's exemption is retained, i.e. access for breeding is maintained. If the new Variety B represents a significant improvement over other varieties, it is very likely that the variety owner and patent owner will come to a mutually beneficial agreement for exploitation of the variety.

21. As explained above, the patent system may require that the permission of the Gen-elem 1 patent holder is obtained ***before any breeding work can begin***. In such circumstances, it might be more difficult for agreement to be reached between the variety owner and patent holder because the value of the end variety cannot be reliably estimated.

22. The nature of the difference which exists between the two systems is not always fully understood. Thus, certain mechanisms, such as cross-compulsory licensing between patent holders and plant breeders' rights holders, which have been introduced by some members of UPOV to address an imbalance might fail to resolve the problem unless they ensure that the patent system allows the breeding of new varieties in the same way as provided by the UPOV Convention.

23. Furthermore, with regard to the possible development of such mechanisms, it might be noted that the UPOV Convention makes it unnecessary to obtain a compulsory license for anything other than that strictly justified by public interest, as provided in Article 17(1) of the 1991 Act. Bearing in mind the breeder's exemption in the UPOV Convention, the introduction of a mechanism for a compulsory license on the basis of important technical advance of considerable economic significance, such as that provided in the TRIPS Agreement (Article 31(l)(i)) may not be justified, because if the new variety satisfied such a test, there would be a very strong incentive for the patent holder and variety owner to find a mutually beneficial arrangement.

24. In conclusion, it is important to recognize that a basic principle of the breeder's exemption, which allows the breeding of new varieties of plants using protected varieties, is not affected by the EDV

concept and that the introduction of the EDV concept maintains the access all varieties for breeding. However, it does provide a mechanism to ensure a suitable reward for plant breeders.

The ability to exercise the breeder's exemption in the case of varieties containing patented inventions

25. The situation outlined relates to a situation where the starting point is a patent holder with a genetic element and a variety owner with a protected variety. However, it is clear that another situation will arise where there is a protected variety which contains a patented invention—let us say a genetic element for the purpose of discussion. The purpose of the patent is to protect the developer of the genetic element, and the purpose of the plant breeder's right is to protect the developer of the unique combination of plant germplasm forming the variety. However, in certain circumstances, a lack of a similar provision in the patent system might, indirectly, constrain the exercise of the breeder's exemption for the protected variety.

26. The rapid progress in the development of genetic engineering raises the prospect that, in the foreseeable future, an ever increasing number of plant varieties will contain patented inventions. Furthermore, the varieties may contain several patented genetic elements. The practical consequence of this development would be that the breeder's exemption, which is an essential principle in the UPOV system of plant variety protection, would be lost or greatly weakened.

III. PROVISIONS WITHIN THE TRIPS AGREEMENT WHICH MIGHT ALLOW THE PRESERVATION OF THE BREEDER'S EXEMPTION

27. Article 7 of the TRIPS Agreement states that "The protection and enforcement of intellectual property rights should contribute to the ***promotion of technological innovation*** and to the ***transfer and dissemination of technology***, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a ***balance of rights*** and obligations" (emphasis added). Furthermore, the TRIPS Agreement provides (Article 8(2)) that "Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or ***adversely affect the international transfer of technology***" (emphasis added).

28. As explained above, the exceptions to the rights conferred by a patent under Article 30 of the TRIPS Agreement are not specific. This means that a State may be able to implement Article 30 in a way that protects the breeder's exemption.

ANNEX I

International Convention for the Protection of New Varieties of Plants*

UPOV Convention (1961), as revised at Geneva (1972, 1978 and 1991)

Status as of October 23, 2002

State	Date on which State became member of the Union	Latest Act* of the Convention to which State is party and date on which State became party to that Act	
Argentina	December 25, 1994	1978 Act	December 25, 1994
Australia	March 1, 1989	1991 Act	January 20, 2000
Austria[1]	July 14, 1994	1978 Act	July 14, 1994
Belgium	December 5, 1976	1961/1972 Act	December 5, 1976
Bolivia	May 21, 1999	1978 Act	May 21, 1999
Brazil	May 23, 1999	1978 Act	May 23, 1999
Bulgaria	April 24, 1998	1991 Act	April 24, 1998
Canada	March 4, 1991	1978 Act	March 4, 1991
Chile	January 5, 1996	1978 Act	January 5, 1996
China	April 23, 1999	1978 Act	April 23, 1999
Colombia	September 13, 1996	1978 Act	September 13, 1996
Croatia	September 1, 2001	1991 Act	September 1, 2001
Czech Republic	January 1, 1993	1978 Act	January 1, 1993
Denmark[1]	October 6, 1968	1991 Act	April 24, 1998
Ecuador	August 8, 1997	1978 Act	August 8, 1997
Estonia	September 24, 2000	1991 Act	September 24, 2000
Finland[1]	April 16, 1993	1991 Act	July 20, 2001
France[1]	October 3, 1971	1978 Act	March 17, 1983
Germany[1]	August 10, 1968	1991 Act	July 25, 1998
Hungary	April 16, 1983	1978 Act	April 16, 1983
Ireland[1, 2]	November 8, 1981	1978 Act	November 8, 1981
Israel	December 12, 1979	1991 Act	April 24, 1998
Italy[1, 2]	July 1, 1977	1978 Act	May 28, 1986
Japan	September 3, 1982	1991 Act	December 24, 1998
Kenya	May 13, 1999	1978 Act	May 13, 1999
Kyrgyzstan	June 26, 2000	1991 Act	June 26, 2000
Latvia	August 30, 2002	1991 Act	August 30, 2002
Mexico	August 9, 1997	1978 Act	August 9, 1997
Netherlands[1]	August 10, 1968	1991 Act	April 24, 1998
New Zealand	November 8, 1981	1978 Act	November 8, 1981
Nicaragua	September 6, 2001	1978 Act	September 6, 2001
Norway	September 13, 1993	1978 Act	September 13, 1993
Panama	May 23, 1999	1978 Act	May 23, 1999
Paraguay	February 8, 1997	1978 Act	February 8, 1997
Poland[2]	November 11, 1989	1978 Act	November 11, 1989
Portugal[1]	October 14, 1995	1978 Act	October 14, 1995
Republic of Korea	December 7, 2001	1991 Act	January 7, 2002
Republic of Moldova	October 28, 1998	1991 Act	October 28, 1998
Romania	March 16, 2001	1991 Act	March 16, 2001
Russian Federation	April 24, 1998	1991 Act	April 24, 1998
Slovakia[2]	January 1, 1993	1978 Act	January 1, 1993
Slovenia	July 29, 1999	1991 Act	July 29, 1999
South Africa[2]	November 6, 1977	1978 Act	November 8, 1981
Spain[1, 2]	May 18, 1980	1961/1972 Act	May 18, 1980
Sweden[1]	December 17, 1971	1991 Act	April 24, 1998
Switzerland	July 10, 1977	1978 Act	November 8, 1981
Trinidad and Tobago	January 30, 1998	1978 Act	January 30, 1998
Ukraine	November 3, 1995	1978 Act	November 3, 1995
United Kingdom[1]	August 10, 1968	1991 Act	January 3, 1999
United States of America	November 8, 1981	1991 Act	February 22, 1999
Uruguay	November 13, 1994	1978 Act	November 13, 1994

(Total: 51 States)

[Annex II follows]

* "1961/1972 Act" means the International Convention for the Protection of New Varieties of Plants of December 2, 1961, as amended by the Additional Act of November 10, 1972; "1978 Act" means the Act of October 23, 1978, of the Convention; "1991 Act" means the Act of March 19, 1991, of the Convention.

[1] Member of the European Community which has introduced a (supranational) Community plant variety rights system based upon the 1991 Act.

[2] Has already amended its law to conform to the 1991 Act.

ANNEX II

Table 2

States or Organizations which have initiated with the Council of UPOV the procedure for becoming members of the Union (18)

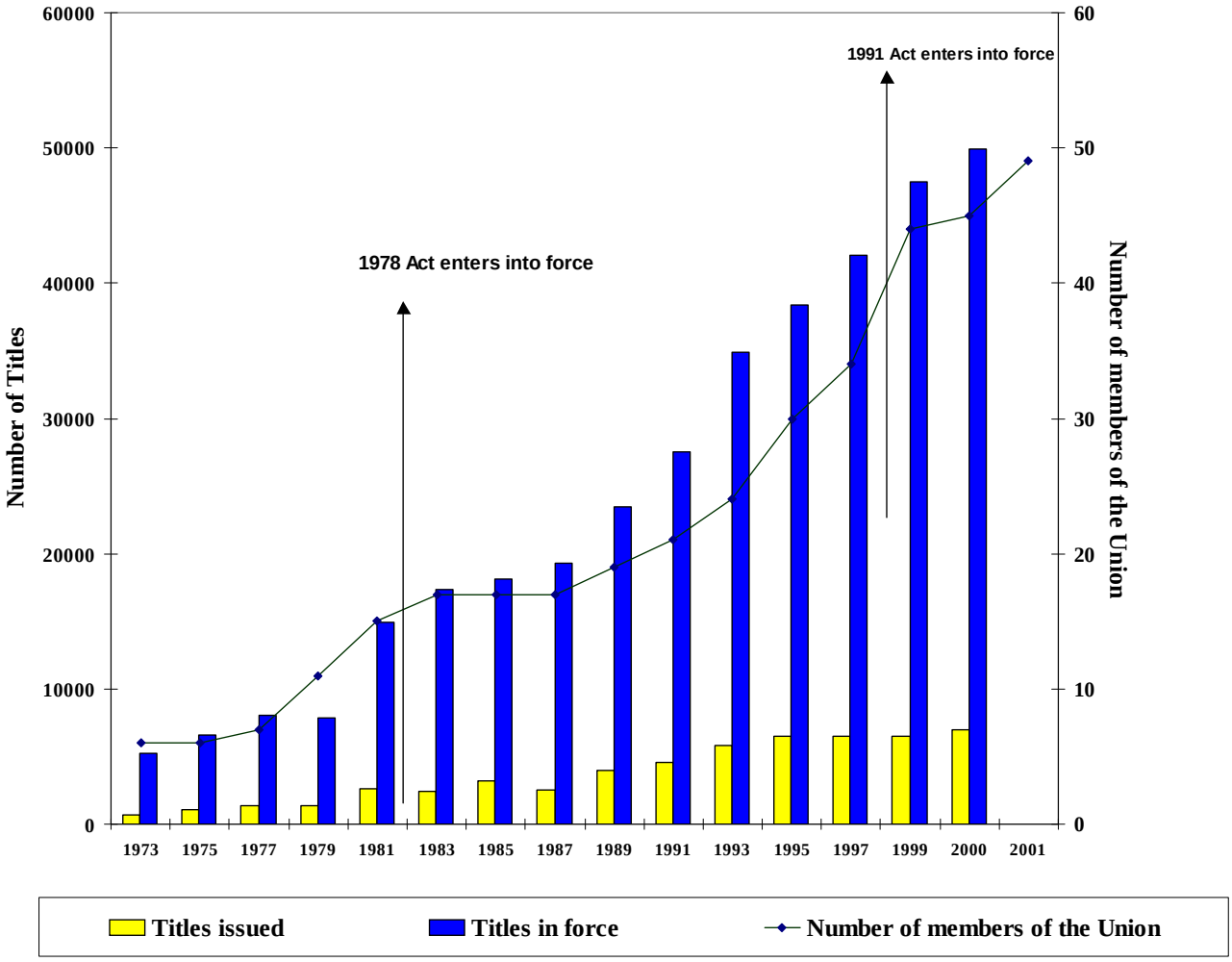
Azerbaijan, Belarus, Costa Rica, Egypt, Georgia, Honduras, India, Kazakhstan, Lithuania, Morocco, Tajikistan, The former Yugoslav Republic of Macedonia, Tunisia, Venezuela, Yugoslavia and Zimbabwe, as well as the European Community and the African Intellectual Property Organization (Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal, Togo (16)).

Other States who have been in contact with the Office of the Union with a view to developing legislation in line with the UPOV Convention (39)

Albania, Algeria, Armenia, Barbados, Burundi, Cuba, Cyprus, Djibouti, Dominica, Dominican Republic, El Salvador, Fiji, Ghana, Greece, Guatemala, Iceland, Indonesia, Jamaica, Kingdom of Bahrain, Madagascar, Malawi, Malaysia, Mauritius, Oman, Pakistan, Peru, Philippines, Saudi Arabia, Seychelles, Sri Lanka, Suriname, Thailand, Tonga, Turkey, Turkmenistan, United Republic of Tanzania, Uzbekistan, Viet Nam, Zambia

ANNEX III

Development of Plant Variety Protection



SECTION II

ACESSIBILITY OF PROTECTED INVENTIONS AND PLANT VARIETIES FOR FURTHER INNOVATION

PLANT VARIETY RIGHTS:- THE BREEDER'S EXEMPTION

Mr. Tim Roberts
Chartered Patent Agent, Bracknell, United Kingdom

This paper deals with Plant Variety Rights (PVP), and more specifically with the Breeder's Exemption.

1. Why a special intellectual property system for plants?

Effective intellectual property rights (as mandated by the TRIPS Agreement[1], Article 27.3) are practically as well as legally essential. They recognize and encourage the work of plant innovators: and, most importantly, they allow the recovery of investments made in breeding. Plant breeding is slow, skilled and expensive work-producing a new variety may easily take ten years. Once produced, the variety (at least if it is open-pollinated) may be very easily copied. Without intellectual property (IP) rights, the breeder could charge a premium for new seed only in the first season. This would make the seed too expensive: few would buy it and the breeder would lose his investment and go out of business.

Without intellectual property rights, private breeding cannot be profitable. Breeding can then only be done by public bodies, publicly financed (universities or Governments, for example). Of course such bodies can do excellent work: indeed they are the only option available in some cases. But where a market exists, or can be developed, private initiative is to be preferred. Governments are fallible. Publicly sponsored work lacks the spurs of the profit motive (Adam Smith's invisible hand) and of competition; though more high-minded, it is less diverse, in approach and in resources.

Accepting that we need IP protection for breeding, why is it necessary to have a special system? Patents are the standard way of protecting technical developments. Though the system remains controversial (and is far from perfect), it is tried and tested. Why not use it for plant varieties? The English philosopher William of Occam laid down a vital principle: '***Entia non sunt multiplicanda sine ratione***[2]' (entities are not to be multiplied without a reason). We apply this principle in the natural sciences to select the simplest explanation that fits the facts. It applies equally to man-made laws and regulations.

Why then is a separate system required for plant varieties? There are various doubts and difficulties in applying the patent system to plant varieties. The patent system evolved to deal with mechanical inventions. Some have argued that it cannot be extended to cover 'life'; or if it can, it should not. 'Life' (it is said) cannot be invented, only discovered[3]. Patenting living organisms (it is claimed) is intrinsically immoral, or will have unacceptable results. These objections are strongly contested, but continue to cause anxieties.

---

1 The Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organisation.

2 Also quote as: "***Entia non sunt multiplicanda praeter necessitatem***".

3 This objection carries much weight in Europe, where 'discoveries' are unpatentable (Art 52 European Patent Convention (EPC)), but little in USA, where 'inventions' are defined as including 'discoveries' (35 USC 100)

Other objections are more specific. Patent rights require an invention, which the public can be taught to carry out by means of a written description. The process of breeding is rarely reproducible, depending on chance events: a variety may be reproducible (indeed must be, to qualify for protection) but the process by which it is first produced generally is not. Further, many new varieties are ***prima facie*** 'obvious'. They are obtained by crossing two parents each with a different desirable property, and picking progeny that have both. This is, broadly, a predictable process, and thus, at least in some countries, may be considered lacking in 'inventive step' and not a proper subject for patent protection. The fact that to produce this 'obvious' product takes ten years of skilled work may count for nothing. Another concern is the right given to the patent owner. In some circumstances, the sole right to make use and sell a patented variety may be considered too broad, preventing re-planting of protected seeds - in others it may be considered too narrow, if selling the seeds gives the buyer the right to use them for their natural purpose, i.e. reproduction.

To get round these doubts and difficulties (all of which, individually, remain contentious and may have satisfactory answers), the UPOV Convention set up a new ***sui generis*** system-a new right specifically for plant varieties. This is not a patent. It has different requirements for protection. The variety need not be inventive or non-obvious, just 'distinct' from known varieties. It need not be reproducible from a written description - just 'stable,' so that it can (somehow) be reproduced in successive generations and retain all its properties. It must also be reasonably uniform. Rights over the variety are not so strong as a patent would give-initially they were limited to the right to reproduce propagating material of the variety for sale, though they have since been extended. Weaker rights reduce the problems of ethics associated with monopolies over organisms that may be important food sources.

UPOV began in the 1960's. Since then patent law has changed somewhat. The TRIPs Agreement (Article 27) has liberalised patenting requirements. Organisms clearly can be patented-though there is no obligation to patent plants (TRIPs Agreement, Article 27.3). The 'written description' requirement for inventions can be at least partially supplemented by a deposit of biological material. However, arguments about 'obviousness' and 'inventive step' remain: as do controversies about the strength of rights over important food crops. The UPOV system retains its importance. It is designed specifically to protect the work of breeders, while taking into account users' needs. In particular, and most importantly, it preserves public rights for further development.

2. The Breeder's Privilege under Plant Variety Protection

A fundamental purpose of intellectual property is to promote technical advance. In the United States of America, IP is only legal provided it serves: "***To promote the progress of science and useful arts ...***" (US Constitution, Art 1, s.6). For this reason, most patent laws have a "research exemption," to allow further development. This is particularly important for breeders, who traditionally work by incremental improvement of existing materials. If they do not have access to new materials, to make further improvements, their work is severely hindered. They need freedom to continue.

What then is the Research Exemption under plant variety rights? The 1991 Act of the UPOV Convention (UPOV 1991), Article 15(1) provides:

> ***(1) (Compulsory exceptions) The breeder's right shall not extend to***
>
> ***(i) acts done privately and for non-commercial purposes,***
> ***(ii) acts done for experimental purposes and***
> ***(iii) acts done for the purpose of breeding other varieties, and, ...[derived varieties aside], acts .. .[of commercial exploitation].. in respect of such other varieties.***

It follows from this that it is never an infringement of a plant variety right to use the variety for further breeding. This does not include, of course, use in commercial production: it is infringement to use a protected variety repeatedly, for example, as the parent of a hybrid. Equally, in general, it is

not an infringement of a PVP to exploit or sell the new variety bred. However, under UPOV 1991 there is an exception to this latter proposition: the case of 'essentially derived varieties.'

"Essentially derived" varieties

Varieties are by definition distinct from each other. Under the 1978 Act of the UPOV Convention (UPOV 1978), no registered variety could infringe another (leaving aside repeated use, of the kind discussed in the previous paragraph). As a result, very similar varieties could be, and were, registered. The coming of gene technology made this situation worse. In principle at least, an existing successful variety could have a new trait, based on a single gene, rapidly introduced. The resulting variety would be separately registrable, and would (it was felt) take unfair advantage of the work of the original breeder.

Such considerations led to the introduction, in UPOV 1991, of protection for 'essentially derived varieties.' Article 14(5)(b) of UPOV 1991 reads (in part:)

> "… ***a variety shall be deemed to be essentially derived from another variety ("the initial variety") when***
>
> ***"(i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,***
>
> ***"(ii) it is clearly distinguishable from the initial variety and***
>
> ***"(iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety."***

Sales of such derived varieties infringe the right in the initial variety. To help with the construction of this paragraph, Article 14(5)(c) of the Convention goes on to give examples. These include new varieties obtained from the originating variety by:

> selection of variants or mutants (naturally occurring or induced)
> selection of somaclonal variants (from tissue culture);
>
> Genetically Modified (GM) technology;
> 'back-crossing'[4]

This list is not exhaustive. Other techniques may give rise to essentially derived varieties. One potentially controversial is marker-assisted crossing and subsequent selection.

What is the effect of this? A holder of rights in a successful protected variety can now challenge 'follow-up' varieties of competitors. If the new variety has a closely similar phenotype, and a closely similar genotype, there is a ***prima facie*** case of 'essential derivation.' This may be rebutted by proof that the new variety was not bred from the original variety, or by showing a different origin for at least some of the shared traits. A major problem with the concept is determining the 'essential characteristics' of the original variety, or, to put it more colloquially, how close is too close? To solve this, the breeding industry is trying to agree norms. These will vary by crop. Undoubtedly they will leave room for argument - and no doubt eventually litigation.

[4] It is not clear whether a single back-cross would necessarily give rise to essential derivation.

Note the following: 'Essential derivation' is a matter of fact-dependency is the (possible) legal consequence. These questions are for courts, not PVP offices, to decide. No question arises for decision until parties disagree. 'Essentially derived' varieties have themselves no protection against further derivation. This is because protection for derived varieties is granted to innovative breeders, and not to copyists. Therefore, it is a defense to the accusation of 'essential derivation' to prove that the claimant's variety was itself 'essentially derived.' Most importantly, the breeder's privilege is unaffected. A derived variety may be bred, and indeed registered: it is only commercial exploitation that requires permission. If, though derived, it has commercial merit, a deal with the owner of the original variety should be possible. The right to use protected varieties in breeding remains-it is only the development of close copies that is deterred.

Thus the plant variety protection system provides reasonably clear rights to use protected germplasm for further development. But is this enough to give breeders the freedom they may need? Several other rights can inhibit this freedom. These include:

patents;
national access rights (such as arise out of the CBD[5]);
trade secrets;
and contractual rights.

Of these, patents are so important as to require their own separate discussion. Access rights are increasingly important, but cannot be dealt with here: However, the FAO-sponsored International Treaty has made useful progress in tackling this problem. This leaves trade secrets and contractual rights to be briefly reviewed.

Trade Secrets

The patent system requires the inventor to teach the public how to operate the protected invention. This is not consistent with secrecy. The inventor's bargain with the public requires disclosure-in some countries, of the inventor's best method. The PVP system does not require the breeder to teach the public. It is sufficient to produce material of the new variety-which, in contrast, a patentee has no general obligation to do. However, material of the new variety may be exploited without being made available to the public. Varieties in the form of pure lines are naturally so made available when sold (and breeders of such lines are always at risk of having their materials illegally multiplied). Hybrid varieties are sold to the public, who however have no easy means of reproducing them. Parent lines are exploited by being used to make hybrids. Thus such parent lines are generally not made publicly available, and indeed considerable trouble is taken to keep them as in-house trade secrets. There is some dispute about whether this is proper, but the view of the industry is clear.

What constitutes a trade secret? Definitions vary, but the following is taken from the US Economic Espionage Act of 1996:

> ***"All forms of information*** [embodied or not] ***... if***
>
> ***"(A) the owner thereof has taken reasonable measures to keep such information secret; and***
>
> ***"(B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public."***

I note in passing that this Act makes misuse of trade secrets in USA a criminal offence, potentially punishable by long terms of imprisonment.

[5] Convention on Biological Diversity, Rio: this came into force in December 1993.

The most difficult question about this definition is what constitutes 'proper means'. Clearly stealing material of the variety from enclosed fields in which it was being grown would not be 'proper means.' However, suppose a farmer finds a protected pure line growing in his field (an unintended contaminant from the process)?

Contractual terms

This is another significant means whereby the access of breeders to protected varieties can be limited. One way in which this can happen is by developing agreements between breeders. One breeder will give another access to germplasm for the purpose of further breeding. Such access will typically be accompanied by restrictions on the use to which the germplasm is to be put, royalties to be paid, etc. In such agreements freely made between parties of generally equivalent status, the obligations undertaken will typically be balanced by the advantages obtained.

Contractual terms inhibiting exploitation may also be found in a quite different type of agreement-that for sales of seed. Since the genetic revolution, the analogies between the seed industry and the software industry grow apace-now the seed industry is starting to use shrink-wrap licences! Increasingly, bags of seed are found to bear labels limiting the rights of the purchaser: to replant seed, to use in breeding, and so on. In such cases, it seems that (as with computer software) the purchaser is not buying seed, but acquiring a temporary and limited license to use it. The terms may vary considerably. They may be directed simply to ensuring that the purchaser obtains no rights in unintended contaminants (parent lines)-such terms are perhaps no more than 'reasonable measures' to keep the lines secret. They may be much broader. Are they effective? This may require litigation to establish-and the answer may differ from country to country. If they are, they may largely nullify the effect of the breeder's exemption.

To summarize: it is contended that the plant variety system makes an important exception to ensure that protected varieties are available for further development, so that the art can progress. However, the same exception is not available in other right systems. Such systems are increasingly prevalent, and may effectively smother the breeder's privilege. Is this what we want?

Slide 1

Plant variety rights - The Breeder's Exemption

Tim Roberts

Slide 2

Topics for discussion

- Why a special IP system for plants?
- The Breeder's Privilege under PVP
- 'Essentially derived'
- Other restrictions on breeding

Slide 3

We need IP for plants

- To recognise and encourage work of plant innovators
- To allow recovery of investment
  - breeding takes much time and money
  - products are easily copied

Slide 4

Without IP

- Breeding must be done by public bodies (eg Governments)
- Governments fallible
- Lose benefits of
  - self-interest ( )
  - competition
  - diversity

25 October 2002 Geneva 4

Slide 5

Why PVP?

- **Patents** are the standard way of protecting technical developments
- **Do we need a separate system?**
- **'***Entia non sunt multiplicanda sine ratione'* **-** William of Occam
  - true of both natural and man-made laws

25 October 2002 Geneva 5

Slide 6

Problems of patenting

- **Can (should?) organisms be patented?**
  - You **can't invent 'life',** only discover it
  - **It's immoral -** intrinsically or in consequences
  - Breeding is **not reproducible**
- **Aren't new varieties 'obvious'?**
- **Are the rights of the patentee appropriate?**
  - **Too weak - or too strong?**

25 October 2002 Geneva 6

Slide 7

UPOV

- ***Sui generis* system**
  - **Provided a new right to protect specific varieties - not a patent**
  - **Because it is not a patent, the variety:**
    - **need not be inventive (non-obvious), just 'distinct'**
    - **need not be reproducible - just 'stable'**
    - **'written description' not essential**
  - **Rights over the variety are not so strong as a patent would give**
    - **problems of ethics, and monopoly, reduced**

25 October 2002 Geneva 7

Slide 8

Is UPOV still needed?

- **Organisms now patentable**
  - TRIPs says so - but plants don't have to be..
  - Need for 'written description' supplemented by deposit
- **BUT**
  - Many varieties still thought 'obvious'
  - continuing controversy over appropriate rights

25 October 2002 Geneva 8

Slide 9

UPOV system

- **Designed specifically to protect the work of breeders**
- **Takes account of users' needs**
- **Specifically reserves rights for further development**

25 October 2002 Geneva 9

Slide 10

Freedom to develop - PVP

- **Important purpose** of IP is to **promote technical advance**
  - **"***To promote the progress of science and useful arts***.."** (US Constitution, Art 1, s.6)
- **Most patent laws have "research exemption"**
- **Breeders traditionally work by incremental improvement of existing materials**
- **Must be free to continue**

25 October 2002 Geneva 10

Slide 11

"**Research Exemption**" in PVP

- **"The Breeders' Privilege" UPOV 91, Art 15(1)**
- (1) ***(Compulsory exceptions)*** *The breeder's right shall not extend to*

  (i) *acts done* ***privately and for non-commercial purposes****,*
  (ii) *acts done* ***for experimental purposes*** *and*

  (iii) *acts done* ***for the purpose of breeding other varieties****, and, …*[derived varieties aside]*, acts ...*[of commercial exploitation]*.. in respect of such other varieties.*
- It is **never** an infringement of a PVP to use the variety for further breeding.
- It is **generally** not an infringement of a PVP to exploit or sell the new variety bred.
- **Exception** for '**essentially derived varieties**'

25 October 2002 Geneva 11

Slide 12

'Essentially derived' varieties

- Varieties are by definition **distinct** from each other
- Under UPOV 1978, **no registered variety could infringe another** (repeated use aside)
- So **very similar** varieties were registered
- GM technology made this worse - single gene differences
- So UPOV 1991 extended protection to **'essentially derived varieties' (Art 14.5)**

25 October 2002 Geneva 12

Slide 13

Essential derivation

- *"a variety shall be deemed to be essentially derived from another variety ("the initial variety") when*
  - *(i) it is **predominantly derived** from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,*
  - *(ii) it is **clearly distinguishable** from the initial variety and*
  - *(iii) except for the differences which result from the act of derivation, it **conforms to the initial variety in the expression of the essential characteristics** that result from the genotype or combination of genotypes of the initial variety."* [Article 14.5.b, UPOV 1991]

25 October 2002 Geneva 13

Slide 14

Examples of Essential Derivation

- Article 14.5.c, UPOV 1991
- Varieties obtained by:
  - selection of mutants (naturally occurring or induced)
  - somaclonal variants (from tissue culture);
  - GM technology;
  - back-crossing (*repeatedly?)*
- List **not exhaustive** - may be others
  - *marker-assisted selection from crosses????*

25 October 2002 Geneva 14

Slide 15

This means…?

- A PVP holder can now challenge a close copy of a successful protected variety
- If the new variety has a closely similar phenotype, and a closely similar genotype, there is a *prima facie* case of 'essential derivation'
- This may be rebutted by proof that the new variety was not bred from the original variety
- **How close is too close**?
  - Industry is trying to develop schemes
  - room for argument - and eventually litigation

25 October 2002 Geneva 15

Slide 16

Points to note

- Essential derivation is for **courts**, not PVP offices, **to decide**
- 'Essentially derived' varieties have themselves **no protection** against further derivation
  - so to prove that the claimant's variety was itself 'essentially derived' is a defence
- **The breeder's privilege is unaffected**
  - the derived variety may be registered, but not exploited
- Of course, there is some deterrence - but the right to use in breeding remains

25 October 2002 Geneva 16

Slide 17

Freedom to develop - general

- Is freedom to develop under PVP enough?
- Other rights
  - **patents**
  - **CBD rights**
  - **trade secrets**
  - **contractual rights**

25 October 2002 Geneva 17

Slide 18

Trade Secrets (1)

- The patent system requires the inventor to teach the public how to operate the invention
- **Not consistent with secrecy**
- The PVP system **does not** require public teaching
- So can (probably) combine with trade secrecy
  - not for seed sold to public
  - but for parent lines of hybrids

25 October 2002 Geneva 18

Slide 19

Trade Secrets (2)

- *"All forms of information.. if "*
  - (A) "*the owner thereof has taken reasonable measures to keep such information secret*"; and
  - (B) *the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public*
- Misuse now a criminal offence in USA
- 'Proper means' - means what?

25 October 2002 Geneva 19

Slide 20

Contractual terms

- Development agreements between breeders
- Restrictions on seed sales - shrink-wrap licences!
  - sale for planting for consumption
  - no rights to breed
  - inbreds *vs* hybrids
- Enforceability?
  - may differ from country to country

25 October 2002 Geneva 20

Slide 21

Conclusion

- PVP allows access for further development
- Other rights may not
- Should they?

****

25 October 2002 Geneva 21

PATENT PROTECTION FOR PLANT MATERIAL

Mrs. Victoria Henson-Apollonio
The Consultative Group on International Agricultural Research (CGIAR), Netherlands

This paper briefly presents the author's views on the subject of patent protection for plant material. It is a quick review of patent types available to the plant breeder or inventor and then goes into a brief discussion of the application of the "experimental use exemption" as a means of exception to infringement. This review is not meant to be exhaustive, but covers patent practice concerned with protection of plants, in several geographic areas, namely, the United States of America., the European Patent Office (EPO), Australia, New Zealand, and Japan.

Plant, Utility, and Standard Patents

United States:

In the United States, there are three main ways in which an inventor or breeder may obtain formal IPR on plant material: Plant Breeder's Rights through the Plant Variety Protection Act (PVPA), patent rights under the Plant Patent Act (PPA), and patent rights (for inventions) as a utility patent, the Utility Patent Act (UPA, under, 35 U.S.C. Section 101 35)[1].

Plant patents are available under the PPA for asexually reproduced, novel plants. The applications must include a cultivar name for the claimed variety. The applicant must clearly identify the novel characteristics of the variety to be claimed by the plant patent application. This must be stated as one claim and often photographs or drawings must be filed to substantiate the claimed difference(s).

U.S. Plant patent would seem to not have a corresponding, "doctrine of equivalents" condition to that afforded directly by such a doctrine for plant material (inventions) covered by a utility patent or indirectly by the "essential derivation" concept of plant variety protection under the UPOV-type of protection.

The applicant must swear that the new plant variety has been asexually reproduced by the applicant and that the plant was found in a cultivate state. Plants found growing in the wild, in an area untended by man cannot be the subject of a plant patent. There have been 777 plant patents (PPA) issued so far in 2002. Approximately 96 of these patents have covered plants used for food and agriculture.

Utility patents may be granted in the U.S. for any new plant in which man has had "a hand" in the creation thereof. This follows from the landmark rulings in the Diamond v. Chakrabarty case and also the Ex parte Hibberd case. In the utility patent application, the applicant must fully disclose how to identify, make and use the claimed invention. When a utility application concerns an invention of a new plant, the public must be informed as to how one can obtain the new plant. Usually, this means that seeds or other propagative material must be deposited in an approved depository, unless breeding lines, cell lines, or other material are generally available to the public or if the plant material can be produced or isolated without "undue experimentation". This availability requirement, either

[1] Trade secrets have frequently been a method of preventing others from propagating plant material, particularly in situations where hybrid seed is produced from particular inbred parental lines. In such cases the identity of the inbred lines, is closely held. This type of trade secret protection has successfully been defended, as in the case of Pioneer Hi-bred v. Holden, 35 F.3d 1226, 31 USPQ2w 1385 (8th Cir. 1994), where genetic fingerprint data, isozyme analysis and phenotypic comparisons were used to prove trade secret misappropriation.

through general availability or by deposit is especially important so that this material will be available to the public, once the patent expires or lapses for other reasons. In the case of hybrid breeding lines, both inbred parental lines must be deposited. Utility patents offer broader coverage, i.e., the protection of a novel plant trait, which embraces more than a single plant variety or cultivar.[2]

A recent Supreme Court ruling in the JEM Ag Supply v. Pioneer Hi-bred case establishes that a plant variety may be the subject of both a Plant Breeder's Certificate awarded under the U.S. PVPA as well as the subject of claims in a utility patent application.

Multiple aspects of a plant invention can be claimed in a utility patent. For example, claims can be made regarding breeding method(s), inbred parental lines, plants and pollen produced by the parents or claimed variety, as well as seeds of the parents or variety, phenotypic characteristics of the claimed variety or inbred parents, plants and seeds produced from regenerative methods. Patent applications for transgenic plants (genetically modified organisms) will have claims covering the transgenic plants, seeds of the plants, novel cloned genes/expression vectors, as well as possibly methods for the production of the transgenic plant. Utility patents are considered to afford "stronger patent protection" than rights obtained with PVP certificates, as the requirements are stricter in order to obtain claims. This results in an awarding of greater rights of exclusion than PVP certificates.

Thus far, in 2002, the United States Patent and Trademark Office (USPTO) has issued 222 utility patents under the U.S. plant classification identifier, with claims to seed. Of these, an initial analysis indicates that 114 had claims directed to novel plant varieties.

European Patent Office - standard patents

In countries that are members of the European Patent Office (EPO), the patenting of plant varieties, per se, is prohibited. Indeed, before a decision by the EPO's Enlarged Board of Appeals on December 20, 1999, it was assumed that no plants could be the subject of a utility patent claim, based on the Directive 98/44/EC of the European Parliament. However, the EPO, Board Of Appeals (BOA) determined that a claim directed to transgenic plants of more than one variety, but that does not claim an individual plant variety, is permissible. Thus, opening the way, for all intents and purposes for the EPO to allow claims to plants.

Japan-Standard Patents

According to the Japanese patent regulations:

> "As to an invention relating to a plant, a claim should be described as follows. In the case of an invention of a plant per se, the plant should be specified by, for example, a combination of any of the species, the distinctive gene of the plant, characteristics of the plant, etc. and may be further specified by the process for creating the plants."

In addition, there is a separate section in the Japanese code for matter relating to the genetic engineering of plants as well.

[2] Indeed it is this characteristic of utility patents that has allowed the patenting of novel plants in countries of the European Union, even though the EU Directive, 98/44/EC, forbids the granting of patents for plants.

Australia-Standard Patents

Australia allows the claiming of protection of plants in standard patents, for plants in general and for specific cultivars. This includes new plant varieties, plant components, reproductive material, products from plant and plant material used in industrial processes.

Australia-Innovation Patents

Plants and the biological processes for the generation of plants are not patentable subject matter for an innovation patent. However, it is possible to obtain an innovation patent on processes that use a plant or parts of plants, but that does not result in the generation of a plant.

New Zealand-Standard Patents

Plant material, especially transgenic plant varieties, are considered to be patentable inventions, under the rules for granting utility patents, in New Zealand.

Infringement of Rights/Experimental or other Use Exceptions to Infringement

U.S. Plant Patents:

The U.S. Court of Appeals for the Federal Circuit (CAFC) decision, Imazio Nursery v. Dania Greenhouses, 69 F.3d 1560, 36 USPQ2d 1673 (CAFC 1995) ruled that a plant patent holder must prove that the accused variety was actually derived ***asexually***, from plant material representing the patented variety. Accordingly, most would hold that the variety protected by plant patent can be used without authorization by others as a parent in a commercial breeding program. Thus, there is a broad, "Breeder's exemption", associated with plant patent practice.

U.S. Utility Patents:

In the U.S., the "Experimental Use Exception" to patent infringement, is a judicially created relief. It is not a part of the patent law. A recent ruling (Madey v Duke University), by the U.S. District Court for the Middle District of North Carolina, reaffirmed a very narrow interpretation of "experimental use", set forth in the prior cases, Embrex v. Service Engineering Corp, (Fed. Cir. 2000), and Roche v Bolar (Fed. Cir. 1984). This prior interpretation holds that a defense of experimental use is limited to actions performed, "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry". In the Madey ruling, the court continued, "Further, use does not qualify for the experimental use defense when it is undertaken in the 'guise of scientific inquiry' but has 'definite, cognizable, and not insubstantial commercial purposes'." The concurring opinion in Embrex expresses a similar view: use is disqualified from the defense if it has the 'slightest commercial implication'." The Court also narrowed the definition of "commercial". It held that Duke University's use of patented technology without the approval of the patent holder was commercial in the sense that such use gave Duke a competitive edge in recruiting high-quality students and in attracting funding through competitive grants. This interpretation was found, even though Duke had no intention of producing any commercial product or claiming a commercial invention, using the technology in question.

EPO-country members

As a rule, it seems that there is a broader interpretation of the meaning of the "experimental use exception" in EPO-countries. For example, in the UK, there is an experimental use exception to infringement that is part of the patent law (Section 60(5)(b) of the Patents Act, 1977).

Australia

There is an "experimental use" exemption from patent infringement under the Patents Act of 1990, in appropriate circumstances.

Japan

The Japanese Patent Law contains a specific provision that excludes from infringement, acts carried out for the purposes of experiment or research.

New Zealand

There are no provisions regarding experimental use in the New Zealand Patent Act. Courts in New Zealand have adopted an, "experimental use from patent infringement", stance. However, the Courts are particularly concerned regarding advancement in the commercial sector under the experimental use exemption.

DISCUSSIONS

Session II: Accessibility of protected inventions and plant varieties for further innovations

Moderators:

Mr. Qiao Dexi, Director General, Department for International Cooperation, State Intellectual Property Office of China

Mr. Tim Roberts, Patent Attorney, United Kingdom

Mrs. Victoria Henson-Apollonio, The Consultative Group on International Agricultural Research (CGIAR), Netherlands

DISCUSSIONS

Mr. Qiao Dexi opened the discussions.

Mr. Jean-Luc Gal, National Expert detached within the Industrial Property Unit of the General Direction of the Internal Market, European Commission, Brussels:

I should like to thank the different speakers for the quality of their presentations. I should like simply and very quickly to refer to the presentation by Mrs. Henson-Apollonio concerning the European Patent Law on the question of plant variety protection. It is perhaps not completely correct to say that there was a difference between the practice of the European Patent Office (EPO) and the Directive No. 98/44 since it is made very clear in the Directive that plants can only be the subject of a patent if they are new, involve and inventive step and are capable of industrial application, but that plant varieties are excluded from patent protection. Furthermore, the decision of the Court of Appeals (***Grande Chambre de recours)*** to which reference is made, takes on, in a more detailed and complete manner, these exact terms. Therefore, there is no difference, as such, between this Directive, the European Patent Convention and the practice of the Court of Appeals of the EPO.

Mrs. Henson-Apollonio: I think that that's what I said except that perhaps in a way in which it was practiced prior to that Decision there was confusion about exactly what the Directive meant. Maybe I misstated that, but I think we have a clear understanding now of what the Directive means.

Mr. Tim Roberts: The interesting thing, from a legal point of view, about the decision of the Enlarged Board was that it based itself entirely on existing law and did not rely on the Directive No. 98/44. So it is a confirmation that, in that instance at least, Directive No. 98/44 was not making new law, but simply harmonizing existing law.

Mr. Huib Ghijsen, Global Manager Germplasm Protection, Bayer BioScience N.V., Astene: I have a question on a subject which has been touched on by three of the speakers about the obviousness or non-obviousness requirement. I am referring to the plant patent, there is a quite good description of what is obviousness in the plant patent system and I wonder whether that could also be applied to other varieties. The instruction in the plant patent system says that techniques are obvious using mutants, chimeric plants and doubling chromosomes. Some speakers say that plant varieties as such are questionable whether they are non-obvious. In the United States, they use utility patents and the definition is that, while a plant variety is the unexpected outcome of a systematic breeding process, it is non-obvious. I have the feeling that it is somewhat a meaningless definition so that every plant variety, whether it is protectable under the PVP system or under utility patent meets, infact, the same requirements. Maybe this is a somewhat complicated subject for a few minutes, but this afternoon we could perhaps proceed on this subject.

Mr. Tim Roberts: This is a fascinating topic and one which we could easily get carried out by. One thing I would say is that, because a technique is obvious, it does not mean that the product you obtain using the technique is obvious. If you take an analogy, if you like, from copyright, anybody can type, it's what they type that is of interest. And the same can apply. The product may not be obvious, although the process is. If it is obvious to apply the process, and when you apply the process you inevitably get a particular product, then that may mean that the product is obvious, but there are some steps, if you like, to be finessed there. This is not an easy question. I personally, and this is a personal opinion, cannot believe that the US Patent Office is right in regarding all plant varieties as automatically patentable simply because not all their features could have been predicted. If that applies for plant varieties, I do not see why it should not apply to other things as well, and that can hardly be right.

Mrs. Henson-Apollonio: My quick comment would be that very often it is the implementation level in which this sort of thing comes into play and that the individual examiner is making a certain judgement or, his examination unit is making a certain judgement. There are certain guidelines of course that are followed in all of the examination Offices in terms of interpreting this language, and so there are several levels of complication.

Mr. Mark Shillito, Partner, Agribio Law Practice, Herbert Smith, London: This is a question for both speakers. Given that the patent research exemption is wider in some countries, but narrower in others, and the fact that in virtually all of them, if you do something for commercial purposes, you are in trouble as far as that exemption is concerned. I would like to ask both speakers what level of success they would expect if they lobbied the patent authorities in their respective jurisdictions to change the research exemption for plant varieties to look more like Article 15(1) of UPOV Convention.

Mrs. Henson-Apollonio: I think, it is of course very much country-dependent and I think it is the sort of thing where you would have to have industrial lobbies that would exert pressure to have something that was legislated so that it was more clear and more stable than the judicial interpretation. So I think, a lot of it has to do with the industry and what the industry can muster in terms of trying to have something that is workable. But I just brought up the Bolar Amendment in the sense that it is possible to do that, but you would have to go back and look at the history of how that amendment was actually amended in order get a clue.

Mr. Tim Roberts: We were asked to comment on our respective countries. But I can not resist a quick comment on the Bolar Amendment. The fact that it was necessary to find a specific statutory exemption for that situation perhaps suggests that there is something not quite satisfactory with the US law in this question and maybe there should not be a specific exemption for the Bolar situation, and I note that the Bolar exemption goes further than the current European law in fact, and indeed there have been objections to it as not conforming to TRIPS. The fact that there is this specific statutory exemption for this specific situation in the United States may suggest that the broad law needs further attention, particularly with this new case. As regards, Europe and the United Kingdom, certainly as regards lobbying in the United Kingdom Government for changes in this respect, experience suggests that it will not be too easy to get any change. There is, of course, the question as to whether a change is required, and we shall be hearing more about this. But many small companies are not satisfied with a situation where they are almost certainly right when they are faced with powerful opponents who think they are wrong and have the money to back it up with.

Prof. Joseph Straus: In order to prevent mixing up things which do not go together. The Bolar exception is something which is really only allowing an early entry on the market, by permitting tests/clinical trials aimed at proving that the drug of the generic producer, the so-called "me to" drug, has the same properties as the drug, the marketing of which had been already approved. If you are talking about the breeder's exemption, to my understanding, breeding is involved, not only proving that what you have is exactly the same as that of your competitors, i.e. what the so-called "ethical drug producer" has. So please be careful on that.

SECTION III

INTELLECTUAL PROPERTY STRATEGY AND LICENSING EXPERIENCE WITH THE CO-EXISTENCE OF PATENTS AND PLANT VARIETY PROTECTION SYSTEMS

INTELLECTUAL PROPERTY FOR BREEDERS

Mr. François Desprez

President, French Society of Plant Breeders (SICASOV), France

INTRODUCTION

THE PRACTICE OF THE PLANT VARIETY CERTIFICATE (PVC)

The advantages of the Plant Variety Certificate (PVC)

- the research exception
- simplicity
- cost

The constraints of the Plant Variety Certificate (PVC)

- farm seeds
- reference collections
- essential derivation

PATENT PRACTICE

The search for licenses

The filing of patents

WHAT INTELLECTUAL PROPERTY STRATEGY FOR BREEDERS?

INTRODUCTION

The point of view which I will describe here is not that of an intellectual property specialist in the plant field, as would be that of a legal expert of an international seed company and a director of one of the bodies responsible, at the national or international level, for managing the assignment of the rights linked to the creation of varieties or biotechnology invention.

My point of view will be that of an experienced user of the Plant Variety Certificate (PVC) and, in more recent times, of the patent. I will adopt the stance of a rights holder but also a licensee so as to attempt, on the basis of the merits and shortcomings of the two types of intellectual property available, to determine a management strategy for a company, the principal task of which is to create varieties rather than develop biotechnology.

I should also point out that intellectual property discussions and, to a greater extent, the development of a relevant strategy, are a relatively recent occurrence among traditional breeders. This is the result of the offer made to seed growers, from the 1990s onwards, to gain access by means of licenses to patented biotechnology inventions.

Thus far, without getting caught up in excessive legal discussions European breeders have operated within an appropriate practical framework provided by UPOV Convention in its different Acts, since the 1961 Convention up to the 1991 Act which, moreover, is still not in force in several European countries including France.

THE PRACTICE OF THE PLANT VARIETY CERTIFICATE (PVC)

Since 1961, breeders from countries which are UPOV members have been able to carry out their work to improve plants within a simple legal framework with which they are familiar; the framework has undoubtedly contributed to the progress made in agriculture, as shown by the International Seed Federation (ISF) in its recent publication ***Seed for Mankind***.

Who would have thought that considerable progress could have been made in Europe in terms of productivity, resistance to parasites and hardiness, if private and also public breeding had been unable to enjoy the benefits offered by the PVC?

THE ADVANTAGES OF THE PVC

The research exception

Free access to protected varieties as an initial source of variation appears to be the major advantage of the UPOV protection system for breeders. It allows all concerned to rely on the most recent innovation in order to try and do better. The research exception also helps to increase the efficiency of the programs designed to improve plants.

To demonstrate this, it is sufficient to consider the origins of the varieties of Wheat most commonly cultivated in France at the present time.

Of the 16 lines forming part of the genealogy of the eight most widespread varieties, 11 are protected varieties and half of them do not belong to the breeder who has cross-bred them.

Furthermore, the protected line appears, on average, ten years after its registration as the parent of a new variety, i.e. a period which conforms to the duration of a conventional breeding cycle. This period is of course shortened, by around two to four years, when the owner of the original variety and that of the new variety are one and the same.

The research exception therefore confers a legitimate advantage on the creator, while leaving all concerned with the opportunity to innovate on the basis of the most recent and most interesting genetic material.

Simplicity

Breeders prefer to be in their nurseries or testing grounds rather than filling in forms, even the electronic versions! One of the other undeniable merits of the PVC is therefore its simplicity.

For example, the formalities required by the Community Plant Varieties Office (CPVO) for a straw cereal variety are limited to an eight-page protection application, a six-page technical questionnaire and a single-page denomination proposal, and each form is user-friendly.

Cost

The cost of the PVC is reasonable. Within the CPVO, a 1000 Euro examination fee is added to a 900 Euro application fee for a cereal variety.

Subsequently, the annual fee will not exceed 1000 Euros, which is reasonable for a variety disseminated in several European Union countries.

This protection system therefore has little weight in research budgets and, in any case, less than the tests for registration in national catalogs.

For most breeders, the direct cost of protection and registration does not exceed two per cent of research expenditure.

THE CONSTRAINTS OF THE PVC

Farm seeds

Until the 1991 Act of the UPOV Convention, the legal framework provided by the PVC and most national laws did not allow the case of farm seeds to be dealt with in a realistic manner, representing as it does 30 to 80 per cent of seed use in many major species and according to different countries.

A right cannot be considered perfect if its enforcement is made impossible by common usage and if the authority responsible for its application refuses to impose it.

In that regard, the optional exception provided for in Article 15(2) of the 1991 Act provides a legal framework which enables realistic solutions to be found in each country, allowing farm seed users to contribute to research funding, apparently contrary to the case of the patent.

Reference collections

The fact that a considerable number of varieties are the subject of applications for protection raises obvious practical problems as to the judgment of the distinction and the maintenance of reference collections.

Furthermore, breeders remain attached to the study of phenotypic characteristics and are somewhat reluctant to use markers on a systematic basis.

Developments in the area should, however, be accepted so as to maintain the cost of protection at the reasonable level I have indicated above.

Essential derivation

The essential derivation concept represents undeniable progress provided by the 1991 Act since it allows technological developments to be taken into account in the field of genetic engineering but also reduces the risk of plagiarism.

However, it obliges the breeder to identify his own genetic material by using dozens, or even hundreds, of markers, thereby generating substantial new costs.

PATENT PRACTICE

The conventional breeder acts essentially as a licensee for technologies devised by others who may also be competitors in the trade of creating new varieties.

THE SEARCH FOR LICENSES

Few breeders, apart from the main multinational companies, are in a position to organize effective biotechnology supervision, while the number of patents that can be used in plant variety models is considerable.

To deal with this situation, the main French breeders have set up a body called VIGIBIO, the aim of which is to finance the creation and operation of a databank in the field of biotechnologies.

This tool allows all concerned to adopt an initial approach to the scientific and legal interest of these patents for the purposes of directing, improving and using their breeding programs.

It should be added that the conclusion of contracts is made difficult, owing to the absence of a "patent culture" among most breeders, linked to the fact that no internal legal service exists.

In practice, such contracts prove to be very restrictive. Since one of their strongest clauses is secrecy, I am unable to illustrate my comments with specific examples.

Since this is the case in general terms, I will cite a number of the most frequently encountered difficulties.

- The multiple nature of the parties

In addition to the patent holder, there is the breeder of the gene pool, who serves as a support for the breeder and proves to be a competitor for the licensee!

- The obligation to provide information

The biological material transfer agreement which is implemented from the experimental phase onwards contains an obligation to provide detailed information on the work undertaken, thereby generating the risk of disclosing the breeding strategy.

- Exclusivity

Where it covers a whole research area, this request limits the capacity to conclude contracts elsewhere. It also makes it difficult to maintain previous cooperation, in particular with public research where there is a strong tradition of publishing in scientific journals.

- Liability

The licensee is liable for any damage or risk stemming from the use of the transferred material, while the patent holder strongly limits his own guarantee.

In most cases, an imbalance therefore exists between the parties, to the benefit of the biotechnology patent holder.

THE FILING OF PATENTS

Even in companies whose first task is to create improved varieties, biotechnologies now play a significant role, in particular in the support provided for breeding programs.

15 per cent of research expenditure is, on average, devoted to such programs.

Moreover, collective forms of labor, such as GABI in Germany or GENOPLANTE in France, help to increase this share.

In this context, discoveries are made which enter the field of patentability. Many breeders therefore use the services of specialized offices in order to conduct the procedure for obtaining the patent and discover that the complexity of the cases, costs and deadlines (several years in cases where there is opposition or an appeal) can in no way be compared with their experience of intellectual property based on the PVC.

Thus, it is estimated that the cost of intellectual property, its creation and protection can reach ten per cent of the sums devoted to the corresponding research.

WHAT INTELLECTUAL PROPERTY STRATEGY FOR BREEDERS?

From a practical point of view, I think that breeders should resolutely choose UPOV protection for the varieties they create.

In the 1991 Act, this system guarantees the promotion of innovation while proving to be suitable for a large variety of development of national seed networks.

We should, however, agree to devote greater resources to the protection of our varieties and our germ plasm, ***inter alia***, by taking account of the concept of essential derivation.

Since we have the potential to use biotechnology inventions much more than we generate them, breeders should, at the same time, either individually or collectively, undertake scientific and legal monitoring allowing them to negotiate, at the right time and in the best possible conditions (in particular as regards the enhancement of their gene pool), access to technologies of interest for the programs.

From a general point of view, I consider that the balance in relations between the two protection systems, as it is introduced in the document ***ISF view on intellectual property***, adopted at the Chicago General Assembly this year, represents an initial approach to finding an equitable and realistic solution.

However, the use, as a source of initial variation, of a protected variety containing a patented biotechnology invention is likely to be one possibility that breeders will not use. The time devoted to eliminating the patented invention will limit the interest of the gene pool which surrounds it. In that sense, a "marking" strategy for a patent in any range of varieties would, in practice, lead to access thereto being prohibited for subsequent breeding purposes.

GENEALOGY AND DATE OF REGISTRATION
OF THE MAIN VARIETIES OF SOFT WHEAT
IN FRANCE

APACHE (1997)	AXIAL (1989) x CAMP REMY (1980)
CAPHORN (2000)	RIALTO (1992) x BEAUFORT (1993)
CHARGER (1996)	FRESCO (1988) x line
ISENGRAIN (1996)	APOLLO (1984) x SOISSONS (1988)
ORVANTIS (1999)	THESEE (1984) x line
SHANGO (1994)	FRESCO (1988) x line
SOISSONS (1988)	IENA (1980) x line
SPONSOR (1994)	MERCIA (1986) x line

CONDITIONS FOR THE DEVELOPMENT OF AGRICULTURAL BIOTECHNOLOGY IN BRAZIL: NATIONAL AND INTERNATIONAL CONTEXT, BIOSAFETY AND LEGAL ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

Mr. Luiz Antonio Barreto de Castro
Brazilian Agricultural Research Corporation (EMBRAPA), Brazil

BIOTECHNOLOGY- NATIONAL AND INTERNATIONAL CONTEXT

After a long period of silence since the Asilomar Conference in 1975, representatives from several Academies of Sciences (United Kingdom (UK), United States of America (US), India, Brazil, Mexico, Argentina, China and the Third World Academy of Sciences (TWAS)), almost a quarter of a century later, produced a document on the safety of state-of-the-art transgenics from the point of view of science. The document is generally favorable to the development of biotechnology. Except for the UK, Mexico and Brazil, none of the countries represented by the Academies of Science cited had campaigns against the use and approval of genetically modified organisms (GMOs). In all the other countries, the research and use of transgenic products are in rapid expansion, a fact which is somehow worrying for the two cited Latin American countries since the US, China, Argentina and India are our main competitors in the international production and commercialization of grain. This happened much later than the commercialization of the first genetically modified transgenic plant obtained through genetic engineering in 1995.

Genetically modified plants were released into the environment in the mid-eighties. Nowadays, over 30,000 field tests have been authorized all over the world, half of which are in the US, Canada and some European countries. Asia and Africa lag behind in this respect. In Latin America, most releases took place in Argentina (¾ of all the tests carried out in Latin America) and in Mexico. Brazil has authorized only about 1,000 field tests since 1996 because its biosafety legislation was not approved until 1995.

The commercialization of transgenic plants started in the mid-nineties with slow-ripening, genetically modified tomatoes, produced by Calgene, and the round-up herbicide resistant soybeans, created by Monsanto. Presently, transgenic plants of some species (soybeans, corn and canola, for example) play a significant part in the agricultural production of countries such as the US, Canada and Argentina. Glyphosate-tolerant transgenic soybeans already represent 62% and 98% of all the soybean plantations in the US and Argentina, respectively. Transgenic plants of many other species such as tomato, potato and cotton are also becoming popular. The total area covered by transgenic crops worldwide has increased from 1.7 million ha in 1996 to 60 million ha in 2002. The main characteristics of the plants mentioned above are resistance to insects, viruses and herbicides, as well as better nutritional qualities. One example of the latter is the modified canola which has a different lipidic composition intended to control the potential adverse effect of that oil in human cholesterol. Most of these plants (around 90%) have been developed by private enterprises already operating in Latin America, such as Monsanto, Syngenta, Aventis, Dupont, BASF, Dow and recently Bayer, amongst others.

Nevertheless, genetic engineering is considered to be in its initial phase since, until very recently, it has not used more than half a dozen genes, mainly from bacteria. Moreover, it has not yet solved the most serious agricultural problems, such as nitrogen fixation in gramineous plants and resistance to different forms of stress in plants, nor has it managed to alter the main physiological process that regulates the energy flow in plants, i.e. photosynthesis. The reason for this is that the main physiological and biochemical processes are very complex and have not yet been deciphered at molecular level, which is required before their manipulation through genetic engineering. The advent of genomics, however, has caused this picture to change rapidly, particularly after the sequencing of the ***Arabidopsis thaliana*** genome. Recent advances in genomics have shown an unequivocal fact: biotechnology is an important tool to deal with the intensification of competition

resulting from a globalized agricultural market, which demands cost reductions and the ability to produce crops in adverse weather and soil conditions, using varieties that are resistant to droughts and to aluminum and that are more efficient in the absorption of phosphorus. The so-called 'gene revolution,' is opposed to the 'green revolution,' which depended heavily on providing inputs. These issues are those which will really change food supply all over the world, but they have been avoided by biotechnology companies because they demand long-term projects.

Due to its concerns with biosafety, the development of the agricultural biotechnology industry in Brazil follows a different route from that of other industrial sectors. ***It must provide the consumer with accurate information about the safety of the products derived from this new technology, making reference to the most reliable scientific bases***. Three main strategic reasons present obstacles to such an approach:

1- Agricultural Biotechnology offers products to the market which incorporate radical modifications to those already available, thereby affecting consolidated markets, such as the seed and the pesticide markets.

2- Many governments, eager to promote the fast development of agrobiotechnology in their countries, have not established a specific legal and institutional framework to deal with biosafety issues in direct relation to biotechnology. Instead, the option has been to adapt previous legislation and infrastructure. This choice prevented an open and formal participation of the scientific academia in the decision-making process related to biosafety. Relevant scientific information is, however, now being offered to the public by organizations such as the International Food Information Council Foundation (IFIC) and the Council for Information in Biotechnology (CIB) in the US and other countries.

3- Other countries, particularly those within the European Union, were late to establish the institutional infrastructure and legal framework to deal with biosafety of GMOs and were apparently unprepared to take decisions when millions of tons of genetically modified grain arrived from the US, Argentina and Canada in the mid-nineties; and when, at the same time, the general public strongly rejected GMOs due to the influence of non-governmental organizations such as Greenpeace .

Although it is impossible to ignore the fact that market protection plays an important role in the decisions taken by the governments with respect to biotechnology and new technologies in general, we will omit this discussion from the present document and focus on the approach given to agricultural biotechnology in countries where it has developed rapidly, such as the US, in contrast to the situation in Europe. Finally, we will make a comparison with the situation in Brazil, with the objective of suggesting some elements to help the construction of a strategy to be followed in the development of this sector in Brazil.

BIOTECHNOLOGY AND BIOSAFETY – BACKGROUND

When genetic engineering began in the United States, in the early seventies, only a few dozen research groups were familiar with the technology, and there were only nine biotechnology companies operating in the whole country. Since then, the US have developed a strong biotechnology industry with financial operations exceeding ten billion dollars per year, predominantly in the area of human health (Biotech 91: A Changing Environment, Editor: Ernst Young). Seventy percent of these companies have their headquarters in the vicinities of the main health centers of the country: California, on the West Coast, and Boston/New York/Washington, on the East Coast. The investments in this area have, over the years, reached several dozen billion dollars, mainly from the private sector.

However, the advent of genetic engineering soon led society to develop a growing concern over the issues of biosafety and bioethics, both in relation to the activities and experiments developed in the laboratories, as well as in connection to possible environmental and ecological damage that might result from contact with transgenic organisms. Such worries derive from the fact that genetic

engineering enables scientists to combine genes of phytogenetically distant and incompatible organisms within plant and animal genomes.

The immediate reaction from the American scientific community to these new possibilities was rather strong and led to the proposal, during the Azilomar conference, in San Diego, California, of a moratorium on the use of genetic engineering on organisms which are highly pathogenic to human beings. This decision was maintained until the National Institute of Health (NIH), at the request of the US Academy of Sciences, developed a set of biosafety guidelines for the use of genetic engineering in laboratories. These guidelines were soon adopted by countries all over the world, including Brazil and other Latin-American countries, satisfactorily guaranteeing laboratory safety.

Meanwhile, North American and European organizations established mechanisms to evaluate and manage the potential hazards involved in the release of transgenic organisms into the environment. As a follow-up, many countries, including Brazil, established biosafety rules through specific institutional infrastructure and legislation based on those guidelines, with the objective of regulating the use of genetic engineering and the release of genetically modified organisms into the environment. Other countries, such as, for example, the United States, preferred to adapt previously existing laws and institutions to deal with this new scientific issue. Some European countries and Japan, however, have not yet taken either step, and are still simply following Guidelines and Directives.

Although different countries use different approaches to evaluate the biosafety of genetically modified organisms, it is a fact that governmental authorities have been following and controlling biotechnology activities and their products worldwide for more than two decades, with very good results: ***since the advent of this science, thirty years ago, there have been no records of any sort of environmental or human damage in the countries which obey the principles of evaluation and risk management supported by biosafety norms.*** In fact, genetic engineering has produced some very important developments, particularly in relation to health and agriculture. Developing countries wishing to practice genetic engineering or to cooperate with leading industrialized countries need to adopt guidelines or specific laws dealing with biosafety as a requisite for receiving funds from international agencies. This requirement was also included in the Biological Diversity Convention (CBD), which led to the Cartagena Protocol, recently approved in Canada.

BIOSAFETY IN EUROPE AND IN THE UNITED STATES

There has been a very strong reaction, particularly in Europe, against human consumption of GMOs and derived products, as well as general concern about the potential harmful effects of such organisms on the environment. Such negative reactions result from campaigns mostly organized by non-governmental organizations. It is important, though not always easy, to distinguish genuine concerns over the possible effects of these plants on the environment from other initiatives which, despite seemingly ecological, are only interested in defending their market share. One important example to be considered is the possibility that the transfer of genes from transgenic plants to similar species could result in so-called "super weeds." Exploratory articles, published in scientific journals, deal with this issue as if developmental biology did not have rules to guarantee evolution and speciation. Species have proper mechanisms, developed over hundreds of millions of years, to 'watch over' their genome at molecular level so as to minimize the possibility of strange genes being introduced into their genetic heritage. The fact that one gene may be transferred from a transgenic plant to a wild species does not necessarily result in a "super weed." The fundamental question to be considered in relation to such transfer is: what would be the advantages in terms of adaptation and evolution?

Two cases that have not followed a sound scientific route are the GM potato expressing a gene that codifies a leguminous lectin, and the effect of a 'Bt' toxin in lepidopterans (Monarch butterfly). The reaction to the first case in the media was totally incompatible with the quality of that scientific experiment, which was later refuted by the British Academy of Sciences. The second case reports a preliminary experiment carried out in conditions different from those naturally found in a corn

plantation. Later experiments reduced entirely the potential impact of the initial research. The scientific quality of such experiments is therefore highly questionable and appears to be typically opportunistic.

The effect of these experiments represented, however, a major disaster for agricultural biotechnology. Some European supermarket chains announced that they would no longer sell transgenic products after Dr. Pusztai's experiment with potatoes. Trials of transgenic plants were literally destroyed in Belgium, Brazil and the United Kingdom. France, Austria and Luxembourg demanded a moratorium on transgenic products and reserved for themselves the right to reject GMOs that had been previously approved for commercialization in Europe, such as corn and canola. After these experiments, no new transgenic products were added to the list of those approved by the European Union. On the other hand, those experiments had no effect in the United States.

There is more than one explanation for such different attitudes. In many European countries, the government's reputation for keeping the consumers well-informed is questionable since the outbreak of mad cow disease with its transmissibility to humans, the commercialization of meat contaminated with bacteria pathogenic to humans, and with dioxin, a carcinogenic substance, and the distribution of HIV contaminated blood. This questioning does not exist in the United States. The Americans have no strong reasons to distrust the USDA, the United States Department of Agriculture (FDA), the Food and Drug Administration (EPA) or the Center for Disease Control (CDC), the agencies in charge of controlling and approving GMOs.

The American Government has an additional interest in developing agricultural biotechnology, namely to seek competitiveness for their agricultural industry demanding subsidies. In Europe, on the other hand, agriculture receives subsidies from the government and is currently going through a retraction process, depending more and more on the importation of products, such as soybeans, for instance. This whole scenario, as we can see, goes much beyond the discussion of whether or not GMOs are safe for human consumption; Europe and the US will be taking the matter before the WTO if the present retaliations concerning the importation of agricultural products continue.

BIOTECHNOLOGY AND BIOSAFETY IN BRAZIL

Brazil has developed scientific competence in practically all areas related to the state-of-the-art biotechnology, such as genetic engineering, genomics and proteomics. For decades, Brazil has demonstrated competence in plant genetics and genetic breeding for the tropics. The country is attractive, being one of the last ones where agriculture will develop substantially and being, at the same time, a mega-biodiversity subcontinent, where most genes needed for the development of modern biotechnology for the tropics can be found.

Compared to other countries, Brazil presents the greatest biodiversity of all, with around 250,000 known plant species, 30% of which are potentially edible. Throughout the centuries, human beings have used no more than 1% of these plants for consumption. In fact, the basis of human nutrition consists of only 0.2% of these species. The tropical rainforest – an area covering around 7% of the planet – contains, according to some studies, about 50% of the world's biodiversity. Other ecosystems and regions, such as the ***caatinga*** and the Atlantic forest, are equally important sources of genes.

In order to enable the safe development of biotechnology, Brazil has established, through specific legislation, biosafety rules to control the use of genetic engineering and the release of genetically modified organisms into the environment. That law created and established the obligation, competence and composition of the Biosafety National Technical Commission – CTNBio - as an integral part of the Ministry of Science and Technology. It is formed by representatives from the executive branch of government, from the biotechnological business sector and from consumers, as well as by a legally constituted agency for the protection of laborers' health. Finally, 18 scientists, selected specialists in every scientific field related to biotechnology, are members of the Commission. The CTNBio was created in June 1996 and has been acting in this area ever since. The Brazilian biosafety legal and institutional infrastructure, which deals with the control of the release of

transgenic products into the environment, was thus created. Since then, CTNBio has operated through monthly meetings and produced most of the necessary biosafety rules for the enforcement of that law, acting with great timeliness and discernment. In addition, it has authorized, under those norms, over 1,000 field tests with transgenic plants, and has licensed several public and private laboratories and institutions to act in various areas of genetic engineering. Unless recognized and licensed by CTNBio, no laboratory dealing with genetic engineering may receive public funds for research.

The opposition to biotechnology in Brazil started in 1997. Greenpeace found other NGO partners, such as IDEC (Consumer Defense Institute), within the Governmental institutions (IBAMA – Brazilian Environment Institute – a branch of the Ministry of Environment), within the Judiciary system, not to mention the role played by the media, which rarely treats this issue without being pejorative and sensationalistic. It is not surprising, therefore, to see, in the state of Rio Grande do Sul, where the Labor Party rules similar reactions to those observed in Europe, where experimental fields tests were destroyed and companies invaded.

As we have seen, Brazil has been facing a number of difficulties which have prevented, by legal action, the release of transgenic products in our country since 1998, as opposed to what happens in the United States, Canada, Australia, Argentina, India and China, all great exporters of commodities and strong competitors in the international market. Who will gain from the moratorium and the campaigns against biotechnology in Brazil? The pesticide industry and Brazil's competitors in the market of commodities. Who is to lose? Brazil alone.

THE LEGAL INTELLECTUAL PROPERTY RIGHTS BIOTECHNOLOGY CONTEXT IN BRAZIL

THE BRAZILIAN VARIETY LAW

Brazil established a legislation to protect breeders' rights, (Plant Variety Protection Law #9456/97) which follows almost entirely the 1978 Act of UPOV - International Convention for the Protection of New Varieties of Plants. Three Articles of UPOV 1978 are cited below for reference:

Article 1: Purpose: to recognize and to ensure to the breeder of a new plant variety a right....

Article 2: Forms of protection: a title of protection or a patent - one of the two.

Article 5: Scope of protection: vegetative propagating materials ..., authorization not required for the utilization of the variety as an initial source of variation for the purpose of creating a new variety.

We have chosen in the Brazilian legislation not to extend the scope of protection to the marketed product. So the scope of protection falls on the propagating material only. Thus, according to the Brazilian legislation, the plant variety protection certificate is the sole form of protection right for plant varieties, that may inhibit the free utilization of plants or of their reproductive or vegetative propagating material (Article 2). Equally, according to Article 8, the protection covers the reproductive or vegetative propagating material of the entire plant. In Article 10, the Brazilian legislation establishes that the right to property of the plant variety shall not be deemed infringed by whoever:

(i) stores and plant seeds for private use on his premises or on the premises of third parties whereof he holds possession;

(ii) uses or sells as food or raw material the product obtained from the planting thereof, except for purposes of reproduction; and

(iii) utilizes the plant variety as a source of variation in genetic improvement or scientific research.

These principles fall entirely within UPOV 1978 Act and underpin the right of the farmers to use their own seed and the right of the breeder to use a protected variety to breed and commercialize a new variety without any restriction except, as we shall see, when the product obtained by the breeder is an essentially derived variety. The Brazilian legislation adopted the concept of an essentially derived variety from the UPOV 1991 Act, assuring the right of the breeder of an initial protected variety, where this variety is used by a second breeder to obtain a variety which is essentially derived from the initial protected variety. The Brazilian legislation concept of an essentially derived variety does not follow entirely that of the UPOV 1991 Act because it does not include Article 14(5)(c) of the Act as will be demonstrated: The definition of an essential derived variety in the Brazilian legislation is stated in Article 3:

- Article 3(ix): A plant variety is essentially derived from another plant variety provided that it is:

(a) predominantly derived from the initial plant variety or from another essentially derived variety, without losing the ability to exhibit the essential characteristics resulting from the genotype or from the combination of genotypes of the plant variety from which it derived, except regarding the differences resulting from the derivation.

(b) clearly distinct from the plant variety from which it derived, by a minimum margin of descriptors, in accordance with criteria established by the competent agency.

Thus, although Article 10 (iii) of the Brazilian legislation permits the utilization of a protected variety as source of variation in genetic improvement or in scientific research, if the protected plant variety is repeatedly used in this process of genetic improvement, and/or if the resultant product is an essentially derived variety from a protected plant variety, the commercial exploitation thereof shall be conditional on authorization from the holder of protection of the initial protected variety (Article 10, paragraph 2, ii).

So the Brazilian framework of the variety law combines principles of UPOV 1978 Act and 1991 Act based upon the concept that a law must not only be fair, but must be enforceable. In addition, it is understandable that any country, particularly if it is a developing country, when establishing its legislation, takes into consideration what is best for the country, in terms of technology development and the need for investment in this new technology from foreign countries as well as from the "domestic" industry. Three main factors were the basis for designing the law in accordance to the concepts cited above, and as opposed to the patenting of plants:

(1) Brazil is a very large country with millions of agricultural properties, the majority of which are very small. The enforcement feasibility of a plant variety protection right which would extend beyond the reproductive or vegetative propagating material was considered to be extremely difficult.

(2) Essentially derived plant varieties would be the fastest and easiest way to combine the best genes available from genetic engineering with the best genetics developed by national and regional plant breeding programs, such as the ones produced by the public and private institutions which have been established in Brazil for decades.

(3) A patent law which allows for patenting of biotechnology products introduced in conjunction with a plant variety protection law is a big challenge, but will favor the best business environment and competitive open trade for gene companies and plant breeding companies, offering the possibility for the same patented gene to be introduced in several protected varieties, as well as transformation of the same protected variety with several patented genes.

It was decided to adopt the principle of essentially derived varieties (EDV) from the 1991 Act of the UPOV Convention, because EDV obtained by back-crossing transformed plant elite events (plant elite events are plants modified successfully by genetic engineering in the sense that they express adequately and stably the gene of interest) to commercially adapted varieties in the process of breeding genetically engineered varieties, has important advantages:

1. it provides excellent biosafety confinement conditions to prevent the unintended release of engineered genes into the environment because the introgression of the genes can be done in the greenhouse;

2. it provides for a very fast and easy introduction of engineered genes of interest in a number of elite, commercially well adapted varieties;

3. lengthy genotype/environment field testing is not required since the resulting essentially derived varieties are, as the name indicates, very much like the elite commercially adapted varieties previously selected for the introgression of the engineered genes.

THE BRAZILIAN PATENT LAW

Brazil adopted a new Patent Law # 9279/96 in 1996, a year before the variety law described above, "stimulated" by the negotiations of the WTO/TRIPS Agreements. Before this patent law was enacted, the Brazilian patent legislation of 1973 did not, of course, consider the possibility of patenting living organisms. Biotechnology began in 1973, when Herbert Boyer, in California, expressed an insulin-coding gene from humans in ***E.coli,*** an intestinal bacteria. So the Brazilian Patent Law was obsolete the same year it was enacted. In addition to this circumstance, the Brazilian Patent Law of 1973 was very restrictive, prohibiting patenting of pharmaceuticals and other processes and products, in conflict with the WTO/TRIPS Agreement. It was not surprising then that the performance of Brazilian residents in terms of patenting abroad was very modest during the period preceding the new law as compared to other developing countries:

THE BRAZILIAN VAREITY AND PATENT LAWS – ARE THEY COMPATIBLE?

The experience of patent laws with variety laws based on the UPOV 1978 Act are somewhat limited worldwide because:

1 – many countries adopted the UPOV 1991 Act, which poses less conflict with patent laws,

2 – many agricultural countries have not revised their patent laws to include patenting of biotechnology products and processes,

3 – some developing countries, which are important grain producers, have been slow to adopt biotechnology.

The particular case described in this paper is restricted to experience gained in Brazil, particularly by EMBRAPA, where negotiations with large multi-national companies increased substantially after the three laws, which are the object of this paper, were enacted in the mid-nineties. So we will restrict our position to the recent experience of EMBRAPA in a soybean case study.

Over many decades, Brazil has developed considerable competence in the area of plant breeding, particularly for tropical conditions. As a consequence, the participation of EMBRAPA in the seed business scenario is particularly relevant:

SEED PRODUCTION IN BRAZIL: EMBRAPA VARIETIES VS
TOTAL VARIETIES. YEAR AVERAGE DURING 1995 TO 1997 – IN TONS *

CROP	TOTAL	EMBRAPA	%
	(A)	(B)	B/A
COTTON	27.487	2.983	10,9
RICE	96.480	137.091	69,8
BEANS	59.012	25.452	43,1
POTATO	136.770	2.040	1,5
FORAGE	247.776	170.441	68,8
CORN	325.581	72.965	22,4
SOYBEAN	1.716.886	865.770	50,4
WHEAT	449.979	225.275	50,1
TOTAL	3.159.971	1.502.017	47,5

* Source : EMBRAPA

The number of protected EMBRAPA varieties increased substantially, particularly after the new Variety Law was adopted. EMBRAPA operates many of its plant breeding programs, including, in particular, the program for soybean, in partnership with non-profit foundations located in several states. These foundations not only perform the regional field trials, but also coordinate seed certification production programs in a similar way to the American Crop Improvement Association in the US. The tendency in Brazil to date has been that EMBRAPA is approached by gene companies with patented biotechnological processes, such as the processes which make plants resistant to herbicides or insects. The process is incorporated into plants (plant elite events) by transformation of the plants with genetic "constructs" which contain the genes needed for the process to take place. The consequence is that the process is patented, (it must be patented in Brazil) and the genes in the construct cannot be used, as these are elements which determine the functioning of the process. Breeding companies use these plant elite events and breed varieties which are protected by the Variety Law in Brazil. In consequence, seed companies must pay royalties to the breeding company and a technology fee for the owner patented technology and then add a certain margin of profit on top of the seed cost. To build a scenario which brings together all these three stakeholders in the development of biotechnology, (genetically modified) products, breeding (variety development) programs and finally the seed industry, we have constructed the following simple matrix:

Soybean Case Study

This is an EMBRAPA matrix system to describe the soybeans business stakeholders and their expectations in relation to the marketing of genetically modified, glyphosate resistant soybean cultivars

INSTITUTIONS	SC&T	SEED	GRAIN
GENE COMPANY	TF	-	-
PLANT BREEDING COMPANY	-	CR	-
SEED COMPANY	-	-	AV+P

TF=TECHNOLOGY FEE
CR=VARIETY ROYALTY
AV=AGGREGATE VALUE PLUS PROFIT

Considering that each stakeholder is one specialized institution, some conditions are needed in order for the matrix to operate. If these are not met, business will not develop and all stakeholders will lose. In the specific case study:

1. the gene company is a multinational company which provided the patented technology as an plant elite event,

2. EMBRAPA is the breeding company generating the protected variety,

3. private seed companies apply to produce seed under contract to EMBRAPA which offers Foundation Seed according to rules described in public bids. Seed companies then market the seed to farmers.

The first step is that the gene company and the breeding company come to a contractual agreement establishing the rules and which abides by both Brazilian Laws: the Patent and Variety Laws. There are rules in this agreement, for instance, which assure the right of farmers to save their seed. It is impossible in Brazil to take a farmer to Court for saving seed. The gene company and the breeding company negotiate freely and independently with the seed producers for both the royalty and the technology fee. Common sense dictates that the limits for charging seed producers will be such that the product comes to the market and is able to compete with other technologies. This particular contract does not touch the breeder's exemption principle because it is not part of the process of breeding varieties which will be dealt elsewhere in this paper. We can distinguish three general conditions for the matrix to operate:

(1) gene companies and plant breeding companies must devote the best efforts to enforce both legislations in a harmonized and cooperative way, e.g. the enforcement of the patent law cannot ignore the limitations of the Plant Variety Protection Law, and vice versa;

(2) plant breeding companies will be in the best position to negotiate with gene companies if they own the exclusive rights for protected varieties, particularly if the final product is an essentially derived variety;

(3) all three stakeholders must fully exercise the "open architecture" (non-exclusive) principle and, as far as possible, concentrate on the roles for which they have most expertise, to avoid unnecessary duplication of efforts. The approach should be such that the new technology

develops at a rate that does not disturb the international competitiveness of the seed and grain business.

It is hard to predict if this system will operate in Brazil because, unfortunately, as previously mentioned, GMOs have been prohibited since 1998. However, EMBRAPA has identified some pitfalls in the matrix system to be avoided for Brazil:

1. several patented gene technologies were deposited many years ago and, therefore, only have a few years of effective patent rights remaining before they enter the public domain;

2. grain producers have the tendency to save and replant seed continuously, which, although not illegal in Brazil, reduces the rate of return for all three stakeholders;

3. essentially derived varieties, although being the fastest and easiest way to introduce the gene technology into adapted genotypes, are limited by the traits exhibited by the initial variety from which the essentially derived varieties originate;

4. plant breeding/genetics is of strategic importance for Brazil. The stakeholders must operate within the relevant laws in a way that ensures sustainable competence in this area, and results in the gradual build up of competence in the gene technology field in the country, taking into account the interests of the public and industry.

The last aspect concerns an elegant way of suggesting to gene companies that they should not try to play all the roles in the matrix. This is dealt with by laws on monopolistic behavior to prevent practices which would be detrimental for the adoption of a new technology. When one single company covers all the three roles, the control of the royalties and technology fee comes under a single control and the tendency is for the seed price to become high. We have the feeling that the technology could be adopted much faster worldwide if this tendency was not exercised by the main life science companies, which are offering the first products. We will present two exercises to demonstrate this possibility. Estimates made in 1997 predicted that the replacement of pesticides by GMOs would cut 1/3 of the insect control of selected crops. In addition, experts had predicted that the size of the genetically modified market would be around US$1.3 billion by 1998.

INSECTS CONTROL COSTS AND VALUE OF REPLACEMENT BY TRANSGENICS

CROP	INSECT CONTROL COSTS	TRANSGENIC
COTTON	1,870	1,161
CORN/MAIZE	620	158
RICE	1,190	422
FRUIT&VEGETABLES	2,465	891
OTHER	1,965	*
TOTAL (US$ million)	8,110	2,632

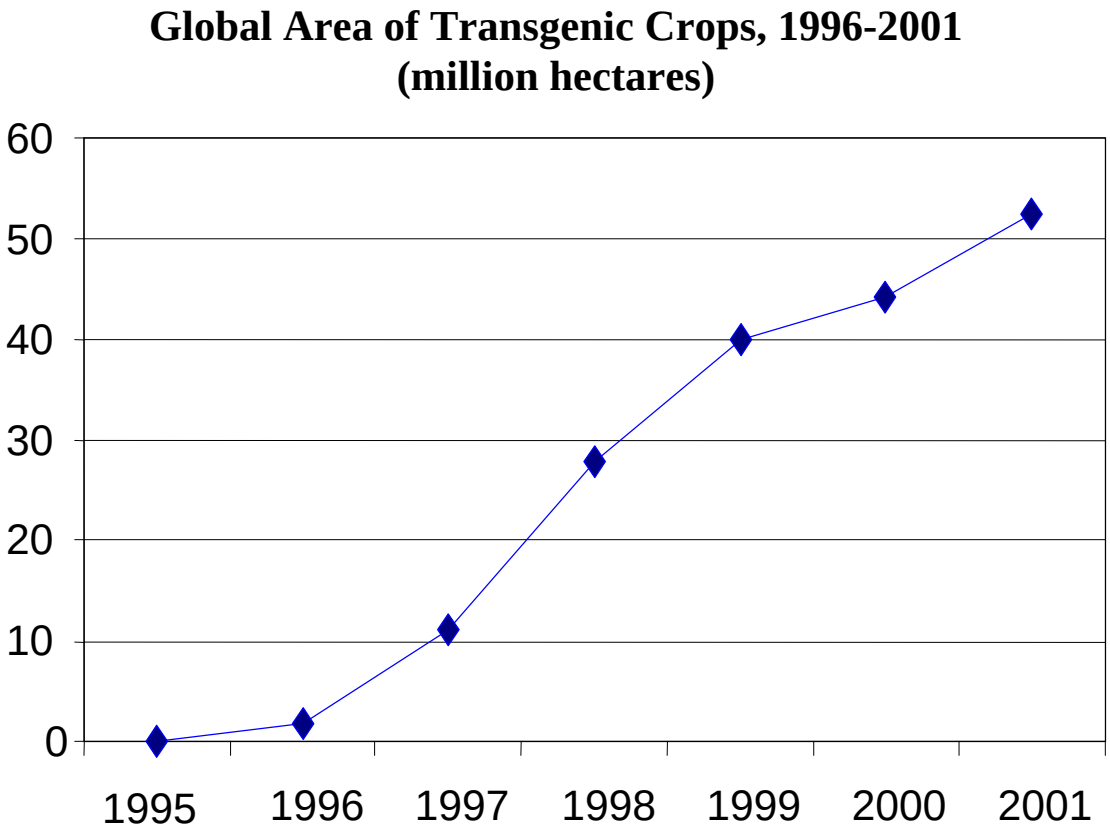
Modified and extended after James (1991) by Krattiger (1997).* Cannot be estimated because are related to many different species

If we use updated figures corresponding to the area cultivated with GMOs, as shown in the figure below, it is possible to estimate the value of the GMO market today.

ESTIMATED VALUE OF THE GENETICALLY MODIFIED CROP MARKET

YEAR	US$ MILLLION
1995	75
1996	235
1997	670
1998	1,350

Source: Clive James, 1998



A simple calculation reveals that the area cultivated with GMOs doubled from 1998 to 2001. Thus, the updated estimate of the size of the market will be 1.35 X 2 = US$2.7 billion, 50% of which can be estimated to be 'Bt' varieties (varieties containing the 'Bt' toxin which confers insect resistance). This market corresponds to seed incorporating the new technology. If we adopt this approach, the seed cost of Bt varieties, incorporating resistance to insects, will be around 50% of the predicted replacement cost of insecticides by this kind of GMO, which was estimated in 1997 to cut 1/3 of the insect control of selected crops (50% of US$3.0 billion). This explains why, worldwide, the adoption of cotton Bt varieties is moving so fast and that of corn Bt varieties is not. Corn farmers are not stimulated to pay more for the new technology seed, because insects harmful to corn cannot be predicted to occur every year.

A more general exercise starts with the area cultivated with GMOs today, which is, in fact, around 60 million Ha. Average grain production is estimated at 3 Tons/Ha and the average value is estimated at US$100/Ton, thus the value of the grain market will be approximately US$18 billion. Brazil imports US$ 2.5 billion worth of pesticides, which is applied to 40 million Ha for the control of pests and weeds. Thus, pesticides cost US$62.5/Ha for Brazilian agriculture. If we extrapolate this for the 60 million Ha of GMOs cultivated worldwide, the cost of pesticides without the new technology amounts to US$3.75 billion. If the adoption of the technology is stimulated by a reduction of pesticides of the order of 30% of this cost, this reduction corresponds to US$1.125 billion, which is close to the figures available. The question then is how much the farmer is paying for the seed which incorporates the new technology? The profit margin for farmers is narrow, between 10 and 20%. So, if we estimate the size of the grain GMO market to be US$18 billion, 10 to 20% corresponds to US$1.8 to 3.6 billion. A reduction of US$1.125 billion may correspond to a profit increment of 31.25 to 62.5%; however, this figure for cost reduction is below the predicted GMO seed market estimated to be US$2.7 billion. These are just exercises. Of course, if the technology is being adopted as shown above, it is because other benefits are incorporated with the pesticide reduction costs. No-tillage, for instance, associated with herbicide resistance, is extremely profitable to the soybean farmers and the financial return goes much beyond the herbicide substitution. The final question is: Is the adoption fast enough? What could be done in countries like Brazil to reverse the ban? Perhaps reduce seed costs.

IS THE BREEDERS EXEMPTION PRINCIPLE COMPATIBLE WITH THE PATENT SYSTEM IN PLANTS ?

There is no answer, or there will be no consensus in relation to this question, unless we exercise the best common sense by assuming that it is vital to have co-existence of the two principles for the adoption of agricultural biotechnology. If we have the Patent and Variety Laws in effect in Brazil, it is because we are convinced that this is the best IPR approach for plants. Legislators considered alternatives, but the option was to establish the two systems for the reasons already mentioned. Let us explore how these two basic concepts could be made compatible. We mentioned before how a breeding company, such as EMBRAPA, agreed with a gene company to introduce herbicide resistance into its soybean varieties. The question, now, is what will be the right of other breeders to use the protected variety of EMBRAPA which has the gene for herbicide resistance incorporated in its genome? According to the Variety Law in Brazil, the breeder is free to breed and commercialize a new variety unless it is an essentially derived variety. It is understood that breeders cannot use the gene, or probes of the patented gene, or the promoter in the construct, to speed up their breeding program. However, if a breeder has no interest in herbicide resistance, it would be unfair to deny the breeder's exemption in relation to that variety because even if the gene is patented, the whole genome of the soybean plant is not. According to my view, if the breeder uses that herbicide resistant variety to breed another soybean variety, without the herbicide resistance trait, and consequently for that reason, does not make use of the gene or parts of the gene as probes for their breeding program, the Variety Law in Brazil would assure the breeder this right. Again, a law must be fair and enforceable. It is not fair to prevent the breeder from using all other parts of the soybean genome for a breeding program because a single gene of this genome is patented. The gene itself, however, cannot be used. This principle is easily enforceable when the breeders presents their new variety to be protected.

We have seen, therefore, that Brazil has the opportunities, the competence and the legal and institutional infrastructure that are necessary for the development of agricultural biotechnology. This new context has led EMBRAPA, among other institutions, to be approached repeatedly by genetic engineering companies from all over the world, eager to introduce genes of agricultural interest into the best genetics (developed over the past 25 years) for the tropics.

* The author is an Agricultural Engineer graduated from the National Agronomy College in 1962, MSc. in Seed Technology from the Mississippi State University in 1970, Ph.D. in Plant Physiology from the University of California, Davis, in 1977, and Post-Doctorate in Plant Molecular Biology from the University of California, Los Angeles. He was the President of CTNBio from 1996 to 1999, and was elected President of the Brazilian Biotechnology Society in 1999.

DISCUSSIONS

Session III: Intellectual Property Strategy and Licensing Experience with the Co-Existence of Patents and Plant Variety Protection Systems

Moderators:

Mr. Bernard Le Buanec, Secretary General, International Seed Federation (ISF), Switzerland

Mr. François Desprez, President, French Society of Plant Breeders (SICASOV), France

Mr. Luiz Antonio Barreto de Castro, Brazilian Agricultural Research Corporation (EMBRAPA), Brazil

DISCUSSIONS

Mr. Bernard Le Buanec opened the discussions.

Mr. Bernard Le Buanec: A question for Mr. de Castro. You indicated that in the Brazilian Patent Law there is a breeder's exemption?

Mr. Luiz Antonio Barreto de Castro: No, I did not say that. The Patent Law follows very much what is in the TRIPS Agreement, a living organism can be patented, but we decided only to patent microorganisms. Animals and plants are not patented as we thought it would be very difficult to do that, but microorganisms can be patented if, of course, they satisfy the patenting requirements.

Mr. Huib Ghijsen, Global Manager Germplasm Protection, Bayer BioScience N.V., Astene: In the lecture of Mr. Desprez there is one remark that I would like to have clarified. He states that the farmer's privilege is the privilege of the UPOV system and not of the patent system, but in the EC Directive there is a provision for farmer's privilege as well.

Mr. François Desprez: I think that my presentation is somewhat biased because of the fact that I am deliberately in favor of the plant variety protection certificate rather than the patent. The question of seeds has been treated in different countries in Europe in the framework of the plant variety certificate and it is in that area that we have looked for solutions, which fortunately came our way through the Convention and the 1991 Act. But your comment is perfectly valid.

Ms. Nuria Urquía Fernández, Networking Officer (Plant Genetic Resources), Seed and Plant Genetic Resources Service, Plant Production and Protection Division, Agricultural Department, FAO, Rome: In the presentation of Mr. Desprez, it was mentioned that the position of the International Seed Federation is defined in a document which is called "ISF View on Intellectual Property." Could you very briefly describe what the ISF view is concerning protection of varieties outside the patent system?

Mr. François Desprez: ISF's position, for the time being, is the one which has been released under this consolidated paper "ISF View on Intellectual Property." You have to know that this document was put forward for adoption on the occasion of our last Congress and that it was not adopted with unanimity, but there were some concerns from our colleagues from the United States mostly, but it is a position paper and a position can change and evolve so we will be working on this document in the Intellectual Property Group of ISF and together with others in the Board, to reach consensus on this issue and, according to what I know from the discussion occurring in the United States, I think some slight improvement has already been made. But we think that it is a good standpoint for the time being, but maybe Mr. Le Buanec will comment as the Secretary General does not always agree with the President.

Mr. Bernard Le Buanec: In fact your question was what is the position of ISF and it is a quite long document, so it is not so easy to summarize it. But very briefly, the paper indicates that we, in ISF, consider that the development of intellectual property tools is depending on the socio-economic, technical and cultural level of various countries and that you have different systems in different countries, and that those systems are all legitimate. Regarding the topic of today, which is the co-existence or the compatibility between patents and plant breeders' rights, we in that paper, indicate that when a plant variety is protected by a plant breeders' right, but contains patented traits, that variety should be freely available for further plant breeding. If the progeny contains the patented trait, then, of course, if depends on the patent of the owner of the patented trait and, if it is essentially derived, then of course, it depends on the right of the owner of the initial variety. So that is, very briefly, the position of ISF. As Mr. Desprez says, it was almost unanimously adopted, except by one country, and that was obviously known because it was during the General Assembly. We are continuing discussion to find whether it is possible to find a consensus on that issue.

Prof. Joseph Straus: May I just add because of the question on farmers' privilege. Whether or not that variety would contain a patented gene or not, farmers would be allowed to use saved seeds, under the European situation, legally acquired. Not everybody is pleased by that outcome, but it should be clarified because this is a confusion around the world and it is covered more or less by Article 30 of the TRIPS Agreement.

SECTION IV

MEASURES NECESSARY FOR THE BALANCED CO-EXISTENCE OF PATENTS AND PLANT BREEDERS RIGHTS

ARE THERE TRIPS-COMPLIANT MEASURES FOR A BALANCED CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS? SOME LESSONS FROM THE UNITED STATES OF AMERICA

Professor Charles McManis

Washington University, St. Louis, Missouri, United States of America

This paper will attempt to answer the question posed in its title by drawing on the United States of America's (U.S.) experience to date under its dual—or more accurately, its tripartite-system of patent and ***sui generis*** plant variety protection for plant innovation which I will briefly summarize in Part I of this paper.[1] The paper as a whole is based in significant measure on the work of Professor Mark D. Janis, of the University of Iowa College of Law, who, together with Professor Jay P. Kesan, of the University of Illinois College of Law, is publishing a series of studies on optimizing intellectual property regimes for plant innovation. In Part II of this paper, I will expand on a point that Professor Janis makes in his recently published article, ***Sustainable Agriculture, Patent Rights, and Plant Innovation,***[2] with respect to how patent regimes might be modified, consistent with the TRIPS Agreement, to accommodate concerns traditionally addressed in ***sui generis*** plant variety protection regimes. [3]

I am also indebted to Professor Janis and Kesan for making available to me the manuscript of a soon-to-be published article that offers a critical reassessment of U.S. approaches to intellectual property protection for plant innovation in light of the recent decision of the United States Supreme Court in ***J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.***,[4] which confirmed that plants and seeds are eligible subject matter for utility patent protection, notwithstanding the availability of concurrent protection under the Plant Patent Act (PPA) of 1930[5] or the Plant Variety Protection Act (PVPA) of 1970.[6] I am likewise indebted to Professor Jerome Reichman, of the Duke University School of Law, for his pioneering studies both on developing pro-competitive strategies for implementing the TRIPS Agreement,[7] and on the problem of "legal hybrids" between the patent and copyright

---

1 In summary, under U.S. law, plants are eligible for utility patent protection, plant patent protection, and plant variety protection, as will be explained in Part I of this paper. Although plant patent protection is nominally treated as a mere "variety" of patent protection, in reality it comes closer to being an entirely different "species" of intellectual property protection—or at the very least a "hybrid" variety of protection, falling somewhere between utility patent and plant variety protection. As we will see, the patent-contributed "genes" in this hybrid variety of protection are recessive, and the resulting protection, or "fruit," of this hybrid bears far more similarity to ***sui generis*** plant variety protection than to utility patent protection.

2 Mark D. Janis, ***Sustainable Agriculture, Patent Rights, and Plant Innovation,*** 9 IND. L. REV. 91, 116 (2001).

3 Mark D. Janis & Jay P. Kesan, ***U.S. Plant Variety Protection: Sound and Fury . . .?,*** __ HOUSTON L. REV. 727 (2002). A manuscript of an earlier version of this article is on file with the author. Unless otherwise noted, page citations are to the published article.

4 534 U.S. 124 (2001).

5 35 U.S.C. §§ 161-164

6 7 U.S.C. §§ 2321-2583.

7 ***See, e.g.,*** J. H. Reichman, ***From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement,*** 29 N.Y.U. J. INT'L L. & POL. 11(1997).

paradigms.[8] I will rely on the work of all three of these colleagues in Part III of this paper, which will consider whether the measures identified in Part II are indeed necessary for a balanced co-existence between patents and plant breeders' rights.

I. The Tripartite U.S. System for the Protection of Plant Innovation

As a result of the United States of America Supreme Court's recent decision in the ***J.E.M Ag Supply*** case, three distinct forms of legal protection for plant innovation are now clearly available in the U.S. In order of their historical development, these forms of protection are as follows:

The Plant Patent Act (PPA) of 1930, as amended in 1954 and 1998, provides protection for anyone who invents or discovers and asexually reproduces any distinct and new variety of plant, other than a tuberpropagated plant or a plant found in an uncultivated state, that meets a variant of the utility-patent standard of non-obviousness.[9] A plant patent holder has a right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States.[10]

The Plant Variety Protection Act of 1970, as amended in 1994, provides protection to the breeder of any sexually reproduced or tuberpropagated plant variety (other than fungi or bacteria) who has so reproduced the variety, or the successor in interest of the breeder, if the variety is "new," "distinct," "uniform," and "stable," within the meaning of the PVPA.[11] Unlike the Plant Patent Act, the PVPA contains no non-obviousness requirement. Moreover, unlike plant patent protection, plant variety protection is not unconditionally available to nationals of other countries. Foreign nationals are entitled to protection only to the extent such protection is required by treaty or, in the absence of a treaty, only to the extent that protection "is afforded by said foreign state to nationals of the United States for the same genus and species"[12]—in other words on the basis of material reciprocity. A plant variety protection certificate confers on the owner the exclusive right, for a term that is now 20 years from date of issue (25 years for trees and vines) to exclude others from selling the variety, or offering it for sale, or reproducing it, or importing or exporting it, or using it in producing, as distinguished from developing, a hybrid or different variety, or marketing, tuber-propagating as a step in marketing, or to condition a variety for the purpose of propagating (except by farmers replanting their own holdings), or to stock a variety for any purpose that constitutes infringement.[13] The 1994 amendment eliminated a proviso that allowed farmers to sell saved seed.[14] Nevertheless the scope of a certificate holder's exclusive rights is quite narrow and subject to a number of limitations. Among these limitations are an exemption for any act done privately and for non-commercial purposes, another for the use and reproduction of a protected plant variety for plant breeding or other ***bona fide*** research, and a grant of authority to the Secretary of Agriculture to

---

8 ***See, e.g.,*** J. H. Reichman, ***Legal Hybrids Between the Patent and Copyright Paradigms,*** 94 COLUM. L. REV. 2432 (1994).

9 The non-obviousness requirement is incorporated in the PPA by virtue of the concluding sentence of 35 U.S.C. § 161, which states that '[t]he provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise noted. ***See*** Yoder Bros., Inc. v. California-Florida Plant Corp., 537 F.2d 1347 (5th Cir. 1976) ***cert. denied*** 429 U.S. 1094 (1977) (holding that a version of the non-obviousness requirement did apply to plant patents). Section 162 goes on to specify that a plant patent is not to be declared invalid for non-compliance with the disclosure provisions required for utility patents if the description is "as complete as is reasonably possible." 35 U.S.C. § 162.

10 35 U.S.C. § 163.

11 7 U.S.C. § 2402. As Janis and Kesan point out, the definition of "new" is actually a statutory bar provision, not a first-to-invent novelty provision; the definition of "distinct" comes closest to a patent law novelty requirement. Janis & Kesan, ***supra*** note 3, at 746.

12 7 U.S.C. § 2403.

13 7 U.S.C. §§ 2483, 2541.

14 Pub. L. 103-349, § 10 (1994).

order compulsory licensing of plant varieties when necessary to insure an adequate supply of fiber, food, or feed in the U.S at a price reasonably deemed fair.[15]

Finally, as a result of a series of cases, beginning with the decision of the Board of Patent Appeals and Interferences in ***Ex parte Hibbard***[16] in 1985, and culminating with the recent U.S. Supreme Court decision in ***J.E.M. Ag Supply***, plant innovators may obtain utility patent protection for plant genomes, coding for non-plant proteins, plant tissue, cells and cell cultures, seeds, or whole plants, provided that the substantive utility patent requirements of utility, novelty and non-obviousness and the procedural requirements of an enabling written disclosure (and in some cases an "enabling" deposit of plant material)[17] are met. Plant innovation that meets these more exacting requirements will grant the patent holder to the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, the right to exclude others from using, offering for sale or selling throughout the United States or importing into the United States products made by that process.[18]

Although the U.S. has chosen this tripartite system of protection for plant innovation, WTO members are, of course, under no obligation to adopt a similar approach. Indeed, Article 27.3(b) of the TRIPS Agreement seems to envision a variety of possible approaches to the protection of plant innovation. In the next part of this paper, I will identify various possible TRIPS-compliant measures for achieving a different balance than the one adopted in the U.S. and in both Parts II and III of this paper I will assess the desirability of these measures.

II. TRIPS-Compliant Measures for Balancing Patents and Plant Breeders' Rights

In his article, ***Sustainable Agriculture, Patent Rights, and Plant Innovation,*** Professor Janis is specifically concerned with exploring various patent law doctrines that might serve as possible vehicles for furthering sustainable agricultural policy initiatives. However, his points are equally pertinent with respect to measures that might be employed consistently with TRIPS to achieve a balanced co-existence of patents and plant breeders' rights.

In his article, Professor Janis first considers the doctrine of subject matter eligibility as applied to plant innovation. Under Article 27.3(b) of the TRIPS Agreement, of course, WTO members may exclude from patentability "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological processes and microbiological processes," so long as members provide for the protection of plant varieties "either by patents or by an effective ***sui generis*** system or by any combination thereof." On this point, however, Professor Janis concludes that "while proponents of sustainable agriculture may be tempted to support efforts to impose restrictions on patent eligibility for plant innovation, it is very doubtful that any such subject matter restrictions on patent protection would advance a policy agenda of sustainable agriculture concepts."[19] I draw a similar conclusion about the use of subject matter restrictions on patent eligibility for plant innovation to achieve a balanced co-existence between patents and plant breeders' rights.

Professor Janis then considers the doctrine of experimental use--which, as a defense to patent infringement, provides a means for shaping patent scope—and finds that doctrine to be more promising as a policy tool, though he counsels caution in its use.[20] Again, I come to the same general conclusions, though for slightly different reasons than Professor Janis offers.

---

15 ***See*** 7 U.S.C. §§ 2541(e) (private commercial uses); 2544 (research exemption); 2404 (compulsory licensing).

16 227 USPQ 443 (Bd. Pat. App. & Int., 1985).

17 ***See*** 1 CHISUM ON PATENTS § 1.05[3].

18 35 U.S.C. §§ 154, 271.

19 Janis, ***supra*** note 2, at 93.

20 ***Id.***

A. Restrictions on Patentable Subject Matter

Professor Janis notes that restrictive patent eligibility rules make especially clumsy policy instruments for two major reasons. First, U.S. (and European) experience to date "has demonstrated that eligibility restrictions stimulate counterproductive ancillary litigation over efforts by patent lawyers to draft around the restrictions."[21] Second, "whereas policymakers may assume that restricting utility patent eligibility forces innovation into the public domain, the fact is that in some areas of technology—especially plant breeding—restricting utility patent eligibility may simply divert innovation either to less socially desirable intellectual property regimes or to other protection schemes."[22]

To illustrate his first point, Professor Janis notes that while a superficial policy analysis might suggest that a rule excluding plants from the subject matter of patent protection will have major policy ramifications, in actuality such a rule is likely simply to stimulate "gamesmanship in the semantics of claim drafting."[23] Claims drawn expressly to a plant will obviously fall within the rule, but what about claims to 1) a seed or other plant parts, such as pollen, 2) cells or tissue cultures, 3) a method of producing a hybrid or transgenic seed, or 4) a hybrid seed or a transgenic cell or seed produced by a biotechnological process? As Professor Janis notes, these are not hypothetical questions, as he bases all of his specific examples on an actual, litigated U.S. case—namely the ***Pioneer Hi-Bred*** case.[24] He then demonstrates how a more focused restriction excluding claims to "plant varieties" would run into similar problems, using illustrations drawn from the European experience under the European Patent Convention.[25]

If the scenario Professor Janis describes has an oddly familiar ring to it, he points out that it should, as the U.S. patent system has occupied itself for at least three decades with the question whether and to what extent computer software inventions should qualify as patent-eligible subject matter.[26] That experience, he notes, should inform any debate over patent restrictions on plants, and the lesson to be learned is quite clear: eligibility restrictions have the potential to create considerable chaos, but lack demonstrated ability to force major policy reform.[27]

Professor Janis goes on to note that, even if an ideal subject matter restrictions on patent protection could be drafted, that does not mean that plant innovation would necessarily be freely available in the public domain. Rather, it will simply be redirected towards other forms of protection, such as ***sui generis*** plant variety protection, trade secret protection, or even technological protection measures, such as the notorious "Terminator technology." While redirecting plant innovation toward plant variety protection may be precisely the underlying policy for creating a restriction on patent eligibility, it should be noted that there is no guarantee that innovators will in fact choose this form of protection over the two other alternatives that Janis lists. Indeed, as illustrated in the data presented in the unpublished Janis and Kesan article, which I will discuss in Part III of this paper, the U.S. experience under its Plant Patent Act and Plant Variety Protection Act is not very reassuring in this regard.

B. Restrictions on Patent Scope—Experimental Use and Compulsory Licensing

While Janis concludes that the doctrine of patent eligibility is a demonstrably ineffective instrument for shaping the scope of patent protection, he does identify a number of other patent doctrines which might serve better to fine-tune the patent system to promote principles of sustainable

---

21 Janis, ***supra*** note 2, at 95.

22 ***Id.***

23 ***Id.*** at 99.

24 ***Id.***

25 ***Id.***at 100-101.

26 ***Id.*** at 101-102.

27 ***Id.*** at 102.

agriculture, and discusses at some length the possibilities offered by the experimental use exception. He notes that the notion of liability-free experimentation is intuitively appealing because it seems consonant with one of the core aspirations of the patent system.[28] While he does not explicitly address the issue of compulsory licensing, his points with respect to a TRIPS-compliant, plant-specific experimental use limitation seem equally applicable to a plant-specific compulsory licensing provision.

The judicially developed experimental use exception in the U.S. is exceedingly narrow and has had virtually no impact on actual litigated cases, and yet even so has been severely criticized in a recent Federal Circuit concurring opinion.[29] Nevertheless, Congress did consider adding a generic experimental use exception to U.S. patent law in 1990,[30] just as it had previously enacted a narrower provision stating that it is not an infringement to make, use or sell a patent invention (other than certain new animal drugs or veterinary biological products) solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.[31]

Janis suggests that one explanation for both the narrowness of the judicially developed experimental use rule and the failure of Congress to enact a more robust legislative version may be due to the difficulty in crafting a satisfactory ***generic*** experimental use rule.[32] However, he points out that proposals for a plant-specific experimental use rule could arise, because the courts or Congress might be tempted to borrow the very broad experimental use concepts from the Plant Variety Protection Act and use them to formulate a rule for patented plant innovation.[33] While he explains in some detail why U.S. courts, at least, should resist that temptation,[34] he does acknowledge the possibility of a legislatively created plant-specific experimental use provision, and considers whether such a provision would violate the TRIPS Agreement.

Because Article 27.3(b) allows members to exclude plants from patent eligibility altogether, so long as they enact an effective ***sui generis*** regime for plant variety protection, Professor Janis notes that some may argue that members necessarily have the lesser authority to place plant-specific limitations on the utility patent right.[35] He also notes that the same issue has been raised by a 1996 amendment of U.S. patent law, which effectively prevents patent owners of medical procedure patents from obtaining any relief against medical doctors or related health care activities for infringing medical activities.[36]

While I agree with Professor Janis that a WTO member could choose to amend its patent statute to provide a plant-specific experimental use exception patterned on experimental use provisions of the sort contained in the U.S. PVPA without violating the TRIPS Agreement, I base my conclusion, not on the "implied lesser authority" argument that Professor Janis suggests, but rather on the specific language of Article 27.3(b) itself, which states that WTO members are to provide for the protection of plant varieties "either by patents or by an effective ***sui generis*** system ***or by any combination thereof.***" This language, explicitly permitting "any combination" of patent and ***sui generis*** protection for plant varieties, seems to offer ample authority for the enactment of a broad, plant-

---

28 ***Id.*** at106.

29 ***Id.*** at 107-108, ***citing*** Embrex, Inc. v. Service Engineering Corp., 216 F.3d 1343, 1352-53 (Fed. Cir. 2000) (Judge Rader's concurring opinion).

30 Janis, ***supra*** note 2, at 109.

31 35 U.S.C. § 271(e). This 1984 amendment legislatively modified the extremely narrow version of the judicially developed experimental use rule articulated in Roche Prod., Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984, ***cert. denied,*** 469 U.S. 856 (1984).

32 Janis, ***supra*** note 2, at 108-109.

33 ***Id.*** at 110.

34 ***Id.*** at 110-115.

35 ***Id.*** at 116.

36 ***Id.***, citing 35 U.S.C. § 287(c), and Cynthia M. Ho, ***Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)***, 33 U.C. DAVIS L. REV. 601 (2000). Professor Ho herself expresses concern that this provision does indeed violate the TRIPS Agreement, and will in any event be used as a precedent for creating other limitations on patent liability.

specific experimental use exception (and for that matter, a "saved seed" or even a "brown-bag sale" exception) to utility patent protection, thus making it unnecessary to rely on the more controversial "lesser implied authority" argument.[37]

If such an exception is TRIPS-compliant, it would seem to follow that a compulsory licensing provision of the sort that is also a part of the U.S. PVPA would likewise be TRIPS-compliant, so long as the provision meets the exacting standards contained TRIPS Article 31.[38] Of these two possible measures for achieving a balance between private rights and public access to plant innovation, however, the experimental use provision would seem to be the more potent. The only remaining question is whether such an experimental use provision would indeed achieve a desirable and balanced co-existence between patents and plant breeders' rights. To answer that question, one must look at the underlying premises of plant variety protection and its practical effect on plant innovation.

III. Achieving a Balanced Co-existence Between Patents and Plant Breeders' Rights

In their soon-to-be-published paper, Professors Janis and Kesan analyze the emergence of the concept of breeders' rights in the United States and elsewhere, delineate the "essential traits" of the PVPA and its points of divergence from a patent-like model, and provide an empirical study of PVPA acquisition, licensing, and enforcement activity for corn and soybean crops. On the basis of this empirical study, Professors Janis and Kesan conclude that, contrary to the assertions of many, experience under the PVPA does not support the claim that it provides patent-like incentives for plant innovation, and that the PVPA in fact serves primarily as a marketing device and a vehicle by which to satisfy international obligations.[39]

In this part of my paper, I will summarize the basic points covered in the Janis and Kesan paper, add comments and empirical data of my own, and conclude with observations about what measures, if any, are indeed necessary for a balanced co-existence of patents and plant breeders' rights. My general conclusion is that the most pressing need is for greater conceptual clarity (of the kind provided by Professor Reichman) about what sort(s) of intellectual property protection should be given plant innovation and why. This matter takes on particular urgency in light of the obligation imposed by Article 27.3 of the TRIPS Agreement on all WTO members to provide for the protection of plant varieties either by patents or by an "effective ***sui generis*** system" or by any combination of the two—yet unaccompanied with any substantive standard for determining whether a given ***sui generis*** system is indeed "effective."

Conceptually, the choices of protection schemes for plant innovation seem to be three: 1) ***Patent-like protection***-characterized by relatively high substantive standards and rigorous examination procedures for the acquisition of robust exclusive rights designed to provide strong incentives to innovate and prevent others from exploiting the innovation without authorization; 2) ***copyright-like protection-***characterized by relatively low substantive standards and minimal procedural requirements for the acquisition of rights, resulting in broad but thin exclusive rights to prevent the "copying" (defined broadly to include the preparation of derivative works) of tangible expressions of the innovation; and 3) ***constructive trade secret and/or misappropriation protection***-characterized by relatively low substantive standards and minimal procedural requirements to qualify for protection designed to provide a limited term of artificial lead-time protection for and/or prevent competitive

[37] My suggested interpretive approach seems more consistent with the interpretive principles enunciated by the WTO Appellate Body in India—Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/AB/R (WTO App. Body, Dec. 19, 1997).

[38] The compulsory licensing provision contained in the U.S. PVPA, 7 U.S.C. § 2404, seems to meet the standards of TRIPS Article 31.

[39] ***See*** Janis & Kesan, ***supra*** note 3, at 730 and 777.

misappropriation of plant innovation, as two variant species of unfair competition protection for "incremental innovation bearing know-how on its face."[40]

The specific measures necessary for a balanced co-existence of patents and plant breeders' rights will depend in large measure on what sort of protection and limitations on protection are thought necessary and appropriate for plant breeders and plant innovation generally. My own conclusion, based on the U.S. experience to date, is that, while plausible arguments can be made for providing all three of the foregoing forms of protection for plant innovation, the ***sui generis*** forms of protection for plant innovation that are currently offered in the U.S. today are neither necessary nor particularly effective. Thus, before engrafting features of ***sui generis*** plant variety protection on the patent system, it is important to consider what sort of impact such features would have on plant innovation. To answer this question, it is necessary to examine how ***sui generis*** systems of plant variety protection, such as the U.S. PPA and PVPA, operate in practice.

A. An Empirical Analysis of Plant Variety and Plant Patent Protection in the U.S.

As a result of their empirical study of the acquisition, licensing, and enforcement of PVPA rights, Janis and Kesan conclude that these rights are burdensome to acquire, and yet the expected post-issuance licensing and enforcement activities common to other intellectual property regimes are virtually non-existent.[41] The more summary data that I have been able to gather about the PPA lead me to draw similar conclusions about the U.S. experience under that act. Following Janis and Kesan, I will first discuss the acquisition of rights under the PVPA and the PPA and then discuss licensing and enforcement activity.

1. Acquisition of Rights

In the initial draft of their article, Janis and Kesan first note that in general the vast majority of PVP applications survive the examination process, though about 12-15% are either abandoned or withdrawn by the applications in the course of prosecution.[42] They then turn their attention to data provided by the PVP Office for soybean and corn applications over the past 30 years, viewing these as two good, complementary exemplars of U.S. plant variety protection.

They note that, as of May 3, 2002, 1,343 applications for soybean certificates have been filed in the past 30 years, the status of the disposition of which are summarized in their Figures 1 and 2. Excluding pending applications, over 85% of the soybean applications successfully issued as PVP certificates. Approximately 13% of the applications were ineligible, abandoned or withdrawn, and 11% are pending.

A detailed breakdown of the current holders of soybean certificates is provided in Figure 2A. Although over 109 companies, universities and research institutes currently hold PVP certificates, over half of the certificates are owned by just three companies—Pioneer Hi-Bred International (206 or 27%), Novartis Seeds, Inc. (100 or 13%), and Asgrow Seed Company (100 or 13%). As for pending soybean applications, almost half are again from just three companies—this time, Asgrow Seed Company (36 or 23%), Delta and Pine Land Company (25 or 16%), and Pioneer Hi-Bred International (15 or 10%), as indicated in Figure 2B.

The status of the disposition of PVP corn certificates is summarized in Janis and Kesan's Figures 3 and 4. Excluding pending applications, over 80% of the applications successfully issued as certificates. Approximately 15% have been withdrawn or abandoned, while 17% are still pending. A detailed breakdown of the current issues of corn certificates is contained in Figure 4A. More than

---

[40] The phrase is Professor Reichman's. ***See, e.g.,*** Reichman, ***supra*** note 8, at 2444, where he notes that "incremental innovation bearing know-how on its face has become a dominant characteristic of key technological paradigms evolving at the end of the twentieth century."

[41] Janis & Kesan***, supra*** note, at 754.

[42] Janis & Kesan, unpublished manuscript***, supra*** note at 36-37.

60% of the corn certificates belong to two companies—Pioneer Hi-Bred International (269 or 44%) and Holden's Foundation Seeds (110 or 18%). As indicated in Figure 4B, pending applications for corn certificates account for 17% of the total applications ever filed and almost 50% of these have been filed by one company, DeKalb Genetics Corporation, while an additional 34% were filed by two other companies, Pioneer Hi-Bred International, and Holden's Foundation Seeds.

Janis and Kesan report that the total number of PVP applications has increased from around 100 applications per year in the 1970s to a high of about 440 applications in 1999. Since 1999, however, the total number of applications has decreased steadily. As shown in Figure 5, the number of soybean and corn applications tracks this overall trend of increasing applications from 1971 to the mid-1990s, with a decline in the number of applications since 1999.

Janis and Kesan also examined the durations between the filing dates and the issue dates to determine durations for issued certificates and durations between filing dates and the end of the data set examined for pending durations. The object was to determine whether the simplified application and review process has shortened the waiting period, as compared with utility patent applications, which generally require 2-3 years (730-1095 days) of administrative prosecution. Janis and Kesan also examined durations in relation to the number of pages in the certificates to determine if the number of pages played any role in determining the duration of the process.

The soybean PVP certificate data reveals that the average duration of issued certificates is just below 600 days or over 1½ years. However, the average duration for pending applications is almost 1200 days, double the average duration of issued certificates. The corn PVP certificate data reveals that the average duration for issued certificates is 625 days and that the average duration for pending certificates is 714 days. Janis and Kesan conclude that the data do not support including numbers of pages as a statistically significant covariate in a model for issuing and pending durations for PVP certificates. Rather, the issuing durations seem to reflect the overall workload of the PVP Office in terms of the number of new applications filed per year, as the issuing durations increased steadily from the early 1970s to the mid 1990s and then as the number of applications decreased in recent years, the issuing durations have decreased as well.

While the data I have collected for plant patents is more general, it nevertheless reveals that plant patents and applications have accounted for only a miniscule part of the overall patent activity in the United States since 1931. As indicated in the attached table of yearly U.S. patent activity at ten-year intervals between the years 1931 and 2001, plant patent applications accounted for only .04% of the total patent applications in 1931 and .27% in 2001, while issued plant patents accounted for .009% of patents issued in 1931 and .31% of patents issued in 2001. To give you some idea of how plant patent and PVP activity compare with each other and other patent activity in the U.S. in the years 2000 and 2001, you will note that the USPTO granted 548 plant patents in the year 2000 and 584 in 2001. By comparison, the PVP Office granted 241 PVP certificates in the year 2000 and 511 in 2001. [43] By contrast, the USPTO granted 157,495 utility patents in the year 2000 and 166,039 utility patents in 2001.

2. Post-Issuance Licensing and Litigation

Janis and Kesan conducted extensive interviews with numerous practicing attorneys and in-house counsel at DuPont/Pioneer to determine the magnitude of PVP licensing activities. They report a consensus among the persons they interviewed that there is no licensing activity for plant varieties protected solely by PVP certificates, apart from the bag-tag licensing that accompanies sales of the protected variety. DuPont/Pioneer were granted 381 certificates in the years 1997-2001 and yet report that they have neither licensed nor initiated infringement lawsuits based on PVP certificates. In contrast, during that same five-year period, Dupont/Pioneer has initiated 15 patent lawsuits and have been sued for patent infringement 11 times.

[43] ***See*** http:www.ams.usda.gov/science/pvpo/Current%20News/newsrealeases.htm.

Janis and Kesan state that there have been fewer than 10 reported PVP judicial decisions involving infringement of PVP rights in the last thirty years, and a continuously updated annotation on the construction and application of the PVPA confirms the paucity of reported PVP infringement litigation.[44] A similar annotation on the construction and application of the PPA likewise indicates that there has been little reported plant patent infringement litigation over the past 70 years.[45]

B. Achieving a Balance Between Patents and Plant Breeders' Rights

Not surprisingly, based on their own empirical study, as well as a number of other studies that they cite, Janis and Kesan conclude the PVPA regime as presently constituted "plays only a marginal role in stimulating plant breeding research in the United States," and that, indeed, its role in the U.S. appears to be "very modest."[46] They acknowledge that it may serve as a marketing tool, provide some non-propagation licensing rights akin to shrink-wrap licenses, enforceable against those who deal in "saved seeds," and perhaps provide a superior alternative to simple trade secret protection. However, because the PVPA is so easy to circumvent, and its research and saved seed exemptions are so broad, it simply does not provide patent-like ***ex ante*** innovation and investment incentives, nor has it generated substantial ***ex post*** licensing and enforcement activity. Given these results, Janis and Kesan question the appropriateness of future experimentation with ***sui generis*** IP regimes tailored to satisfy perceived needs in different technology areas.

In his many studies of legal hybrids between the patent and copyright paradigms, Professor Reichman makes much the same point. As Professor Reichman notes, "[t]inkering with the dominant paradigms or concocting hybrid variants lacking any solid theoretical or economic foundations merely aggravates the long-term disutilities resulting from a progressive inability of ancillary liability rules ... to mediate effectively between legal incentives to create and free competition."[47] In his view, "reformers should elaborate an improved set of ancillary liability rules ... [that will] emulate the functions of classical trade secret law while rationalizing and adapting its modalities to current conditions."[48]

In Reichman's view, this new intellectual property paradigm "should provide a limited, non-exclusionary form of relief for innovators who routinely apply unpatented, non-copyrightable know-how to publicly distributed industrial products."[49] While one embodiment of this kind of protection might provide a limited period of "artificial lead time" protection against any exact duplication of "incremental innovation bearing know-how on its face," another embodiment would provide an indefinite period of protection against any competitive "misappropriation" of such innovation. Indeed, the latter form of protection is currently available as a matter of state unfair competition law in the U.S.,[50] and Congress is currently considering creating similar federal statutory protection for the uncopyrightable contents of databases.[51]

Meanwhile, on the international front, in response to industrialized country demands that the developing world make greater efforts to combat intellectual property "piracy," the developing world has expressed its own widespread concerns over "gene piracy,"[52] leading to a recent upsurge

---

44 ***See*** Ann K. Wooster, ***Construction and Application of Plant Variety Protection Act (7 U.S.C.A. §§ 2321 et seq.,*** 167 ALR Fed. 343 (2001). By my count, there are only 4 reported cases alleging infringement under the PVPA.

45 ***See*** Ann K. Wooster, ***Construction and Application of Plant Patent Act (35 USCS §§ 161 et seq.,*** 135 ALR Fed. 273 (1996). By my count, there are only 8 reported cases alleging infringement under the PPA.

46 Janis & Kesan, ***supra*** note 3, at 777.

47 Reichman, ***supra*** note 8, at 2445.

48 ***Id.***

49 ***Id.*** at 2444-2445.

50 ***See, e.g.,*** National Basketball Association v. Motorola, Inc., 105 F.3d 841 (2d Cir. 1997).

51 ***See generally*** Charles R. McManis, ***Database Protection in the Digital Information Age,*** 7 ROGER WILLIAMS U. L. REV. 7 (2001).

52 ***See generally*** Charles R. McManis, ***The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology,*** 76 WASH. U. L. Q'TLY 255 (1998); Charles R.

in international attention to the interrelated issues of biodiversity and biotechnology protection, particularly as these issues relate to the protection of traditional knowledge, innovations and creativity. I need only refer you to work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore,[53] as well as the recent "Doha Declaration," issuing from the Fourth WTO Ministerial Conference, specifically instructing the TRIPS Council to examine the relationship between the TRIPS Agreement and the Convention on Biological Diversity, giving particular attention to the protection of traditional knowledge and folklore.[54]

Much of the traditional knowledge in question is botanical or agricultural, and any of it that is widely known could be characterized as "incremental innovation bearing know-how on its face." Among the specific proposals for the protection of traditional knowledge are various suggested ***sui generis*** schemes of protection, and proposals to modify international standards for patent protection, requiring disclosure of the origin of genetic resources used in the development of inventions for which patents are subsequently sought, as well as evidence of prior informed consent by both national governments and local innovators providing those genetic resources.

The proposals to modify patent standards so as to require disclosure of genetic resources and evidence of prior informed consent seem to reflect an effort to construct patent rules designed to encourage private contractual arrangements that will hopefully ensure that traditional innovators receive an equitable share of the benefits emanating from the world's patent systems. While requiring disclosure of the origin of genetic resources and evidence of prior informed consent as a condition for obtaining patent protection would appear not be TRIPS-compliant and would thus require an amendment to the language of Article 27, Dr. Nuno Pires de Carvalho, currently Head of the Genetic Resources, Biotechnology & Associated Traditional Knowledge Section of the WIPO, has persuasively argued that conditioning enforcement of a patent on disclosure of the origin of genetic resources and evidence of prior informed consent would be TRIPS-compliant.[55] Yet, any proposal of the sort discussed in Part II of this paper to modify existing patent systems by engrafting upon them a broad experimental use exception of the sort found in ***sui generis*** plant variety protection schemes would seem to undercut the effort to create patent rules requiring disclosure of the origin of genetic resources and evidence of prior informed consent as a means of rewarding the contributions of traditional plant innovators. Indeed, rather than watering down the scope of available patent protection for plant innovation, a better way to protect traditional plant innovators and encourage plant innovation would arguably be to reduce the administrative obstacles to acquiring plant variety protection and broaden the scope of that protection to make it more "copyright-like"—i.e. inclusive of a right to authorize derivative works.

The current debate over the protection of traditional knowledge is useful, because it focuses on the fundamental question underlying any effort to achieve a balanced co-existence of patents and plant breeders' rights—namely, whether the interests of plant breeders and plant innovation generally are better served by 1) broad patent protection for qualifying plant innovation, together with some low-cost form of copyright-like, portable trade secret, or competitive misappropriation protection for incremental plant innovation bearing know-how on its face; or by 2) narrow or no patent protection for plant innovation, and a limited and low-cost form of portable trade secret or competitive misappropriation protection only? Under Article 27.3(b) of the TRIPS Agreement, WTO members have considerable discretion in how they answer this question. To be effective, however, any system for achieving a balanced co-existence between patents and plant breeders' rights must ensure that the cost of protection is commensurate with its scope.

McManis, ***Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally,*** __CARDOZO J. INT'L & COMP. L.__ (forthcoming).

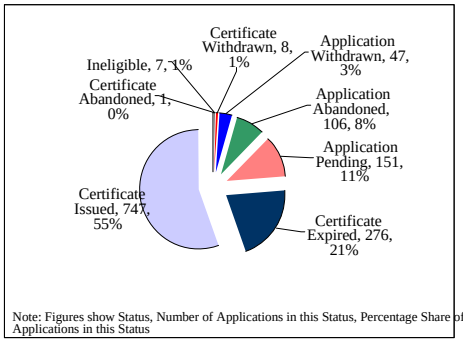
53 ***See, e.g.,*** WIPO, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore—An Overview, WIPO/GRTKF/IC/1/3, March 16, 2001.

54 Doha WTO Ministerial 2001: Ministerial Declaration, WT/MIN(01)DEC/1, Nov. 20, 2001, adopted Nov. 14, 2001, ¶¶ 17 and 19, http:www.wto.org (last visited Sept 29, 2002).

55 ***See*** Nuno Pires de Carvalho, ***Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and The Solution,*** 2 WASH. U. J. L. & POL'Y 371 (2000).

Slide 1

Figure 1: Disposition of Applications for PVP Certificates for Soybeans



Note: Figures show Status, Number of Applications in this Status, Percentage Share of the Applications in this Status

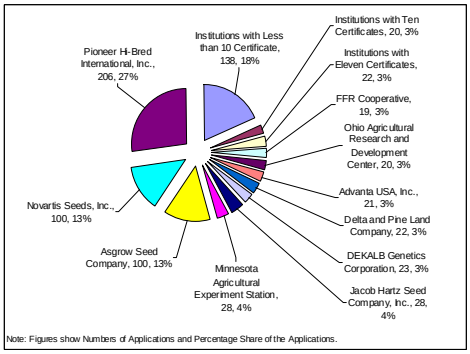
Slide 2

Figure 2: Disposition of Applications for PVP Certificates for Soybeans

Status	Counts
Certificate Abandoned	1
Ineligible	7
Certificate Withdrawn	8
Application Withdrawn	47
Application Abandoned	106
Application Pending	151
Certificate Expired	276
Certificate Issued	747
Total	1343

Slide 3

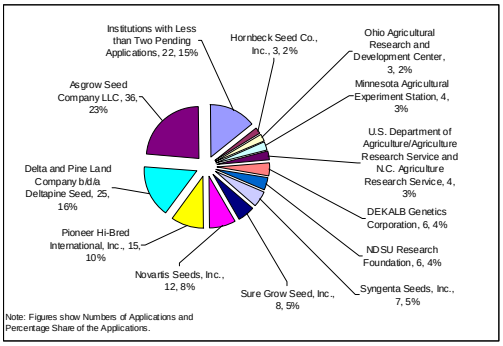
Figure 2A: Certificate Issuees with Effective PVP Certificates for Soybeans



Note: Figures show Numbers of Applications and Percentage Share of the Applications.

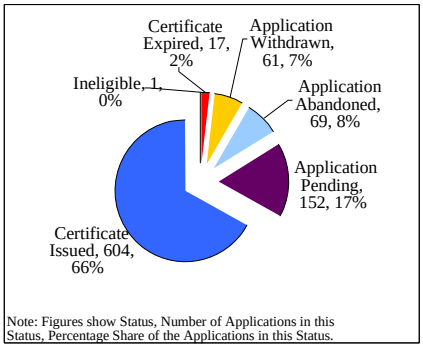
Slide 4

Figure 2B: Pending Applicants for PVP Certificates for Soybeans



Slide 5

Figure 3: Disposition of Applications for PVP Certificates for Corn



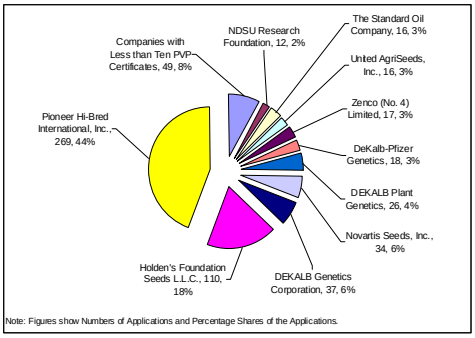
Slide 6

Figure 4: Disposition of Applications for PVP Certificates for Corn

Status	Counts
Ineligible	1
Certificate Expired	17
Application Withdrawn	61
Application Abandoned	69
Application Pending	152
Certificate Issued	604
Total	904

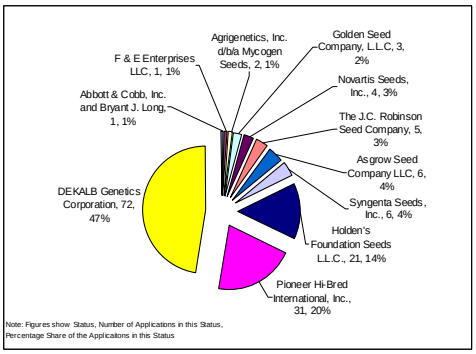
Slide 7

Figure 4A: Certificate Issuees with Effective PVP Certificates for Corn



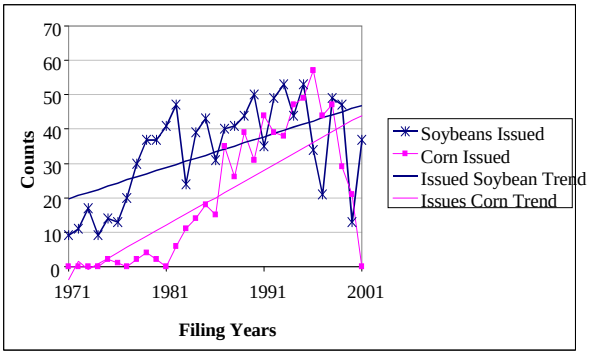
Slide 8

Figure 4B: Pending Applications for PVP Certificates for Corn



Slide 9

Figure 5: Trends in the Number of PVP Corn & Soybean Applications Issued



Slide 10

U.S. PATENT ACTIVITY

Applications			
Issue Year	Patent Invention	Design	Plant
1931	79,740	4,190	37
1941	52,339	7,203	67
1951	60,438	4,279	71
1961	83,100	4,714	107
1971	104,729	6,211	155
1981	106,413	7,375	178
1991	164,306	13,061	463
2001	326,508	18,280	944

Grants		
Patent Invention	Design	Plant
51,756	2,937	5
41,108	6,486	62
44,326	4,164	58
48,368	2,488	108
78,317	3,156	71
65,771	4,745	183
96,513	9,569	353
166,039	16,872	584

Measures Necessary for the Balanced Co-Existence of Patents and Plant Breeders' Rights – A Predominantly European View

Professor Joseph Straus*
Executive Director, Max Planck Institute, Munich, Germany

Introduction

The world is full of anomalies. The discussion of the issue of interface between patents and plant breeders' rights, at least as recently addressed by the Administrative and Legal Committee of UPOV, seemingly is no exception. Thus, it concerns in particular the situation where, for example, the development of genetic engineering can result in a plant variety which will be protected as plant variety, by a plant breeders' right, but will also contain an invention protected by patent (e.g. patented genetic element). What has been entirely left out is the situation where a plant variety can be protected by patents ***and*** plant breeders' rights. The focus, thus, seems to be on Europe and its actual or potential followers, where plant varieties are excluded from patent protection, but where at the same time generic inventions in plants can be patented. On the other hand, the United States (US) system, with its even three protection forms, i.e. utility patents, plant patents and plant variety certificates, as presented by Professor McManis, is not under investigation. Since the debate is around access to patented germplasm, which is indispensable for developing new varieties of plants satisfying the UPOV protection requirements and guaranteed under the UPOV system by "breeder's exemption" enshrined in UPOV Article 15 (1) (iii), but presumably not available under the patent system, the question may be raised, why the US situation is not addressed at all. Is there no need for access to germplasm containing patented elements (e.g. genes?) or is the access available despite patents on plant varieties, plants and plant elements?

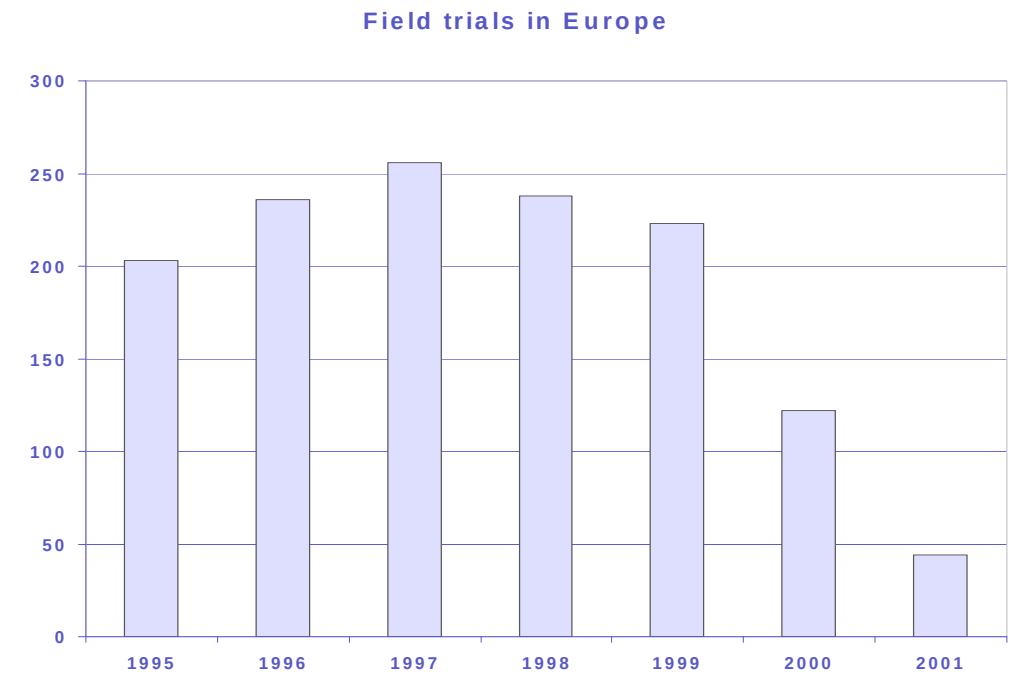
II. Why an anomaly in the context addressed?

Concentrating on Europe at this point in time provokes at least two comments: On the one hand, by adopting the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions in July 1998,[1] the European Union has introduced a regime for protecting innovations in plant area in which the scope of protection of a patent has experienced substantial changes in favour of plant breeders and farmers, and where even a statutory research exemption exists in most patent laws. On the other hand, Europe is actually free of any transgenic plants outside laboratories and some few green houses! Consequently, also free of any commercial use of transgenic germplasm, thus free of innovative and useful products or processes based on genetic engineering. In other words, the question of interface and balance between patents and plant breeders' rights as posed, for the time being in Europe is predominantly not a practical but rather a virtual one, i.e. a prospective issue. This is well revealed by the fact that in 2001 in Europe less than 50 field trials with transgenic crops were performed, down from the peak of more than 250 in 1997.

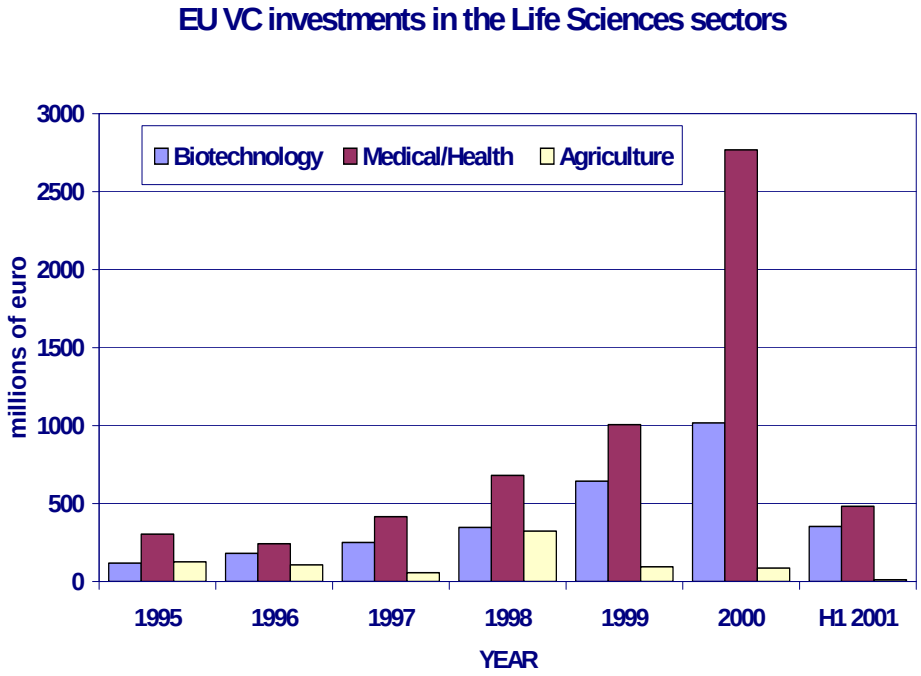
---

* Dr. jur., Dr. jur. h.c. (U. Ljubljana), Professor of Law, Universities of Munich and Ljubljana, Managing Director of the Max Planck Institute for Intellectual Property, Competition and Tax Law, Munich.

1 OJ EC No. L 213/13 of 30.7.98.



Source: E. Magnien, EU-Commission



During the same period of time venture capital investments in agricultural biotechnology in the European Union practically disappeared.

The actual European situation, which can be fully realised only when compared with that of the US, Canada, China or Argentina, where millions of acres have been planted with genetically modified crops,[2] has very little if at all to do with the principles or standards controlling patent protection or plant breeders' rights, but rather exclusively with the regulatory legal framework and the public acceptance of genetically modified crops. Of course, I am not supposed to address these aspects of exploitation of potentials of plant biotechnology, but only wish to draw attention on the impact, which this fundamental difference between Europe and its main competitors in global markets may have on the competitiveness of Europe in the future. One should not overlook that not only Bt-soy beans, Bt-corn or Bt-cotton are at stake, also not the flavour saver tomatoe, but also such technologies as for instance transgenic trees with altered lignification. A product, which may end up in enormous benefits for the environment but, which may equally affect producers of agri-chemicals and the paper prices world-wide.[3]

III. Some Additional Remarks on the US Situation and the TRIPS Rules

Prior to addressing the rules which in Europe control the interface of interest, some remarks on the information contained in Professor McManis' presentation seem advisable:

First, since Professor McManis left the US for Europe, the Court of Appeals for the Federal Circuit (CAFC) in ***John M.J. Madey v. Duke University*** case[4] held, ***inter alia***, in respect to the "experimental use defense" under the US patent law, that

"..., regardless of whether a particular institution or entity is engaged in an endeavour for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and it is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative."

Consequently, if the US Supreme Court will not overturn the case law of the Federal Circuit, the experimental use defense will hardly ever provide the possibility to, without the consent of the patentee, use patented plant germplasm for further breeding purposes. Since access to plant germplasm, be it patented or protected by PBRs, is of key importance for further innovation in plants, be it based on rDNA technology or on conventional plant breeding, or a combination of both, and since the US is the place with the most advanced use of transgenic patented crops, one should not patented process, but also from the acts of: using, offering for sale, selling, or importing for these purposes, at least the product obtained directly by that process, ***plants*** have to be protected as direct products of patented non-biological and micro-biological processes in WTO Members. In other words, plants, i.e. plant germplasm, produced by various patented recombinant DNA methods (non-biological!), can only be used with the consent of the respective process patent owner, unless rules of national or regional legislation complying with Articles 30 and 31 TRIPS provide otherwise.

In this latter context it should be recalled that under Article 30 TRIPS

> "...limited exceptions to the exclusive rights conferred by a patent [are allowed], provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interests of third parties."

---

2 Cf. Stikeman, New Markets for Biotech – Developing Countries turn to genetically modified crops, Technology Review July/August 2001, 29 ss. (at 30); Huang et al., Plant Biotechnology in China, 295 Science 675 (2002); USDA 2002 crop acreage report, 20 nature biotechnology 422 (May 2002).

3 Cf. on this Chiang, From Rags to Riches, Transgenic trees may improve the efficiency of pulp production without detrimental environmental and ecological effects, according to new results from field trials, 20 Nature Biotechnology 557 s. (June 2002), and Pilate et al., Field and pulping performances of transgenic trees with altered lignification, 20 Nature Biotechnoogy 607 ss. (June 2002).

4 Decision of October 3, 2002 (Case 01-1567) explicitly confirming its previous case law, i.e. in Embrex, 55 USPQ 2d at 1163, and in Roche, 221 USPQ at 940, case.

Moreover, Article 31 TRIPS controls the conditions under which WTO Members may allow the use of a patent without the authorization of the right holder. It should suffice to note in the context of interest that such use may also be authorized in order to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), if the following additional conditions are met:

> "(i) The invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
> (ii) The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and
> (iii) The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent."

IV. The Attempted Balance Under EU-Regime

As pointed out at the outset, under the European regime, on the one hand, plant varieties are strictly excluded from patent protection (Article 53 (b) EPC, Article 4(1)(a) EU-Directive) but, on the other hand, inventions concerning plants are patentable if the technical feasibility of the invention is not confined to a particular plant variety (Article 4(2) EU-Directive).[5] On the basis of Recitals 29 to 30 of the Directive, it has to be observed that plant varieties, i.e. plant groupings within a single botanical taxon of the lowest known rank,[6] are defined by their whole genome and are protected by plant variety rights. However, plant groupings of a higher taxonomic level than the variety, defined by a single gene and not by the whole genome, may be protected by patent if the relevant invention incorporates only one gene and concerns a grouping wider than a single plant variety.

The scope of protection conferred by Articles 8 and 9 of the Directive is, in principle, far reaching and covers, in case of product patents on biological material possessing specific characteristics, any biological material derived from the patented one through propagation or multiplication in an identical or divergent ***form and possessing those same characteristics*** (Article 8 (1)). Protection of a product containing or consisting of genetic information extends to all material in which the ***genetic information*** is ***contained and performs its function*** (Article 9).

In case of product patents, the protection extends to biological material directly obtained through that process, as well as to any other biological material derived from the directly obtained one through propagation or multiplication in an identical or divergent form and possessing those same characteristics (Article 8 (2)). It follows from Articles 8 and in particular 9 that an infringement of such patents can only be at hand if the material at issue still ***contains*** the patented genetic information and that information still ***performs its function*** (Article 9) or still possesses the ***same characteristics***. This seems an important clarification, an in fact limitation, specifically if considered in the context of experimental use exemption.

In view of the key role, which access to plant germplasm, be it patented or protected by plant breeders rights, plays for further plant innovation, the so-called ***experimental use exemption***, set forth in many national patent laws, is instrumental.

---

[5] Cf. also the interpretation of Article 53 (b) EPC by the Enlarged Board of Appeal of the EPO, 2000 OJ EPO 111 – Novartis II, which goes along the same lines. For more details cf. the Report from the Commission to the European Parliament and the Council: "Development and implications of patent law in the field of biotechnology and genetic engineering" of October 7, 2002, Doc. COM (2002) 545 final, pp. 19 ss.

[6] Article 2(3) of the Directive explicitly refers to the plant variety definition of Article 5(2) Council Directive (EC) 2100/94 of 1994 on Community plant variety rights, which itself, is entirely in line with the UPOV plant variety definition.

Whereas the US Patent Act (35 U.S.C.) does not dispose of a general statutory research exemption, patent acts of EU Member States disposing of such provisions have their common roots in Article 27 (b) of the Community Patent Convention (CPC), as adopted by the Agreement Relating to Community Patent of 1989.[7] Under Article 27 (b) CPC, the right conferred by a Community Patent does not extend to

> "Acts done for experimental purposes relating to subject matter of the patented invention."

Following a Resolution to the CPC, in which the EC Member States resolved to harmonize their laws with the CPC and notwithstanding the fact that the CPC did not enter into force, all Members of the EU, except Austria, have introduced into their patent acts provisions on research exemptions.[8]

The first court decision to clearly stick to a new European standard of interpretation of the research exemption rule under the influence of Article 27 (b) CPC of far reaching influence was the UK Court of Appeal 1989 ***Monsanto Co. v. Stauffer et al.*** case,[9] in which the court held, ***inter alia***:

> "Trials carried out in order to discover something unknown or to test a hypothesis or even in order to find out whether something which is known to work in specific conditions, e.g. of soil or weather, will work in different conditions can fairly,...., be regarded experiments."[10]

Most importantly, according to the Court, this quality of trial as an "experiment" ***is not affected***, even if they have a commercial end.[11]

The German Federal Supreme Court (BGH) in its C***linical Trials I***[12] ***and Clinical Trials II***[13] decisions, eventually, confirmed by the German Federal Constitutional Court,[14] followed suit. The following comments on those two Supreme Court decisions should suffice:

In C***linical Trials I***, the Court defined the test (experiment) as

> "... any (planned) act for the acquisition of knowledge, independent of the purpose for which the acquired knowledge is intended to serve eventually."[15]

The Court continued:

> "This implies a finality between any act toward a specific test purpose and the subject matter of the invention. The subject matter of the invention must be the object of the test activity for the purpose of gaining knowledge!"[16]

The Court, moreover, emphasized that the research exemption includes, for instance, any act of use for test purposes, which are performed on the subject matter of the invention in order to determine the effects of a substance or new previously unknown applications. It clearly held that it cannot be of any importance whether the tests serve only to verify the information provided in the patent

---

7 Originally Article 31(b) of the CPC of 1975.

8 See for details Straus, On the Admissibility of Biological Equivalence Tests, During the Patent Term for Obtaining a Regulatory Approval for Patented Drugs by Third Parties, ***A.I.P.P.I. Journal of the Japanese Group*** 1998, 211 ss. (214 ss.).

9 [1985] R.P.C. 515.

10 [1985] R.P.C. 542.

11 [1985] R.P.C. 538.

12 1996 GRUR 109 = English translation (1997) IIC 103.

13 1997 Mitteilungen der Deutschen Patentanwälte 253 = English translation [1998] R.P.C. 423.

14 2001 GRUR, 43.

15 (1997) IIC 106.

16 Ibidem.

document, or to obtain further research results and whether they are used to pursue additional objectives such as commercial interests.[17]

It follows from the above that the subject matter of a patented invention, e.g. plant germplasm, ***can be used for further breeding purposes without authorization of the patentee***. If the written disclosure in the patent application satisfied the sufficient disclosure requirement only by complementing it by a deposit of biological material (e.g. a construct containing the patented genetic element) in a publicly accessible depository institution, samples of the deposited germplasm, after certain deadlines, will also become accessible to the public and can then subsequently be used for further breeding activities. Whether the commercial use of the final outcome of such activities, e.g. a new plant variety will eventually infringe the respective patent, will ultimately depend on, for instance, whether it will still contain the patented gene and whether the gene – the genetic information – will still perform its function. In case the breeder would succeed in removing that patented genetic information – e.g. resistance, from the propagating material of the new variety, the variety would be outside the scope of the patent. Thus, its commercial use would not constitute an infringement. If, however, the variety would make use of that information, a clear case of dependency would be at issue.[18] In such a case Article 12 EU Directive containing the compulsory cross-licensing rule, very much along the lines of Article 31 TRIPS could help, if a contractual license could not be obtained. A problem may be seen in this latter context: which yardstick should/could be used as proof that a specific plant variety constitutes "significant technical progress" compared with the invention claimed in dominant patent? Is the cumulation of these two requirements justified and adequate?

V. Conclusions

Sustainable innovation in the area of plants is of crucial importance for the well-being of the globe. A few years ago Phillip Abelson the then editor of Science Magazine observed, that

> "Ultimately the world will obtain most of its food, fuel, fibre, chemical feed stock and some of its pharmaceuticals from genetically altered vegetation and trees."[19]

In order to achieve these partly still very remote goals, all involved in plant innovation activities, be it "modern" plant biotechnologists or conventional plant breeders, must be offered a legal framework, which will ensure optimal incentives and working conditions. For all of them, one of crucial conditions for their R & D activities is access to plant germplasm, i.e. entire plant genomes. At present such access seems to be secured under the described European regime, but not in the US system. It is therefore suggested that introduction of appropriate research exemption rules in the respective patent laws is seriously considered. As pointed out at the outset, it should be understood that this is not only an issue which requires a solution in systems where there is an overlap of protection under patents and plant breeders' rights, but exists to the very same extent where plant varieties ***per se*** are eligible for patent protection!

Moreover, it should be admitted that the European regime as described has not yet been tested in practice. In view of the hope that the interface issue will not remain a virtual one forever, it would seem advisable to clarify these statutory research exemption rules so as to leave no doubt that R & D breeding activities with protected germplasm for developing new plants and plant varieties ***per se***,

---

17 Cf. (1997) IIC 107.

18 Lange, Patentierungsverbot für Pflanzenzüchtungen, 1996 GRUR Int. 586 ss. (at 589) made the point: „Wenn es also dem Züchter gelingt, die gentechnisch verankerte und patentierte Resistenzeigenschaft wieder ‚herauszumendeln', so muss es ihm erlaubt sein, dieses Sortenmaterial frei in seiner weiteren Züchtungsarbeit zu verwenden (beispielsweise durch Einkreuzung, etc.). Gelingt ihm dies nicht, ist sie weiterhin patentrechtlich abhängig..."

19 Editorial, 279 Science 219 (1998).

even if for commercial purposes, do neither constitute an infringement of the patent issued on such germplasm, nor an infringement of a plant variety certificate issued on the respective variety.

I should not end without emphasising that no player in the field should claim to be more equal than equal. No free riding at the expense of the other should be tolerated. It would cause imbalance of the system understood as a whole and would, eventually, hamper the badly needed progress in the field.

PANEL DISCUSSION

Introduction

Mr. Peter Lange
KWS Saat AG, Germany

It is an honor and pleasure for me to chair this final Panel Discussion being surrounded by all these excellent speakers of the WIPO-UPOV-Symposium of today.

It will be a great challenge for me to open a hopefully fruitful discussion between the speakers and the audience and I will try my very best to organize this by structuring the debate and focussing the discussion on some main issues which already stood out during today's meeting.

But first, please allow me the following remarks:

The title of this Symposium is devoted to the "Co-existence of Patents and Plant Breeders' Rights in the Promotion of Biotech Developments." The notion "Co-existence" to my mind is too negative, and thus at least for the following reasons:

- It has a smack of hostility between two totally incompatible systems of protection (comparable with the political endeavors during the Cold War to establish co-existence between two incompatible political systems);

- We should be totally aware of the fact that there is nothing new within the intellectual property regime in having different choices of protection titles which may complement each other, overlap or even compete with each other!

- It has to be clarified that under plant breeders' rights, specific plant varieties are protected, whereas an invention is the subject matter of a biotech patent which normally contains generic claims since such an invention may be realized in an undefined number of plant varieties;

- Last, but not least, and here I would like to underline the statement of Prof. Straus: In view of the fact that in the plant area actually - at least in Europe - we have only an infinitely small number of field trials with patented plant material and virtual no cultivation of such plants: Do we carry on a practical or a theoretical discussion?

Of course, we have to identify the main differences (strengths and weaknesses) between the systems, especially so far as they protect the same subject matter or if they interfere unduly with each other and have to work for necessary improvements in both. The ongoing review of the TRIPS Agreement under the auspices of World Trade Organization (WTO) requests not only minimum standards for the protection of plant varieties and biotech inventions or just a co-existence of different systems, but demands better harmonization of the systems. To achieve this goal we have to look at the needs of world-wide markets, incentives for the development of least developed or developing countries, and have to consider public interest!

It is my understanding that the "public" should comprise a wide range of groups of persons, e.g. direct customers, the farmers, the processing industry, consumers and, of course, the research community. They all should benefit from new knowledge, developments and the promising innovations in biotechnology and plant breeding within research institutions, the breeding and biotech industry. This will only take place if efficient and adequate protection systems are available, thus being the main condition for effective technology transfer.

In this sense, I would like to divide the discussions into the following three main domains which have already been anticipated by the organizers of this Symposium:

1. Accessibility of protected inventions and plant varieties for further innovation:

In this respect, the following aspects should be considered:

- Scope of the research exemption / experimental use defense within the patent regimes (harmonization needed?);
- Scope of the Breeders' Exemption within the plant breeders rights system;
- Consequences / validity of contractual restrictions e.g. by bag tags.

2. What are the experiences with IP strategies and licensing in the area of patents for biotech inventions and PBR systems?

- Are the protection criteria, the scope of protection and the enforcement and prosecution measures well suited for the different objects of protection and for the needs mentioned?
- Are deficiencies in this respect due to the system ***per se*** or due to its implementation or administration?
- Management of the Essentially Derived Varieties concept?

3. Which measures are necessary for a "balanced co-existence" (a better harmonisation) of the systems?

- A well defined and broader research exemption or
- A compulsory license system,
- A cross license system,
- Or just confidence in the negotiation powers of the markets?

PANEL DISCUSSION

Chair: Mr. Peter Lange
KWS Saat AG, Germany

All speakers

Mr. Rolf Jördens introduces Mr. Peter Lange and opens the discussion.

Mr. Rolf Jördens: The idea of this discussion is not to repeat in a short form the presentations which the speakers have given in the course of the day, it is rather the idea to invite the audience, all of you, to raise questions and to join in the discussion with the speakers.

Mr. Peter Lange: It is, of course, not very easy to open such a broad discussion and I will try my very best to structure this discussion so that we are not lost in different issues. It is an honor for me and a pleasure to do this, being surrounded by all the excellent speakers of today. But first of all, please allow me some small remarks. The title of this Symposium is devoted to the co-existence of patents and plant breeders' rights in the promotion of biotechnological developments. The notion "co-existence," to my mind, is too negative, at least for the following reasons: it has a smack of hostility between totally incompatible systems of protection. That is for me comparable with the political endeavors during the cold war to establish co-existence between two incompatible political systems. And we should be totally aware of the fact that there is nothing new within the intellectual property regime in having different choices of protection and different titles which may complement, overlap or even compete with each other. Why not! It has to be clarified that by plant breeders' rights specific plant varieties are protected and that has been already mentioned, whereas an invention is a subject matter of a biotech patent which normally contains generic claims since such an invention may be realized in an undefined number of plant varieties. Last, but not least, and here I would also like to underline the statement of Prof. Straus: in view of the fact that in the plant area actually, at least in Europe, we have only infinitely few field trials with patented plant material, and virtually no cultivation of such plants, are we carrying on a practical or theoretical discussion? Of course, we have to identify the main differences-strengths or weaknesses-between the systems, especially in so far as they protect the same subject matter. Or if they interfere unduly with each other and we have to work for necessary improvements in both. The ongoing review of the TRIPS Agreement under the auspices of WTO requests not only minimum standards for the protection of plant varieties and biotech inventions or just a co-existence of different systems, but demands better harmonization of the systems. To achieve this goal, we have to look at the needs of worldwide market incentives for the development of least developed or underdeveloped countries, and have to consider, the interests of the public. It is my understanding that the public should comprise a wide range of groups of persons, such as our direct customers, the farmers, the processing industry, consumers and of course the research community. They all should benefit from new knowledge, developments and the really promising innovations in biotechnology and plant breeding within research institutions, the breeding and biotech industry. This will only happen if efficient and adequate, and I would like to add fair, protection systems are available. Thus being the main condition for effective technology transfer. In this sense, I would like to divide the discussion into the following three main domains, which have already been anticipated by the organizers of this Symposium. The first issue would be the question of "Accessibility," and perhaps there we need not twenty minutes, but ten minutes for this issue: "Accessibility of protected inventions and plant varieties for further innovation." I will then come back to this issue, perhaps highlighting some arguments/statements which have already come up here within the speeches and the discussions in the morning. The second issue would then be the issue of "what are the experiences with IP strategies and licensing in the area of patents for biotech inventions and plant breeders' rights systems". The third issue then would be "which measures are necessary for a balanced co-existence or, I would prefer to say, better harmonization of the systems". So I invite now the audience to pose

questions to the speakers here at the table, first on the issue of "Accessibility" and, in order to move on or push a little bit the discussion, I think we have to deal with the scope of the research exemption, with the experimental use defense. Is there a harmonization needed especially in the patent regime? Is the scope of breeders' exemption within the plant breeders' rights system sufficient or should it even be diminished? And thirdly, are there consequences with regard to restrictions from contractual use, for instance in the form of bag-tags, or is there a question of validity of such bag-tags involved? Please, now pose your questions to the speakers.

Mr. Huib Ghijsen, Global Manager Germplasm Protection, Bayer BioScience N.V., Astene: I have a question about the American research exemption in the utility patent, because I do not understand how it has developed. I have always understood that a patent is an exchange between a private person or a company and the public: the inventor discloses his invention for teaching and learning of the public and in exchange for that he gets the protection of that invention. And when you see the patent requirements that you have the enablement and the description requirement for teaching and a deposit requirement in the case of biological material, then I cannot understand that experimenting with the invention is not allowed. Jurisprudence in the United States indicates that experimenting with the aim that if there is an improvement of an invention, it may be used in a commercial way. But when it has any dependence with the original patent then you have a case of dependency and there is nothing wrong with that. So, just repeating the question, how has this evolved that this is so narrow an interpretation of something that should be fully allowable in science?

Prof. Charles McManis: I can imagine that my friend Jerry Reichman at Duke University is already preparing a petition for certioari in the case involving Duke University. And while I do not know what he would argue in that case, I think that my argument, if I were to make it, would be based on the fact that patent protection in the United States is to be made available to anyone who invents or discovers any new and useful process, machine, manufacture, composition of matter or any new and useful improvement. How is one to make an improvement of a patented invention without infringing the basic patent if there is no room to consider improvements? I would suggest that our own Court of Appeals, which likes bright-line rules, whether they are just or not, may be in effect led by its overly narrow view of what is permissible in the way of experimental use and is effectively negating the ability to obtain patents on improvements. Now that may be the right thing for them to do, it may be the right thing for the Supreme Court to do because it may be that an experimental use limitation on patent protection is the province of Congress rather than the Courts. And I believe that to be true. But in any event, it does not seem to me that a patent system which recognizes the patentability of improvements could turn around and say "but of course you can never improve anything that is already patented because then you would be infringing the underlying patent." That seems to me to be contrary to the policy embodied in Section 101 of the US Patent Statute.

Mr. Tim Roberts: If I could just say that the question of the research exemption is a particular problem when you are dealing with biological materials. Because, until I got involved in the biological area, I had never encountered any concern about the research exemption. If you are dealing with a mechanical invention you do not have to start with what your competitor has put on the market, you make your own. The patented feature could be left out or redesigned. But in the case of an invention which is as specific as a plant variety, you cannot start by going to a gene bank and assembling individual genes, you have to start with what is on the market and experimenting with that will involve reproducing it, which will be textually infringement. So there is a particular problem here in the biological area.

Mrs. Victoria Henson-Apollonio: I think an additional comment would be something that Prof. Straus touched on and that is that in the biological community itself, researchers are sometimes assuming that there is a research exemption and that patents are free to use. Also, just to agree with Tim Roberts suggestion that so much of the case law that we have in this area is in fields other than biological fields. Maybe, we are not up, yet, to the level of sophistication to understand the need for the research exemption as far as the judiciary is concerned.

Mr. Peter Lange: Any other questions? Perhaps on harmonization. Is harmonization needed for experimental use defense provisions? I take up also the question of contractual restrictions. What do you feel about this problem? Is it actually a problem using bag-tags?

Mrs. Victoria Henson-Apollonio: This is slightly different than the bag-tag situation, but I thought it was quite interesting. I am reading a paper written by Rebecca Eisenberg who, in the US, certainly could not be construed to be a pro-patent person. Actually, she has written that licensing requirements in some of the access to genetic information are much more restrictive than any of the restrictions placed on that sort of information by patents. And I think this is a real problem. When I was in India a couple of weeks ago with a WIPO representative doing some seminars, there were repeated questions from people who were involved in biological research about mutual transfer agreements and the restrictive components of those mutual transfer agreements. So I think it is something that is a real problem.

Mr. Peter Lange: Could I ask a further question on this? If we have in a country a breeders' exemption as it is used in the European system, would you think that bag-tags would really be valid as the Law prescribes a specific situation and allows for such use for breeding purposes? So I would like to question the validity of such a clause.

Prof. Charles McManis: I come rather late to the discussion of bag-tag licensing, but for anyone in the audience who is not familiar with it, I would call attention to what is going on in the United States with regards to clip-wrap and shrink-wrap licensing in the computer software area if you want an idea of possible things to come. Right now in the United States, there has been promulgated an Act called the Uniform Computer Information Transactions Act (UCITA). It has been adopted in two States and, because after it has been adopted in one State, it is possible to become the choice of law in any computer software licensing agreement, you had better become familiar with the Law as adopted by Virginia and Maryland. These two States have essentially adopted an Act that says that clip-wrap and shrink-wrap licenses are enforceable contracts, even when the terms are disclosed after the transaction has been completed, that is to say the money has been paid. You download the software and up pops on your screen a contract program that says "Surprise! You do not own this copy and you can not sell it, and you can not reverse engineer it, etc." So, I am not familiar with how bag-tags will be enforced, but I am certainly familiar with what is happening with regard to clip-wrap and shrink-wrap licenses.

Mr. Peter Lange: Thank you Prof. McManis. But of course the situation in the US is different from other countries. In a case where you have a strong breeders' exemption in a country, the question arises. That situation is not comparable with your situation, I would say. Is there any opinion on this? So we have to ask the lawyers!

Mr. Mark Shillito, Partner, Agribio Law Practice, Herbert Smith, London: I think under United Kingdom Law, the position would be the same as you have just indicated for Virginia and Maryland, clip-wrap and shrink-wrap would be, I think, enforceable in a United Kingdom Court of Law, and I think, although we have not had any experience of it yet, bag-tag licenses probably would as well, on the same basis. And I would like to answer the question with a question. Do the panel think there is any difference between having a bag-tag license which says "Thou shalt not grow or reproduce this material later on other than to produce a consumption crop" and inserting a terminator gene in the material so that you can not do it anyway?

Mrs. Victoria Henson-Apollonio: I think that use of the terminator technology is just an extension of trade-secret, an extension of hybrid technology and so it is enforceable biologically, whereas obviously the contract is enforceable in some places and not in others.

Prof. Joseph Straus: There is a parallel in the copyright area in Europe with the encryption and whether, because you have a fair use exemption, you can remove that encryption in order to be able to make fair use of that. And maybe even in the terminator case—I am not a biologist—maybe you can alter that again and remove that terminator gene. I think it would depend. You have argued like a United Kingdom lawyer with the implied licenses and so forth, in Germany, since 100 years we have never accepted this doctrine of implied license because it actually leaves it up to the owner to

decide whether something is exhausted. In our Patent Law we have the doctrine of exhaustion and not of implied licenses. I would say that, for the time being, the outcome may differ from country to country in the bag-tag issue.

Mr. Bernard Le Buanec: It is not a question, but maybe a continuation of the discussion on your question. My feeling is that the comparison with software is not completely relevant, as you have exactly said Mr. Chairman, because the software is protected by copyright and, of course, it is obvious that you are not allowed to use it for commercial purposes and that probably is the meaning of the clip-wrap. The question asked by Mr. Lange was we have a plant variety that is protected by PVP, PVP gives clearly an indication that breeders' exemption is allowed and is one of the bases of PVP. Could you by contract or by bag-tags say "No, we consider that there is no breeders' exemption and you can not use our variety for further breeding?" It is a completely different issue and what would be your feeling on a bag-tag saying "You can not use my variety for further breeding" if that variety is protected by PVP?

Mr. Jean Donnenwirth, Pioneer Overseas Corporation, Brussels (American Chamber of Commerce): My comment is a follow up to what Mr. Le Buanec just said. I wonder if there is not a misconception about the breeders' exemption here. My reading of Article 15 of the UPOV Convention of 1991 is that "the breeders' rights shall not extend to" and here is "the act of breeding for creating new varieties." When you read Article 1 of the same Convention, a breeder's right is defined as meaning the right of the breeder provided for in this Convention." Therefore, I submit that there would not be a contradiction or an impossibility to find other legal remedies through bag-tag language, for instance, to prohibit breeding from a protected variety.

Mr. Peter Lange: I think that we will not answer this question finally. I just wanted to ask whether there might be consequences which we have to address.

Mr. Barry Greengrass, Chilly, France: I just wanted to draw attention, following up the very same point about the protected variety, that there is a general principle in relation to the licensing of intellectual property laws that you can not in your license or in some contractual arrangements seek to extend the intrinsic scope of the intellectual property law by provisions in the license. Typical examples are being provisions that require you to source your raw materials from a particular source, or the treatment of improvements. So that if indeed this shrink-wrap type provision was to be struck down it is likely to be struck down perhaps by Competition Law, rather than Intellectual Property Law.

Mr. Peter Lange: I now would like to follow the agenda and come to the second issue which is the question-What are the experiences with IP strategies and licensing in the area of patents for biotech inventions and plant breeders' rights systems? I think it came out during the different speeches and the discussion that we have to tackle in this respect two main questions: first, are the protection criteria, the scope of protection and enforcement and prosecution measures well-suited for the different objects of protection and for the needs which I mentioned before? And I would add, are the systems simple enough to follow the remarks of Mr. Desprez and not too costly? The second question I would like to ask here is on the possible deficiencies in this respect due to the systems or due to the implementation and administration of the systems. Thirdly, the aspect of management of the EDV concept is also the question of how to enforce the rights which the 1991 Act offers us. I would like to ask you to pose questions on these issues.

Mr. Dick Crowder, Chief Executive Officer, American Seed Trade Association (ASTA), Alexandria, United States of America: My question is to Prof. McManis and also in response to a comment made by Bernard Le Buanec that the US PVPA has not been an incentive to breeding. Two questions. Because the United States is not without some success in breeding and technology as has been discussed, the two questions are "What do you think it would have been without the System?" and two "Would there have been another system that would have been better?"

Prof. Charles McManis: As I understand the way the current US PVPA System operates, it seems to me that the absence of significant licensing and litigation activity suggests that it is not creating incentives. If you have a system that in 70 years has produced 8 litigated infringement proceedings

and in 30 years has produced 4, it suggests that there is just not a great deal going on from people who take a bad persons view of the law. And at the same time, the absence of any licensing activity suggests the same thing. Would the system be better or worse without plant variety protection? Well, as I understand the system, it seems to be just giving a bit of backing to contractual trade secret protection-in other words those bag-tag licenses would be there whether there was a Plant Variety Protection Act or not and the question of their enforceability might be more acute in the absence of a Plant Variety Protection Act. But my guess would be that the system without plant variety protection would essentially be no different, there would be more demands than there already are for utility patent protection and there would be more aggressive use of traditional trade secret protection.

Mr. Walter Smolders: This is maybe both a question and a comment. The one reason why PVPA is so weak in the United States is that they are doing searches based on databases and that those databases are really quite imperfect. Now, what is the United States Patent Office doing to examine plant varieties in utility patents – exactly the same. They are searching in germplasm databases which are imperfect and they have no clue on what is happening. Normally, one would expect the patent applicants to draw the attention of the Patent Office to the prior art they are aware of in the relevant area. I am not sure that most applicants do that. So the Patent Office is in no position whatsoever to decide on what is novel or not. They have to rely on the applicant. As a result of that, as soon as they have the benefit of novelty, the implied unobviousness criteria plays a role because as soon as you have a shuffling of a specific non-existing combination that's unobvious, you are getting it. And this is a very problematic issue. Now the question is what could one do? There is another question, when you get a claim on a patent for a deposited material, it is not specified what is being claimed. It just refers to the deposited material and that is all. It does not specify what traits are unobvious, what are surprising. There is a very vague description in the patent application, but that does not identify what is so characterizing or surprising. This is a bit of a reaction to Dick Crowders questions. My question is would it not be better to have a good patent examination system so that the real inventive varieties are being protected and is there no way to keep that under control?

Mr. Peter Lange: Before I give the floor to Tim Roberts, just a small remark. Of course, there might be deficiencies in the implementation in the plant variety protection system in the United States, but although this might be the case, we have a lot of applications of plant varieties, and I think we have to look at the numbers that WIPO has issued. They have the last numbers of issued protected plant varieties in 1999. We have no new figures, but there we have about 10,000 protected varieties. And if you compare, for instance for corn, utility patents, numbers of valid patents for lines or hybrids of corn, you have actually in October 2002, 616, and you have 642 titles granted under the Plant Variety Protection Act. If you compare soybean, you have in October 2002, 765 soybean varieties protected by the plant variety protection system and only 424 patents claiming varieties ***per se*** under soybeans. So the comparison is not so bad for plant variety protection titles.

Mr. Rolf Jördens: We had yesterday in the Council of UPOV the latest UPOV statistics about titles of protection granted and enforced. We looked at the situation in the United States of America and saw for both forms of variety protection, the plant patent and the plant variety protection system, an increase. A steady increase in fact. I have now forgotten the exact figure, but I believe we had 4,000 titles in force under the plant variety protection system and about 6,000 under the plant patent system. There are, in fact, relevant systems. Your comparison, Prof. McManis, between the overall patent titles granted for the whole range of possible subject matter, and numbers of titles issued for the relatively limited sector of plant varieties is not very relevant. We see that the UPOV system, with now about 54,000 titles in force worldwide is important and is growing in importance. We have a steady increase and this steady increase occurs mainly, of course, in recent member States, where we observe a clear effect of the system. We see in the first instance foreign varieties being protected, but then in a second phase, the national breeding activities take effect.

Mr. Tim Roberts: Just two points. To go back to the original questions of Mr. Crowder. Prof. McManis has said, and I am sure that that is right, that the PVP system in the United States of America is weak. But his evidence in support of that is the absence of licensing and litigation and I do wonder about this. In Europe, we also have an absence of litigation, though not, I think of licensing, and in Europe one of the advantages of the PVP system that breeders have traditionally seen, is that it does not involve lawyers to any great extent most of the time. This is seen as a real advantage! So I am not disposed to accept on its face value the fact that there is no litigation is an implication of weakness. But if we go to the second point, how could the system have been better, I do not think I have anything very original here to say, it's a bit like Professor Higgins, in My Fair Lady, "Why cannot America be more like Europe?" If one had an examination system of side-by-side testing and if you had stronger or indeed any requirements against farm-saved seed, that would be the way to improve the system in the United States of America.

Prof. Charles McManis: I think I had better answer this question before the list gets longer! I am not going to go all the way back to Mr. Crowder, but will respond to Mr. Smolders.' I would quite agree that just because I am criticizing US PVP as requiring too much to get the protection for too little in return, that the converse is not true for US utility patent protection. I quite agree with you that, at the moment, under US Patent Law perhaps applicants are getting too much protection in return for requirements that are not high enough. Indeed, I would suggest the two phenomena are related and so I would agree that perhaps the Americans could be more like the Europeans on our plant variety protection. That might ease some of the pressures that are now being exerted on our patent protection. On the other hand, I take exception to the view that what we have in the United States at the moment is effective ***sui generis*** plant variety protection. Simply because it may be that it takes lawyers to litigate, but it does not take lawyers to license. In the United States, in fact it does take lawyers to license, but in any event when you see the absence of business activity, you wonder where is the incentive being created if no licenses are issued. With respect to the figures that I used, I quite agree that in some sense I was comparing apples with oranges. On the other hand, in response to Dr. Lange's question, I would simply observe about the patent record, that looking at the patent record is something like an astronomer looking into space. Keep in mind that you are looking back in time when you are looking at granted patent applications, sometimes as many as five or seven years in time. I would point out that it only became absolutely clear that plants are patentable on December 10, 2001, with the issuance of the Supreme Court Decision on J.E.M. Supply vs. Hi-Bred. So it seems to me that what companies were gambling on before the J.E.M. Supply vs. Pioneer Hi-Bred case is no indication of what you will see happening in the patent system now that J.E.M. Supply vs. Pioneer Hi-Bred has been decided. And indeed, I would argue that the decline since 1999 in plant variety protection applications in the United States may be evidence of an increasing sense of which way the J.E.M. Supply vs. Pioneer Hi-Bred case would go.

Mr. Bernard Le Buanec: As I have been quoted by Dick Crowder I would like to answer as I do not want to be misinterpreted. First of all, I think that we all agree that the US plant breeding has been very successful, that is very clear, but we have to think on what crops. It is mainly in hybrids and vegetables. On other crops it has been rather poor, or not as successful, because the PVP is weak. This is my personal feeling. Because the question is what could we do to improve that it is just simply to have a stronger protection regarding farm-saved seed. To me that is the main weakness of the US PVP Law and it is, of course, the main weakness for breeders working in self-pollinating crops. That was expressed very clearly some years ago when one of the major companies in the USA said we have to drop our breeding in wheat because we have no protection by the PVP. So that is very clear. My second point is that I do not share the views of my neighbor (Mr. Smolders). I am not concerned with the way the PVP system works in the USA and I am convinced that it is not because distinction in US testing is different from Europe that that is a major issue. I am not convinced at all and, to speak frankly, I am even convinced that in the future we will probably have to mix the two systems to be efficient, but that is a very personal view.

Mr. Thomas Kramer, Responsible for Intellectual Property Protection, Seminis Vegetable Seeds, Wageningen: I would like to make two comments. I think for the future of the PVP system, it is very important that we start thinking about an international application and granting procedure. An international application and granting procedure, somewhat similar to the PCT that we have for patents. In order to keep it at a reasonable cost and also to keep it manageable administratively. I

would like to add to it that my own thinking at the moment is that such a system, in combination with official testing, would be a very strong system. I agree to a large extent with the comments made by Walter Smolders, that I would like to see improvements in the US system, but not only in the US, also in many other countries and especially the developing countries. My experience has been that, and now I am making some comments on the remark that was made by Mr. Jördens about total number of titles that are in force-54,000-in some of those countries we have no other option of protecting our material than the PVP system. But this does not necessarily mean that this is effective. Then another comment also related to the official testing, which I am in favor of. We see that it is difficult in a breeding company, at least in our company, to get the breeders to complete the administrative procedures for variety protection. The breeder's main job is to breed commercial, successful varieties and, based on the number of applications in our company that we file in Europe or in the United States, the main explanation for a much larger number of applications being filed in Europe is that the procedure is simple and is not a burden on the breeder. Whereas in the United States, it is a considerable burden on the breeder and our breeders do not like to spend their time filling in the required forms.

Mr. Jean-Christophe Gouache, Directeur scientifique, Groupe Limagrain Holding, Chappes, France: One comment. I was very surprised by what was said about the absence of licensing activity in the United States. I do not believe that this is true. Actually, in the corn and soybean business, a tremendous level of activity of licensing exists through the Foundation Seed Companies and I do believe that licensed varieties from those Foundation Seed Companies to seed companies do represent, in both species, more than 30% market share. So I do not understand what was stated there. I think licensing activity goes on and it's a tremendous amount of business in the US in crops such as corn and soybeans.

Mr. Peter Lange: There is another topic that I would like to tackle, also concerning this issue, and that is the enforcement of the essentially derived varieties (EDV) concept. Do we have any ideas on how to get cases and to enforce this improvement of the UPOV Convention?

Mr. Luiz Antonio Barreto de Castro: When I saw the idea of this seminar and I looked at the title, the impression I had was that co-existence of the laws was being pursued to promote biotechnology and I hope that this is what we are looking for, at least in the long run. These two institutions, WIPO and UPOV, have an important role to play in this direction. But after being here for one whole day, and listening to all these technical discussions, I wish somebody could reassure me that this is the idea at the end. I have followed biotechnology and recombinant DNA for 30 years and I have decided to dedicate the rest of my life as a scientist to promote biotechnology. When early in the 1980s we, in Brazil, had to look for state of the art knowledge in recombinant DNA in plants, we looked for Jeff Schell, in the Max-Planck-Institute and Mark Montague at the University of Gent. When I see Prof. Straus' data on field trials of transgenics in Germany, only fifty field trials last year, it is sad. Really sad. I come to Europe often and my friends, still scientists in many countries, do not have funds to do science in their fields of plant molecular biology with the recombinant DNA methodology. Recombinant DNA technology, or perhaps as we call it today, biotechnology, properly monitored as it has been, is one of the most extraordinary products of science to be used for the benefit of mankind. We should not interfere with the flow of knowledge. Society always loses out when we mix science and politics. I recently wrote a paper for a Brazilian newspaper, the title was "Lysenko, Stalin and Morgan." I do not have to tell you this story, but that's what I think we should be afraid of. Never mix science with politics. We have to promote the flow of science and act properly to use for the benefit of society. I think I could not go back without at least letting you know the way I feel coming here to discuss this co-existence of the laws.

Mr. Peter Lange: Thank you very much Mr. Barreto de Castro. I think that this is a statement which we would all totally agree with. But of course, we have to discuss these problems which I think became clearer even today through the discussions and I just would like to finalize this issue with perhaps a remark. How to enforce the rights which been offered under the UPOV Convention by the EDV concept? I think this is really a big advantage of the system, but we have to work with it and have to find good rules.

Mr. François Desprez: I think that although we have the feeling that, up to now, this EDV concept has not been used or enforced a lot, I think, in fact within the breeding companies it has been sought after. We have avoided having some more plagiarism for varieties because we have let our breeders know that this concept exists and that they should think about that concept when they are applying for a new variety. And it is a success that we do not have many cases that we are aware of.

Prof. Joseph Straus: Just a small provocative remark. I hope that this EDV concept is not only aimed at providing eternal protection for the owner of the original plant variety. Because if that would be the case, that would not be entirely in line with what has been said so far about the access and of course if you use that system only to this aim then you will never have litigation. Maybe less plagiarism, but for the rest, I think it would not be the ideal way forward for innovation in the plant area.

Mr. Bernard Le Buanec: Two comments to try to answer your question. Firstly, I cannot tell you the details, but I know that a first case on EDV will be before the Courts very soon in Europe, so we will have an answer. Second comment is that in the concept of EDV, what is difficult is not to implement it on a legal basis, what is difficult is to define what is an EDV or not. As soon as you have agreed that it is an EDV, it is extremely simple and there is no difficulty. For instance, in one of the simplest cases, that is an introduction of a gene in a plant protected variety, it is extremely easy. I am sure that it is working very well and that all the companies with patented genes in protected varieties are following the rule of EDV.

Mr. Peter Lange: I would like to add that I also know about a case. So we will have Court cases and I think that it is good to have a clear interpretation of the scope of protection. I would like to come now to the third issue which is the most important and interesting one. "Which measures are necessary for a balanced co-existence, or, I would say, a better harmonization of the systems." In this respect, I would also like to identify some possible statements in the discussion. Do we need a well-defined and broader research exemption, a compulsory license system, an extension of the existing compulsory licensing system, a cross-license system – what do we mean by all this? Or, should we just be confident in the negotiation powers of the market?

Mr. Graham Dutfield, Herchel Smith Senior Research Fellow, Queen Mary Intellectual Property Research Institute, University of London: I have heard about half an hour ago that the UPOV 1978 Act is ineffective in the TRIPS concept because, among other reasons, it allows for the saving of harvested seed. This got me thinking about three questions. One, has the restriction on seeds-saving introduced in Europe in recent years made a different in the rate of plant variety innovation and investment? And what is the evidence? Now I have heard this case of Pioneer closing its research in some kind of wheat program in Kansas mentioned again today. I have heard it mentioned twice. If I hear the same thing said more than once, it makes me wonder if people are stumbling for evidence. Second, what has happened to make seed-saving constitute an ineffective system when it was presumably all right before? And three, linked to that, if the answer relates to changes in the seed business, or changes in scientific technology, then what does it imply for developing countries being encouraged not only to join UPOV, but to accept the 1991 revision rather than the 1978 revision. And finally, just one point. The whole idea that you can separate science from politics to me is impossible. If science is mixed with business, politics is going to intrude whether you like it or not.

Mr. Rolf Jördens: Whether the 1978 Act of the UPOV Convention is an effective system of plant variety protection or not, there may be different views. I do not think that UPOV itself has doubts about effectiveness. It is clear that breeders are looking for a reasonable, or a relatively high level of protection. With regard to the possibilities of farmers saving seed, there are certainly differences between the 1978 Act and the 1991 Act, but this does not permit to say that the 1978 Act is not an effective system. There was also reference made earlier to the fact that the 1978 Act does not require including all genera and species. This does, however, not mean that members of UPOV may not go beyond what is the minimum requirement of the 1978 Act.

Mr. Peter Lange: Although I am the Chairman, I would like to answer from my knowledge coming from the Diplomatic Conference of the 1991 Convention which we had here ten years ago. I would

say there are at least three aspects of stronger protection by the 1991 Act. The breeders themselves have very much asked for that. Of course the 1978 Act might be, legally, an effective ***sui generis*** system according to the definition of TRIPS, but that is a question of interpretation. We, as breeders, think it is not really effective, because, first of all, you cannot protect all varieties, all species, you have not the EDV concept so plagiarism is possible, and the scope of protection has been enormously widened by the 1991 Act, especially with regard to the farmer's privilege because there was an uncertain situation before. Now you can claim as a breeder to get remuneration for such use and I think that this is really justified in the interests of the breeders.

Mr. François Desprez: I think that this farm-saved seed issue is very important. We have said earlier this morning that a good law was a law which was enforceable and which was fair. And it is really fair that a law made provisions for farmers using farm-saved seed to compensate the breeders. Because if it is not the case, the return for the breeders will only rely on farmers using certified seeds and in most countries it turns out that these farmers are the smaller farmers and not the ones taking the better profit of innovation for new varieties.

Prof. Charles McManis: I would like to make two remarks in response and I find myself in a somewhat odd situation of responding perhaps for the developing world, coming from the United States, but the first observation I would make about the TRIPS Agreement is that when the TRIPS Agreement wants to incorporate a specific treaty by reference, it knows how to do that. Indeed it knows how to specify that certain provisions of the Berne Convention will apply under TRIPS and others will not apply. The developing world takes the view, since in Article 27.3(b) there is not a specific incorporation of UPOV 1991 Act, but only an effective system of ***sui generis*** protection, that that leaves perfectly open to the developing world the adoption of UPOV 1978 Act. Now the other comment I want to make is the irony that the United States believes it has complied with UPOV 1991 Act and yet I would argue that it is an ineffective system. This brings me back to the point that I made in my remarks earlier today. TRIPS requires an "effective" ***sui generis*** system, but pray what is the test for effectiveness.

Prof. Joseph Straus: Where there is no protection for anybody, can you explain that this is an effective system?

Mr. Peter Lange: Are there any remarks about my suggestion on whether a compulsory license system could be a solution? Or widening this system, not just for public interest, but as it is normally established in the different laws?

Prof. Joseph Straus: I would really like to raise that question. In Europe, as we have seen, we can not have the problem in practice. But how is it in the United States? Is there a real problem with the access so that one should go further with the research exemption we have discussed? But now you have addressed the compulsory licensing system. As far as the access to germplasm is at stake, is there a real problem? We are academics, I have no problems with that, but what do the practitioners say?

Mr. Bernard Le Buanec: Firstly to answer Prof. Straus. I do not know if there are real cases, but there are real threats by companies. When you have large companies threatening small companies saying we will sue you, it is something you have to take into account. But regarding the compulsory licensing, I think that we have to be extremely clear for what the license would be given. Here we are speaking about access and not development of a final product. The compulsory licensing as it is included for instance in the European Directive, is just dealing with the final product because you will have compulsory license if the product is of technical importance. You have first to have the product to implement the license, but if you are not allowed to have access to the germplasm, you do not have the product. So the compulsory licensing as it is included in the European Directive is not for accessing genetic resources, it is after having had access, then to have the possibility of trading the product.

Mr. Peter Lange: I wanted to come in the next step to the question of cross-licensing systems. This is of course, under specific conditions, a compulsory licensing system.

Dr. J.S. Sindhu, Director, Asia and Pacific Seed Association (APSA), Bangkok: I am a plant breeder by profession, so I have got 100% faith in PVP, but at the same time, I want to put before you the aspects of the users, particularly when you were discussing the measures required for co-existence or harmonization of the two systems. I would like to draw your attention to the way patents are used. Based on human welfare, some of the patents are either put in the public regime, for free-use or restricted free-use for the welfare of the farmers living in the developing world who cannot afford or access these technologies against cost. For the benefit of the third-world countries where the farmers cannot get access to these technologies, the restricted permission to use the PVP and the patents together may be a solution. Perhaps we should try to consider this point when we are discussing the measures required for the co-existence.

Mr. John Gerard, President, Access Plant Technology, Inc., Plymouth, United States of America: I am neither a plant breeder nor a scientist nor a lawyer. I am responsible to my banker. The question was asked, and I would like to answer, are there licensing issues in the United States with germplasm. I have spent the last 35 years of my life professionally in the licensing business in soybeans, corn and wheat in the USA and there has been a phenomenal amount of extensive licensing in the USA. I do not know of one technology in those three crops that have not been licensed and the germplasm licensing is very extensive, has been and continues to be. There are agreements that have to be signed, but it creates the opportunity for phenomenal amount of varieties to be developed, hybrids to be developed. It has been a very extensive and very prolific and, frankly, I consider, a highly successful event. I thought I need to respond to that question.

Mr. Huib Ghijsen, Global Manager Germplasm Protection, Bayer BioScience N.V., Astene: I want to proceed on your question concerning the compulsory licensing. Personally, I do not think this is a good way to go forward, because that means some kind of litigation finally. It may cost quite a lot of energy and money, and when you talk about accessibility and harmonizing the two systems, I do not think that it is a good solution to have a system of compulsory licensing on research.

Mr. François Burgaud, Directeur, Groupement national interprofessional des semences et plants (GNIS), Paris: It seems to me all day that there is a large majority of people who think that it is important to improve the research exemption and to introduce this in the regulation for patents and also at the international level. But, when you regard the discussion in WTO, in FAO, about genetic resources, you have the feeling that there is more discussion about traditional knowledge than about this type of problem. So my question is, you talked about the review of the TRIPS Agreement after Doha, do you have the feeling really that there is a possibility to introduce this problem in WTO discussion and to have a result and to have the possibility to introduce in Article 27.3(b) a compulsory research exemption for all types of intellectual property rights?

Prof. Joseph Straus: If I may, I would not argue along your lines. I think that this type of exemption is covered by Article 30 of the TRIPS Agreement because, if Bolar is allowed, and it is clearly allowed, that is also covered. Something which is clearly dealing with research and further improvement of a technology should be covered. So there is no need to revise either Article 27 or 30. It is covered in the sense as it is regulated in part by the EU Directive already so that would be a question of harmonizing the patent law, either here in the draft Substantive Patent Law Treaty, which would be at the universal level, or in national laws.

Prof. Charles McManis: I find myself again speaking for the developing world. It is interesting that Prof. Straus said what he did because there was a built-in review of Article 27.3(b) of the TRIPS Agreement. When it was agreed on it was fairly clear that that built-in review was at the insistence of the United States, which said we will compromise on limitations on patent protection for others than micro-organisms now, but in four years we want a review. The interesting thing is what a change has occurred in the world of politics since that time. Because now it is the developing world that is saying "Yes we want that review, but we do not want it to be limited to what the United States of America wants it limited to." And the United States is saying "Well, maybe we do not want a review after all, maybe it is all covered" just as Prof. Straus has suggested. So I think that there is some political chance that the review process, if it opens, will be more responsive to developing country concerns that to industrialized concerns, European or American. The only comment I would put in here is that as I tried to suggest earlier today, it is not clear to me that the

research exemption will necessarily be embraced by the developing world, at least that part of the developing world concerned with exploitation of traditional knowledge who will see the research exemption as a modern European form of gene piracy.

Mrs. Karla Tatiana Ornelas Loera, Third Secretary, Permanent Mission of Mexico, Geneva: I also would like to thank all the speakers, because it has been a very interesting day, especially for those of us who are not experts in plant breeding and I am very glad that Prof. Straus and Prof. McManis have referred to the current negotiations going on in intellectual property. I would like to say that one of the reasons why the United States may not be interested in reviewing the TRIPS Agreement, in relation to this subject of the expansion and increase of patentable material, is because this is now an ongoing discussions in the draft Substantive Patent Law Treaty at WIPO. It is on this that I want to raise my question because the United States has stated that they want to eliminate the exceptions under Article 27.3 of TRIPS and that they want animals and plants to be subject to patenting, as well as other things that currently are not patentable subject matter. This is a major source of concern. Most countries agree on the need to maintain breeders' rights and the exceptions under Article 27.3. Therefore, I would like to know what would the speakers think about the very remote possibility to eliminate these exceptions, because there is a lot of opposition to this?

Mr Peter Lange: Do we have any response to this? Perhaps from the American Delegation? Not so easy. But I think we have heard your message and of course this will be discussed internationally and I hope that an adequate solution will be found, especially for the least developing and developing countries. So may I now, at the end of this discussion, conclude. And of course, this is not very easy, we have heard a lot of different views and statements, but I think there was a general agreement on some major issues. I have written down something which I would now like to present as a first conclusion of this very interesting Symposium. I have divided my conclusions into the three different issues which we had discussed during this meeting:

1. Access to plant germplasm, be it patented or protected by plant breeders' rights (PBR), is of key importance for further innovation in plants:

- Within the PBR system, this is ensured by the breeder's exemption for entire plant genomes;

- As far as patents for biotechnological inventions (protecting elements or properties in plant material) are concerned and as far as patents for plant varieties ***per se*** are available, access can be assured by a well defined research exemption or experimental use defense;

- At present this seems to be ensured by the European system (and comparable systems in the world), but to a lesser extent in the system provided in the United States of America.

2. The legal framework for the protection of plant innovations must offer efficient (enforceable) and adequate (fair) protection which ensures optimal incentives for investment and good working conditions for further innovation:

- In this respect deficiencies within or caused by the implementation and administration of plant breeders' rights and patent systems should be identified and eliminated;

- In the interest of an efficient technology transfer system-especially for developing countries-effective and adequate protection systems should be offered worldwide, being harmonized as far as possible.

3. A broad majority of the participants of the WIPO-UPOV Symposium in Geneva, held on October 25, 2002, prefers a better harmonization and balancing of the interfaces of the systems by ensuring within the patent system a well defined and broad enough research exemption/experimental use defense, whereas any extension of existing compulsory licensing provisions is not acceptable:

- Compulsory cross-licensing systems may also be helpful, but need further consideration and clarification;

- Private "clearing house systems" for organized access to plant innovations should be encouraged.

CLOSING REMARKS

Mr. Karl Olov Öster
President of the UPOV Council

Ladies and Gentlemen,

The Symposium has given an excellent opportunity to understand relevant matters and to identify measures which might be necessary for the balanced co-existence of patents and plant breeders´ rights, in particular:

- the necessity of well identified measures based on reliable research;
- clarification of the scope of the research exemption in the national laws;
- the policy that the industry is likely to follow concerning protection of biotechnological inventions or breeding work;
- good cooperation in the fields of patents and plant breeders' rights.

On behalf of Dr. Kamil Idris, in his capacity as Director General of WIPO and Secretary-General of UPOV, I would like to express thanks:

- to all the participants that have congregated here;
- to the speakers who have contributed to a decisive extent to enlighten discussions on this subject;
- the moderators for guiding discussions; and
- from an organizational point of view, particular thanks is given to all those who, whithout being specifically mentioned, have put a great effort into making this Symposium a success;
- - Moreover, I would like to express my gratitude to the interpreters for their efficient work.

I would like to mention that this WIPO-UPOV Symposium has had around 220 participants, including speakers, moderators and the Secretariats.

On behalf of the participants, speakers and moderators, I would like to thank WIPO and UPOV for the successful organization of this event and, more particularly, for having the foresight to identify this important issue.

Finally, I declare the WIPO-UPOV Symposium on the Co-existence of Patents and Plant Breeders´ rights in the Promotion of Biotechnological Developments closed.

List of Participants

* Les noms et titres qui figurent dans la liste ci-après sont reproduits tel qu'ils ont été communiqués au Secrétariat jusqu'au 25 octobre 2002.

* Names and titles in the following list are reproduced as communicated to the Secretariat by October 25, 2002.

* Los nombres y cargos que figuran en la presente lista están reproducidos tal y como fueron comunicados a la Secretaría hasta el 25 de octubre de 2002.

I. ÉTATS/STATES/ESTADOS

(dans l'ordre alphabétique des noms français des États)
(in the alphabetical order of the names in French of the States)
(por orden alfabético de los nombres en francés de los Estados)

ALGÉRIE / ALGERIA / ARGELIA

Amina-Amal BENCHEHIDA, Chef, Bureau des homologations des variétés au niveau de la Sous-direction des homologations, Ministère de l'agriculture et du développement rural (MADR), Alger

Abdelkarim OULD RAMOUL, Sous-directeur des homologations, Ministère de l'agriculture et du développement rural (MADR), Alger

ALLEMAGNE / GERMANY / ALEMANIA

Udo VON KRÖCHER, President, Federal Office of Plant Varieties, Hanover

Michael KÖLLER, Head of Legal Section, Federal Office of Plant Varieties, Hanover

Hans Walter RUTZ, Head of Section, Federal Office of Plant Varieties, Hanover

Franck GOEBEL, Pres. Judge, Plant Variety Protection Senate, Federal Patent Court, Munich

AUSTRALIE / AUSTRALIA

Doug WATERHOUSE, Registrar, Plant Breeders' Rights Office, Department of Primary Industries and Energy, Commonwealth Department of Agriculture, Fisheries and Forestry, Canberra

AUTRICHE / AUSTRIA

Heinz-Peter ZACH, Federal Ministry of Agriculture, Forestry, Environment and Water Management, Vienna

Birgit KUSCHER (Mrs), Federal Ministry of Agriculture, Forestry, Environment and Water Management, Vienna

BÉLARUS / BELARUS / BELARÚS

Irina EGOROVA (Mrs.), First Secretary, Permanent Mission, Geneva

BELGIQUE / BELGIUM / BÉLGICA

Camille VANSLEMBROUCK (Mme), Ingénieur, Office de la propriété intellectuelle, Ministère des affaires économiques, Bruxelles

BOLIVIE / BOLIVIA

Roberto GALLO ARÉBALO, Responsable Técnico, Programa Nacional de Semillas, Ministerio de Agricultura, Ganadería y Desarrollo Rural, La Paz

Jorge ROSALES KING, Director, Oficina Regional de Semillas, Ministerio de Agricultura, Ganadería y Desarrollo Rural, Santa Cruz de la Sierra

Carmelo JUSTINIANO, Jefe, División de Registros, Oficina Regional de Semillas, Ministerio de Agricultura, Ganadería y Desarrollo Rural, Santa Cruz de la Sierra

BRÉSIL / BRAZIL / BRASILIEN / BRASIL

Ariete DUARTE FOLLE (Sra.), Chefe, Serviço Nacional de Proteção de Cultivares (SNPC), Secretaria de Desenvolvimento Rural, Ministério da Agricultura e do Abastecimento, Esplanada dos Ministérios, Brasilia

Alvaro A. NUNES VIANA, Coordinador, Serviço Nacional de Proteção de Cultivares (SNPC), Secretaria de Desenvolvimento Rural, Ministério da Agricultura e do Abastecimento, Esplanada dos Ministerios, Brasilia

CANADA / CANADÁ

Valerie SISSON (Ms.), Commissioner, Plant Breeders' Rights Office, Canadian Food Inspection Agency (CFIA), Nepean

Cameron MACKAY, First Secretary, Permanent Mission, Geneva

CHILI / CHILE

Rosario SANTANDER KELLY (Sra.), Asesora de la Dirección Nacional, Servicio Agrícola y Ganadero (SAG), Santiago

Enzo CERDA, Jefe de Registro de Variedades Protegidas, Departamento de Semillas, Servicio Agrícola y Ganadero, Ministerio de Agricultura, Santiago

CHINE / CHINA

LÜ Bo, Director, DUS Test Division, Development Center for Science and Technology, Ministry of Agriculture, Beijing

HAN Li (Mrs.), First Secretary, Permanent Mission, Petit-Lancy, Geneva, Switzerland

COLOMBIE / COLOMBIA

Ana Luisa DÍAZ JIMÉNEZ (Sra.), Coordinador Nacional, Derechos de Obtentor de Variedades y Producción de Semillas, Instituto Colombiano Agropecuario (ICA), Bogotá

Marta Olga GALLON (Sra.), Consejero Comercial, Misión Permanente, Ginebra

Luis G. GUZMAN VALENCIA, Ministro Consejero, Misión Permanente, Ginebra

CROATIE / CROATIA / CROACIA

Irena SCHMIDT (Mrs.), State Intellectual Property Office, Zagreb

Ruica ORE (Mrs.), Head of Plant Variety Protection and Registration, Institute for Seeds and Seedlings, Osijek

Zlata SLADI, Head, Patent Examiners Office, State Intellectual Property Office, Zagreb

CUBA

Lázara SORAVILLA HERNÁNDEZ (Sra.), Jefa, Registro de Variedades Comerciales y Protegidas, La Habana

DANEMARK / DENMARK / DINAMARCA

Hans Jørgen ANDERSEN, Head of Division, Danish Plant Directorate, Ministry of Food, Agriculture and Fisheries, Lyngby

ÉGYPTE / EGYPT / EGIPTO

Gamal EISSA ATTYA, Director, Breeders' Rights Department, Central Administration for Seed Testing and Certification (CASC), Cairo

ESPAGNE / SPAIN / ESPAÑA

Martín FERNÁNDEZ DE GOROSTIZA YSBERT, Director, Oficina Española de Variedades Vegetales (OEVV), Ministerio de Agricultura, Pesca y Alimentación (MAPA), Madrid

Luis SALAICES, Jefe de Área del Registro de Variedades, Oficina Española de Variedades Vegetales (OEVV), Ministerio de Agricultura, Pesca y Alimentación (MAPA), Madrid

Francisco Javier HAERING PÉREZ, Técnico Superior Examinador, Departamento de Coordinación Jurídica y Relaciones Internacionales, Oficina Española de Patentes y Marcas, Madrid

ESTONIE / ESTONIA

Pille ARDEL (Mrs.), Head of Department, Plant Production Inspectorate, Variety Control Department, 71024 Viljandi (tel.: +372 4334 650 fax: +372 4334 650
e-mail: pille.ardel@plant.agri.ee)

ÉTATS-UNIS D'AMÉRIQUE / UNITED STATES OF AMERICA / ESTADOS UNIDOS DE AMÉRICA

Karen M. HAUDA (Mrs.), Patent Attorney, Office of Legislative and International Affairs, United States Patent and Trademark Office (USPTO), Washington, D.C.

Paul M. ZANKOWSKI, Commissioner, Plant Variety Protection Office, Agricultural Marketing Service, United States Department of Agriculture (USDA), Beltsville

FÉDÉRATION DE RUSSIE / RUSSIAN FEDERATION / FEDERACIÓN DE RUSIA

Yuri ROGOVSKI, Deputy-Chairman, Chief of Methods Department, State Commission of the Russian Federation for Selection Achievements Test and Protection, Moscow

Madina OUMAROVA (Mrs.), Expert, Methods Department, State Commission of the Russian Federation for Selection Achievements Test and Protection, Moscow

FINLANDE / FINLAND / FINLANDIA

Arto VUORI, Director, Plant Variety Rights Office, Ministry of Agriculture and Forestry, Helsinki

FRANCE / FRANCIA

Bernard MATHON, Chef, Bureau des semences, Ministère de l'agriculture et de la pêche, Paris

Nicole BUSTIN (Mlle), Secrétaire général, Comité de la protection des obtentions végétales (CPOV), Ministère de l'agriculture et de la pêche, Paris

Joël GUIARD, Directeur adjoint, Groupe d'étude et de contrôle des variétés et des semences (GEVES), Guyancourt

François BURGAUD, Directeur, Groupement national interprofessional des semences et plants (GNIS), Paris

Philippe GRACIEN, Groupement national interprofessional des semences et plants (GNIS), Paris

GRÈCE / GREECE / GRECIA

Evagelos ZAGILIS, Head, Section of Vegetable Seed, Directorate of Inputs for Plant Production, Ministry of Agriculture, Athens

HONGRIE / HUNGARY / HUNGRÍA

Karoly NESZMÉLYI, General Director, National Institute for Agricultural Quality Control (NIAQC), Budapest

Mária HORVAI-GORKA (Mrs.), Deputy-Head, Agriculture and Plant Variety Protection Section, Hungarian Patent Office, Budapest

Anna LÖRINCZ (Mrs.), Legal Officer, Hungarian Patent Office, Budapest

Gusztáv VÉKÁS, President, Hungarian Intellectual Property Protection Council, Hungarian Patent Office, Budapest

Mária PETZ-STIFTER (Mrs.), Patent Examiner, Hungarian Patent Office, Budapest

IRLANDE / IRELAND / IRLANDA

John V. CARVILL, Controller of Plant Breeders' Rights, Plant Variety Rights Office, Department of Agriculture and Food, Leixlip

ISRAËL / ISRAEL

Shalom BERLAND, Legal Advisor of Ministry of Agriculture and Plant Breeders' Registrar, Plant Breeders' Rights Council, Volcani Centre, Bet-Dagan

JAPON / JAPAN / JAPÓN

Jun KOIDE, Deputy Director, International Affairs, Seeds and Seedlings Division, Ministry of Agriculture, Forestry and Fisheries (MAFF), Tokyo

Toyoharu FUKUDA, Director, Seeds and Seedlings Division, Ministry of Agriculture, Forestry and Fisheries (MAFF), Tokyo

Masayoshi MIZUNO, First Secretary, Permanent Mission, Geneva

KAZAKHSTAN / KAZAJSTÁN

Murat TASHIBAYEV, Counsellor, Permanent Mission, Geneva

KENYA

John Chagema KEDERA, Managing Director, Kenya Plant Health Inspectorate Service (KEPHIS), Nairobi

Evans O. SIKINYI, Registrar, Plant Breeders' Rights Office, Kenya Plant Health Inspectorate Service (KEPHIS), Nairobi

MAROC / MOROCCO / MARRUECOS

Khalid SEBTI, Premier secrétaire (OMC), Mission permanente, Grand-Saconnex, Switzerland

MAURICE / MAURITIUS / MAURICIO

Rojoa HASSAMBHYE, Principal Research and Development Officer, Ministry of Agriculture, Port Louis

MEXIQUE / MEXICO / MÉXICO

Enriqueta MOLINA MACÍAS (Sra.), Encargada del Despacho de la Dirección, Servicio Nacional de Inspección y Certificación de Semillas (SNICS), Secretaría de Agricultura, Ganadería y Desarrollo Rural, Tlalnepantla

Jesús VEGA HERRERA, Instituto Mexicano de la Propiedad Industrial (IMPI), México

Karla Tatiana ORNELAS LOERA (Mrs.), Third Secretary, Permanent Mission, Geneva

NORVÈGE / NORWAY / NORUEGA

Kåre SELVIK, Director General, Head of Plant Variety Board, Royal Ministry of Agriculture, Oslo

Haakon SØNJU, Registrar, Plant Variety Board, Royal Ministry of Agriculture, Ås

Grethe EVJEN (Ms.), Senior Advisor, Royal Ministry of Agriculture, Oslo

PANAMA / PANAMÁ

Sergio DOMÍNGUEZ, Secretario Ejecutivo, Comité Nacional de Semillas (CNS), Panamá

PAYS-BAS / NETHERLANDS / PAÍSES BAJOS

Chris M.M. VAN WINDEN, Account Manager Propagating Material, Ministry of Agriculture, Nature Management and Fisheries, The Hague

Krieno Adriaan FIKKERT, Secretary, Board for Plant Breeders' Rights, Wageningen

POLOGNE / POLAND / POLONIA

Edward S. GACEK, Director General, Research Centre for Cultivar Testing (COBORU), Slupia Wielka

Julia BORYS (Mrs.), Head, DUS Testing Department, Research Centre for Cultivar Testing (COBORU), Slupia Wielka

PORTUGAL

Carlos PEREIRA GODINHO, Head, National Center for Plant Variety Protection Registration, General Directorate of Cultivar Protection (DGPC), Ministry of Agriculture, Rural Development and Fisheries, Lisbon

Ligia GATA-CONÇALVES (Mrs.), Examiner, National Institute of Intellectual Property (INPI), Lisbon

RÉPUBLIQUE ARABE SYRIENNE / SYRIAN ARAB REPUBLIC / REPÚBLICA ÁRABE SIRIA

Mohammad KHAFIF, Conseiller, Mission permanente, Genève

RÉPUBLIQUE DE CORÉE / REPUBLIC OF KOREA / REPÚBLICA DE COREA

LEE Byung-Muk, Director, Plant Variety Protection Division, National Seed Management Office (NSMO), Anyang City

CHOI Keun-Jin, Examination Officer, Plant Variety Protection Division, National Seed Management Office (NSMO), Anyang City

RÉPUBLIQUE DE MOLDOVA / REPUBLIC OF MOLDOVA /
REPÚBLICA DE MOLDOVA

Dumitru BRINZILA, President, State Commission for Crop Variety Testing and Registration, Chisinau

RÉPUBLIQUE TCHÈQUE / CZECH REPUBLIC / REPÚBLICA CHECA

Ivan BRANOVSKY, Head of Section, Department of Agricultural Production, Ministry of Agriculture, Tesnov 17, 11705 Praha

Jirí SOUCEK, Head of Department, Department of Plant Variety Rights and DUS Tests, Central Institute for Supervising and Testing in Agriculture (ÚKZÚZ), Praha

Daniel JUREKA, Head, Plant Variety Testing Department, Central Institute for Supervising and Testing in Agriculture, Brno

Ludmilla ŠTRBOV (Ms.), Second Secretary, Permanent Mission, Geneva

ROUMANIE / ROMANIA

Adriana PARASCHIV (Mrs.), Head, Light Industry and Agricultural Division, State Office for Inventions and Trademarks (OSIM), Bucharest

Ruxandra URUCU (Ms.), Legal Adviser, Legal and International Affairs Division, State Office for Inventions and Trademarks (OSIM), Bucharest

Mihaela-Rodica CIORA (Mrs.), Expert, State Institute for Variety Testing and Registration, Ministry of Agriculture, Food and Forestry, Bucharest

ROYAUME-UNI / UNITED KINGDOM / REINO UNIDO

Heather HAMILTON (Mrs.), Controller, Head of Seeds Division, Plant Variety Rights Office and Seeds Division, Department for Environment, Food and Rural Affairs (DEFRA), Cambridge

Michael MILLER, Policy Administrator, Plant Variety Rights Office and Seeds Division, Department for Environment, Food and Rural Affairs (DEFRA), Cambridge

ARABIE SAOUDITE / SAUDI ARABIA / ARABIA SAUDITA

Abdullah AL ZAMIL, Director, Technical Services, King Abdulaziz City for Science and Technology (KACST), Riyadh

SLOVAQUIE / SLOVAKIA / ESLOVAQUIA

Milan MÁJEK, First Secretary, Permanent Mission, Geneva

SLOVÉNIE / SLOVENIA / ESLOVENIA

Joze ILERSIC, Counsellor, Administration for Plant Protection and Seeds, Ministry of Agriculture, Forestry and Food (MAFF), Ljubljana

SUÈDE / SWEDEN / SUECIA

Karl Olov ÖSTER, Director-General, National Board of Fisheries; President, National Plant Variety Board, Göteborg and President of UPOV Council

Eva BERNDTSSON (Ms.), Legal Advisor, Ministry of Agriculture, Food and Fisheries, Stockholm

Marianne SJÖBLOM, Senior Administrative Officer, Ministry of Agriculture, Food and Fisheries, Stockholm

Carl JOSEFSSON, Deputy Director, Ministry of Justice, Stockholm

Hampus RYSTEDT, Director, Swedish Patent and Registration Office, Stockholm

SUISSE / SWITZERLAND / SUIZA

Pierre Alex MIAUTON, Station fédérale de recherches en production végétale de Changins, Nyon

Olivier FÉLIX, Chef de division, Office fédéral de l'agriculture, Berne

Sonia BLIND (Mme), Conseillère juridique, Division droit et affaires internationales, Institut fédéral de la propriété intellectuelle, Berne

Lukas BÜHLER, Co-chef, Service juridique brevets et designs, Division droit et affaires internationales, Institut fédéral de la propriété intellectuelle, Berne

Alwin KOPSE, Office fédéral de l'agriculture, Berne

Robert MARTIN, Expert en brevets (biotechnologie), Division des brevets, Institut fédéral de la propriété intellectuelle, Berne

THAÏLANDE / THAILAND / TAILANDIA

Tanit CHANGTHAVORN, National Center for Genetic Engineering and Biotechnology (BIOTEC), Bangkok

Supark PRONGTHURA, First Secretary, Permanent Mission, Geneva

TURQUIE / TURKEY / TURQUÍA

Kamil YILMAZ, Director, Seed Registration and Certification Centre, Ministry of Agriculture and Rural Affairs, Yenimahalle - Ankara

UKRAINE / UCRANIA

Roman SHMIDT, Deputy State Secretary, Ministry of Agrarian Policy, Kyiv

Mykola BOYKO, Leading Expert, State Service on Right Protection for Plant Varieties, Kyiv

VENEZUELA

Virginia PÉREZ PÉREZ, Primer Secretario, Misión Permanente, Grand-Saconnex, Suissa

YOUGOSLAVIE / YUGOSLAVIA

Ivana DULIC MARKOVIC (Mrs.), Director, Plant Variety Protection and Registration Department, Federal Institute for Plant and Animal Genetic Resources, Belgrade

Goran DRINI, Deputy Director General, Maize Research Institute "Zcmun Polje", Belgrade-Zemun

II. ORGANISATIONS INTERNATIONALES INTERGOUVERNEMENTALES/ INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS/ ORGANIZACIONES INTERNACIONALES NO GOBIERNAMENTALES

ORGANISATION DES NATIONS UNIES POUR L'ALIMENTATION ET L'AGRICULTURE (FAO) / FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS (FAO) / ORGANIZACIÓN DE LAS NACIONES UNIDAS PARA LA AGRICULTURA Y LA ALIMENTACIÓN (FAO)

Nuria URQUÍA FERNÁNDEZ (Ms.), Networking Officer (Plant Genetic Resources), Seed and Plant Genetic Resources Service, Plant Production and Protection Division, Agricultural Department, Rome

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO) / ORGANIZACIÓN MUNDIAL DE LA SALUD (OMS)

Ms Yukiko MARUYAMA (Mrs.), Scientist, Traditional Medicine, Geneva

ORGANISATION MONDIALE DU COMMERCE (OMC) / WORLD TRADE ORGANIZATION (WTO) / ORGANIZACIÓN MUNDIAL DEL COMERCIO (OMC)

Xiaoping WU (Mrs.), Counsellor, Intellectual Property Division, Geneva

COMMUNAUTÉ EUROPÉENNE (CE) / EUROPEAN COMMUNITY (EC) /
COMUNIDAD EUROPEA (CE)

Bart KIEWIET, Président, Office communautaire des variétés végétales (OCVV), Union européenne, 3, blvd. Maréchal Foch, Boîte postale 2141, 49021 Angers

José M. ELENA ROSSELLÓ, Vice-President, Community Plant Variety Office (CPVO), 3, blvd Maréchal Foch, Boîte postale 2141, 49021 Angers

Jean-Luc GAL, Expert national détaché au sein de l'Unité propriété industrielle de la Direction générale Marché intérieur, Commission européene, Bruxelles

ORGANISATION DE COOPÉRATION ET DE DÉVELOPPEMENT ÉCONOMIQUES (OCDE) / ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD) / ORGANIZACIÓN DE COOPERACIÓN Y DESARROLLO ECONÓMICOS (OCDE)

Jean-Marie DEBOIS, Administrateur principal, Codes et systèmes agricoles, Division des échanges et marchés agricoles, Direction de l'alimentation, de l'agriculture et des pêcheries, Paris

ORGANISATION EUROPÉENNE DES BREVETS (OEB) / EUROPEAN PATENT ORGANISATION (EPO) / ORGANIZACIÓN EUROPEA DE PATENTES (OEP)

Bart CLAES, Patent Law Department, Munich

III. ORGANISATIONS NON GOUVERNEMENTALES/ NON-GOVERNMENTAL ORGANIZATIONS/ ORGANIZACIONES NO GUBERNAMENTALES

ACTIONAID

Gichinga NDIRANGU (Mrs.), Food Rights Analyst, London

Ruchi TRIPATHI (Ms.), Food Trade Research Office, London

ASIA AND PACIFIC SEED ASSOCIATION (APSA)

J.S. SINDHU, Director, Bangkok

ASSOCIATION DES OBTENTEURS HORTICOLES EUROPÉENS (AOHE) / ASSOCIATION OF EUROPEAN HORTICULTURAL BREEDERS (AOHE) / ASOCIACIÓN DE OBTENTORES HORTÍCOLAS EUROPEOS (AOHE)

Pierre TRIOREAU, Secrétaire général, SNHF, Paris

CENTRE D'ÉTUDES INTERNATIONALES DE LA PROPRIÉTÉ INDUSTRIELLE (CEIPI) / CENTER FOR INTERNATIONAL INDUSTRIAL PROPERTY STUDIES (CEIPI)

François CURCHOD, Professeur associé à l'Université Robert Schuman de Strasbourg, Genolier, Suisse

COMMISSION AFRICAINE DES PROMOTEURS DE LA SANTÉ ET DES DROITS DE L'HOMME (CAPSDH)

Claude CITON, Representative, Genève

CROPLIFE INTERNATIONAL

Robin BORDIE, Manager, International Regulatory Affairs, Brussels

Patricia POSTIGO, Manager, Global Political Affairs and Society Issues, Brussels

THE EUROPEAN UNION COMMITTEE OF THE AMERICAN CHAMBER OF COMMERCE

Jean DONNENWIRTH, Pioneer Overseas Corporation, Brussels

AGENCE EUROPÉENE DES SEMENCES (ESA) /
EUROPEAN SEED ASSOCIATION (ESA)

Joachim WINTER, Secretary General, Brussels

Garlich VON ESSEN, Director, Brussels

Andreas J. BÜCHTING, KWS SAAT AG, Einbeck

Manfred POHL, KWS Saat AG, Einbeck

CENTRE D'ÉCHANGES ET DE COOPÉRATION POUR L'AMÉRIQUE LATINE
(CECAL) / EXCHANGE AND COOPERATION CENTRE FOR LATIN AMERICA
GENETIC RESOURCES ACTION INTERNATIONAL (GRAIN)

Renée VELLVÉ (Ms.), College Los Baños

ASSOCIATION INTERNATIONALE DES PRODUCTEURS HORTICOLES
(AIPH) / INTERNATIONAL ASSOCIATION OF HORTICULTURAL PRODUCERS (AIPH)

M. Hopperus BUMA, Secretary, AIPH Novelty Protection Committee, International Association of Horticultural Producers (AIPH), Leiden

COMMUNAUTÉ INTERNATIONALE DES OBTENTEURS DE PLANTES
ORNEMENTALES ET FRUITIÈRES DE REPRODUCTION ASEXUÉE
(CIOPORA) / INTERNATIONAL COMMUNITY OF BREEDERS OF
ASEXUALLY REPRODUCED ORNAMENTAL AND FRUIT-TREE VARIETIES
(CIOPORA) / COMUNIDAD INTERNACIONAL DE OBTENTORES DE
VARIEDADES ORNAMENTALES Y FRUTALES DE REPRODUCCIÓN

René ROYON, Secrétaire général, Mougins

FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ
INDUSTRIELLE (FICPI) / INTERNATIONAL FEDERATION OF INDUSTRIAL
PROPERTY ATTORNEYS (FICPI) / FEDERACIÓN INTERNACIONAL DE
AGENTES DE PATENTES (FICPI)

Heléne FAGERLIN (Ms.), Chair, Group 5 (Biotechnology) - Study and Work Commission (Sweden)

FÉDÉRATION INTERNATIONALE DES SEMENCES (ISF) / INTERNATIONAL SEED FEDERATION (ISF) / FEDERACIÓN INTERNACIONAL DE SEMILLAS (ISF)

Bernard LE BUANEC, Secretary General, Nyon

Richard CROWDER, Chief Executive Officer, American Seed Trade Association (ASTA), Alexandria

Orlando DE PONTI, Managing Director, Nunza BV, Nunhem

Theo ELLENBROEK, Legal Counsel, Nunza BV, Nunhem

John GERARD, President, Access Plant Technology, Inc., Plymouth

Huib GHIJSEN, Global Manager Germplasm Protection, Oilseeds Department, Bayer BioScience N.V., Astene

Christopher HERRLINGER, Bundesverband Deutscher Pflanzenzüchter e.V., Bonn

Nelly HOEK (Ms.), Hoek Breeding BV, S-Gravenzande

Thomas KRAMER, Responsible for Intellectual Property Protection, Seminis Vegetable Seeds, Wageningen

Martine MARCHAND (Ms.), Secrétaire général, SEPROMA, Paris

Kees NOOME, IPR Manager, Advanta BV, Kapelle

Radha RANGANATHAN (Mrs.), Technical Director, Nyon

Ferdinand SCHMITZ, Managing Director, Bundesverband Deutscher Pflanzenzüchter e.V., Bonn

Mark SHILLITO, Partner, Agribio Law Practice, Herbert Smith, London

Joel SMITH, Solicitor Advocate, Agribio Law Practice, Herbert Smith, London

Marick VAN DIJK (Ms.), Plantum NL, Gouda

Jan VAN ROMPAEY, Bayer BioScience N.V., Astene

Wilhelm WICKI, Delley Seeds and Plants Ltd. (DSP), Delley

Susan WIGZELL (Ms.), Licensing Manager, British Society of Plant Breeders, Ely

LATIN-AMERICAN FEDERATION OF SEED ASSOCIATIONS (FELAS) / FEDERACIÓN LATINOAMERICANA DE ASOCIACIONES DE SEMILLISTAS (FELAS)

Juan Carlos MARTÍNEZ, Responsable de la Comunicación Externa, Zaragoza

LICENSING EXECUTIVE SOCIETY (LES)

Rinaldo PLEBANI, International Delegate, Torino

Dirk GROENEWEGEN, LESI Lifescience Committee, Baarn

WORLD SELF-MEDICATION INDUSTRY (WSMI)

Reto NIEVERGELT, Pharmaton SA, Lugano

INSTITUT MAX PLANCK POUR LA PROPRIÉTÉ INTELLECTUELLE (MPI) /
MAX PLANCK INSTITUTE FOR INTELLECTUAL PROPERTY (MPI) /
INSTITUTO MAX PLANCK PARA LA PROPIEDAD INTELECTUAL (MPI)

Sabine WEIDLICH (Mrs.), Ph.D. Research Fellow, Munich

IV. PARTICULIERS / INDIVIDUALS / PARTICULARES

(dans l'ordre alphabétique des noms français des États)
(in the alphabetical order of the names in French of the States)
(por orden alfabético de los nombres en francés de los Estados)

ALLEMAGNE / GERMANY / ALEMANIA

Michael KOCK, Patent Attorney, Patents, Trademarks and Licences, BASF Aktiengesellschaft, Ludwigshafen

Dirk VOESTE, Senior Manager, Global Seed Activities, BASF Plant Science Holding, Linburgerhof

Gert WÜRTENBERGER, Wuesthoff & Wuesthoff, Patent Attorneys and Lawyers, Munich

AUSTRALIE / AUSTRALIA

Mark O'DONNELL, Patent Attorney, Blake Dawson Waldron Patent Services, Melbourne

FRANCE / FRANCIA

Thomas BOUVET, Véron & Associés, Lyon

Monique CASSIER (Mme), Chargée d'études, Unigrains S.A., Paris

Jean-Christophe GOUACHE, Directeur scientifique, Affaires scientifiques, Groupe Limagrain Holding, Chappes

Barry GREENGRASS, Chilly

Patrick MARCHAND, Président, Syndicat des Trieurs à Façon de France (STAFF), Saint Nicolas de Port

ITALIE / ITALY / ITALIA

Marcello BROGGIO, Head, Biodiversity and Biotechnology Division, Instituto Agronomico Oltremare, Florence

Alexander OCHEM, Scientist (Genetic Engineering and Biotechnology), International Center for Genetic Engineering and Biotechnology (ICGEB), Trieste

JAMAHIRIYA ARABE LIBYENNE / LIBYAN ARAB JAMAHIRIYA /
JAMAHIRIYA ARABE LIBIA

Abdelhamid HAMEID, Researcher, Biotechnology Research Center, Tripoli

NIGÉRIA / NIGERIA

Christopher Kunle ADEMOLA, Laboratory Officer, Housky Biotech Inc., Ibadan

NORVÈGE / NORWAY / NORUEGA

Hans Morten HAUGEN, Doctoral Research Fellow, Norwegian Institute for Human Rights, Oslo

PAYS-BAS / NETHERLANDS / PAÍSES BAJOS

Ronald KORENSTRA, PBR Trademark Attorney, Algemeen Octrooibureau, Rijswijk

Jan Anne VOS (Mrs.), Asser Institute, Arnhem

ROYAUME-UNI / UNITED KINGDOM / REINO UNIDO

Emma BRIERLEY (Ms.), Scientific Executive, GW Pharmaceuticals, Hornsea

Graham DUTFIELD, Herchel Smith Senior Research Fellow, Queen Mary Intellectual Property Research Institute, University of London, London

Terence HAY-EDIE, Research Associate, University of Cambridge, Cambridge

Muriel LIGHTBOURNE (Mrs.), Senior Research, Queen Mary Intellectual Property Research Institute, London.

Tim WILKINSON, Manager, GW Pharmaceuticals, Tonbridge

SUÈDE / SWEDEN / SUECIA

Agnes COURADES ALLEBECK (Mrs.), Senior Research Officer, National Board of Trade, Stockholm

SUISSE / SWITZERLAND / SUIZA

Stéphane COILLET-MATILLON, Institut européen, Genève

Anne-Marie FLURY (Mme), Docteur en droit, Delémont

Alfred KÖPF, Patent Attorney, Feldmann & Partner AG, Glattbrugg

Estela MUJICA (Ms.), BATS, Basel

Luca ROSSI, Manager Biotechnology Research, Philip Morris International, Neuchâtel

Tzen Chew Chin WONG (Ms.), Researcher, University of Geneva, Geneva

V. ORATEURS / SPEAKERS / CONFERENCIANTES

Luis Antonio BARRETO DE CASTRO, Head of National Center for Genetic Resources and Biotechnology (CENARGEN), Brazilian Agricultural Research Corporation (EMBRAPA), Brasilia, Brazil

François DESPREZ, President, French Society of Plant Breeders (SICASOV), Cappelle en Pevele, France

Victoria HENSON-APOLLONIO (Mrs.), Manager, The Consultative Group on International Agricultural Research (CGIAR), The Hague, Netherlands

Charles McMANIS, Professor, Washington University, St. Louis, Missouri, United States of America

Tim ROBERTS, Patent Attorney, Bracknell, United Kingdom

Joseph STRAUS, Executive Director, Max Planck Institute, Munich, Germany

VI. MODÉRATEURS / MODERATORS / MODERADORES

Peter LANGE, KWS SAAT AG, Einbeck, Germany

Bernard LE BUANEC, Secretary General, International Seed Federation (ISF), Nyon, Switzerland

Walter SMOLDERS, Head of Biotechnology Patenting, Syngenta Crop Protection AG, Basle, Switzerland

QIAO Dexi, Director General, Department for International Cooperation, State Intellectual Property Office of China, Beijing, China

VII. SECRÉTARIAT DE L'OMPI / WIPO SECRETARIAT / SECRETARÍA DE LA OMPI

Francis GURRY, Assistant Director General, Office of Legal and Organization Affairs and PCT System

Antony TAUBMAN, Acting Director and Head, Office of Legal and Organization Affairs and PCT System, Traditional Knowledge Division

Richard KJELDGAARD, Senior Counsellor, Biotechnology and Genetic Resources, Traditional Knowledge Division

Karen LEE (Mrs.), Counsellor, Office of the Special Counsel to the Director General

VII. SECRÉTARIAT DE L'UPOV / UPOV SECRETARIAT / SECRETARÍA DE LA UPOV

Rolf JÖRDENS, Vice Secretary-General

Peter BUTTON, Technical Director

Raimundo LAVIGNOLLE, Senior Counsellor

Makoto TABATA, Senior Counsellor

Yolanda HUERTA (Mrs.), Senior Legal Officer

Paul Therence SENGHOR, Senior Program Officer

Vladimir DERBENSKIY, Consultant

PART II:

WIPO-UPOV SYMPOSIUM ON INTELLECTUAL PROPERTY RIGHTS IN PLANT BIOTECHNOLOGY

Geneva, October 24, 2003

Biographical Information on Speakers

FRANCIS GURRY

Francis Gurry, a national of Australia, is Assistant Director General and the Legal Counsel of the World Intellectual Property Organization (WIPO) in Geneva. He is responsible for WIPO's activities in the area of patents, which include patent policy questions and the administration of the Patent Cooperation Treaty (PCT), under which over 114,000 international patent applications were filed in 2002; biotechnology and genetic resource policy questions; traditional knowledge; and the WIPO Arbitration and Mediation Center, which administered nearly 3,000 disputes over Internet domain names in 2002.

Dr. Gurry holds law degrees from the University of Melbourne and a Doctor of Philosophy from the University of Cambridge in the United Kingdom. He is a Vice President of the International Federation of Commercial Arbitration Institutions (IFCAI).

Before joining WIPO in 1985, he practiced as an attorney in Melbourne and Sydney and also taught law at the University of Melbourne. He is the author of a textbook on the law of trade secrets and confidential information, entitled ***Breach of Confidence***, published by Oxford University Press in the United Kingdom in 1984 and re-printed in 1990, and co-author, with Frederick Abbott and Thomas Cottier, of ***The International Intellectual Property System: Commentary and Materials***, published by Kluwer in July 1999.

Tel. +41 22 338 9428
E-mail: francis.gurry@wipo.int
Languages: English and French

ROLF JÖRDENS

Born in 1946, Celle, Germany

Rolf Jördens graduated in Agricultural Economics from the University of Stuttgart-Hohenheim, Germany, and obtained a Doctor's degree from the same Institute. He held a two-year research position at the ***Institut National Agronomique*** in Paris, France

Vice Secretary-General,
International Union for the Protection of New Varieties of Plants (UPOV)
(July 2000 – present)

President, German Federal Office of Plant Varieties (Bundessortenamt), Hanover, Germany
(July 1997 – June 2000)
Overall responsibility of the Office: variety testing, plant breeders' rights, listing of varieties

Head of Division, Federal Ministry of Food, Agriculture and Forestry, Bonn
Alternatives to Food Production; Energy, Renewable Resources (March 1994 - July 1997)
Agriculture and Environment (March 1993 – February 1994)

Deputy Head/Head of Division, Federal Chancellor's Office, Bonn
(October 1987 - February 1993)
Food, Agriculture and Forestry

Federal Ministry of Food, Agriculture and Forestry, Bonn (May 1976 - October 1987)
Fisheries Policy, Research Planning and Research Coordination

European Commission (Cabinet level), Brussels (March 1980 – August 1980)
Research and Energy

Memberships:
Royal Swedish Academy of Agriculture and Forestry
German Society of Agriculture (DLG)

Tel. +41 22 3389155
Fax +41 22 7330336
E-mail: rolf.joerdens@upov.int

ADRIAN OTTEN

Mr. Adrian Otten is Director of the Intellectual Property Division of the Secretariat of the World Trade Organization (WTO), the responsibilities of which include intellectual property, competition policy and government procurement.

Mr. Otten is a graduate of the University of Cambridge, England. After posts with the Commonwealth Secretariat in London, working on international trade questions, and with the Swaziland Government in Brussels, assisting them in their negotiations with the EEC in the context of the first Lomé Convention, he joined the GATT Secretariat in 1975. He held a variety of posts within the GATT Secretariat. Between 1986 and 1993, he was Secretary of the Uruguay Round Negotiating Group on Trade-Related Aspects of Intellectual Property Rights.

Tel. +41 22 739 5136
Fax +41 22 739 5790
E-mail: adrian.otten@wto.org

STEPHEN SMITH

Dr. Smith is a Research Fellow and Germplasm Security Coordinator at Pioneer Hi-Bred International. The main applications of his work are to support intellectual property protection and to thereby promote innovation and the use of a broader array of genetic diversity in production agriculture. Dr. Smith earned his Bachelors degree in plant science at the University of London. His Masters degree (Conservation and Utilisation of Plant Genetic Resources) and Ph.D. (Biochemical Systematics of Zea, Tripsacum and Related Genera) were earned at the University of Birmingham in England. He conducted post-doctorate research at North Carolina State University in Raleigh on isozyme diversity in maize and teosinte

Dr. Smith participates in discussions pertaining to biodiversity, germplasm access issues, the merits of various variety fingerprinting techniques for identification and pedigree analysis and the evolution of intellectual property systems for plant varieties. Significant time is spent in support of litigation to secure Pioneer's intellectual property rights. He co-chairs the Pioneer/DuPont Genetic Resources Issues Team. Dr. Smith is involved in working groups associated with the use of molecular markers to identify varieties within UPOV. He serves on intellectual property committees of the American Seed Trade Association (ASTA), the National Council of Commercial Plant Breeders (NCCPB), the International Seed Federation (ISF), CropLife International and the International Chamber of Commerce. He is a Board member of the International Plant Genetic Resources Institute (IPGRI), a member of the international agricultural organization (CGIAR). He also provides expert advice to the Global Trust Fund for the Conservation of Plant Genetic Resources.

Dr. Smith is a member of the Crop Science Society of America and of the Economic Botany Society. He has published upwards of 70 scientific papers on fingerprinting techniques, biodiversity, germplasm conservation, and intellectual property protection of plant varieties. He chaired the Genetic Resource Division of the Crop Science Society in 2000. He is a member of the editorial board for the journal " Plant Genetic Resources: Characterisation and Utilisation". He serves on the Boards of the International Plant Genetics Resources Institute and the Des Moines Symphony Orchestra.

Tel. +1 515 270-3353
Fax +1 515 270-4312
E-mail: stephen.smith@pioneer.com

PHILIP PARDEY

Philip Pardey, an Australian native, is Professor of Science and Technology Policy in the Department of Applied Economics, University of Minnesota. Previously he was a senior research fellow at the International Food Policy Research Institute, Washington D.C. and prior to 1994 at the International Service for National Agricultural Research in The Hague, Netherlands. He has (co-)authored more than 160 books, articles, and papers and currently serves on the U.S. National Research Council's Standing Committee on Agricultural Biotechnology, Health and the Environment. Philip's research deals with the finance and conduct of R&D globally, methods for assessing the impacts of research, and the economic and policy (especially intellectual property) aspects of genetic resources and biotechnologies.

Tel. +1 612 625-2766
Fax +1 612 625-3186
E-mail: ppardey@apec.umn.edu

ALEXANDER E. OCHEM

Alexander E. Ochem, a national of Nigeria, graduated in Pharmaceutical Chemistry from the University of Trieste (Italy) and holds a Doctor of Philosophy in Molecular Genetics and Biotechnology.

Dr. Ochem has over 15 years of research experience in molecular biology and biotechnology. In 1987, he joined the International Centre for Genetic Engineering and Biotechnology (ICGEB) in Trieste after working for a brief period as a Research Fellow in the Institute of Industrial Chemistry at the University of Trieste. The ICGEB is an international centre of excellence dedicated to research, training and transfer of technology to Developing Countries. At the ICGEB, he has carried out research and studies in the areas of cell-cycle regulation, the molecular mechanisms and enzymology of DNA replication, proteomics and mass spectrometry. He also collaborates with the Biotechnology Development Unit with regards to biotechnology projects and products adaptable to the needs of Developing Countries. He has made presentations at both national and international fora. Recently, he participated in the Preparatory Workshop for the Launching of the Activities of the Multinational Project "Studies for the Elaboration of an African Program for the Development of Commercial Biotechnologies" at the African Agency of Biotechnology, Algiers.

Dr. Ochem collaborates with the Faculty of Pharmacy and the Department of Natural Resources & Commodity Economics of the University of Trieste where he has given Seminars and delivers lectures in Applied Biotechnology. He has authored/co-authored several articles published in scientific journals.

Memberships:
The Italian Society for Biochemistry and Molecular Biology (SIB)
The American Society for Biochemistry and Molecular Biology (ASBMB)
The Research Project "Biomolecole per la Vita Umana" of the Italian National Research Council (CNR), Italy.

Tel. +39 040 3757326
Fax + 39 040 226555
E-mail: ochem@icgeb.org

RAINER MOUFANG

1986 – 1988 Attorney, private law firm; Research Fellow, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, Munich

1988 Dr. jur., Ludwig Maximillian University of Munich, Ph.D. thesis on genetic inventions in industrial property law

1988 – 1998 Head of Department and Legal Researcher, Max Planck Institute of Foreign and International Patent, Copyright and Competition Law

1998 – 2002 Principal Lawyer, Directorate Patent Law, European Patent Office

Since 2003 Legal Member of the Boards of Appeal, European Patent Office

Tel. +49 89 2399 3111
Fax +49 89 2399 3014
E-mail: rmoufang@epo.org

JEFF KUSHAN

Jeffrey P. Kushan represents companies and trade associations on a diverse range of intellectual property matters, particularly strategic patent procurement, licensing, policy advice and enforcement. He currently represents clients in Hatch-Waxman and other types of patent litigation, has served as a patent expert in legal proceedings in the United States and other countries, and has been lead counsel in ***amicus filings*** in several significant patent law appeals. In 2003, he was named one of the top 45 lawyers in the United States under the age of 45 by ***American Lawyer*** magazine.

Prior to entering private practice, Mr. Kushan worked for the United States Government for over a decade. For two years, he served in the Office of the U.S. Trade Representative in Geneva, where he represented the United States on intellectual property matters before the WTO and WIPO. In Geneva, he was part of the U.S. legal team in WTO dispute settlement proceedings involving intellectual property matters, and was the chief U.S. negotiator in the WIPO "Internet" treaties. Prior to Geneva, he was an attorney advisor in the Patent and Trademark Office, where he helped develop U.S. patent policy, including by leading efforts to develop examination standards for biotechnology and software inventions. He also assisted in legislative and regulatory implementation of the TRIPS Agreement, and participated as a patent expert in negotiations on the Convention on Biological Diversity and in numerous bilateral treaty negotiations. Initially, Mr. Kushan was a biotechnology patent examiner with responsibility for evaluating pharmaceutical and diagnostic protein-based inventions.

Mr. Kushan is a frequent lecturer on domestic and international intellectual property policy issues, particularly those relating to patents in the pharmaceutical and biotechnology industries. He is a member of the adjunct faculty and of the Intellectual Property Advisory Board of the George Washington University, where he has taught courses on international and comparative patent law and on biotechnology patent policy. He serves on the executive committee of the US Committee of the AIPPI, is chair of the Patent Legislation Committee of the ABA Section on Intellectual Property Law and is an active member of the American Intellectual Property Law Association.

Tel. +1 202 736-8914
Fax +1 202 736-8711
E-mail: jkushan@sidley.com

WANG QINFANG (MS.)

Education:

1989-1992: Masters of Science, University of the Philippines and International Rice Research Institute (IRRI)

1979-1983: Bachelor of Science, Hangzhou University

Professional experience:

1999-date: Associate Professor, Deputy Director of Scientific Research Management Division, Biotechnology Research Institute (BRI), Chinese Academy of Agricultural Sciences (CAAS)

1996-1998: Assistant professor, BRI, CAAS

1993-1995: Project Officer, Zhejiang Environmental Protection Foundation, the World Bank

1990-1992: Assistant researcher, Tissue Culture Lab, Plant Breeding Dept. of IRRI

1983-1988: Assistant engineer, Zhejiang Research Institute of Environmental Protection

Tel. +86 10 68919850
Fax +86 10 68975402
E-mail: qfwang@mail.caas.net.cn

EVANS SIKINYI

Evans Sikinyi graduated from the University of Nairobi in 1981 with BSc. Agriculture (Upper 2nd class honors), upon which he was employed by the Scientific Research Division of the Ministry of Agriculture, at the National Horticultural Research Station, Thika as a Research officer. His responsibilities included introduction and evaluation of upland rice and sorghum. In 1984, he returned to the University of Nairobi, under the IDRC sponsored Pigeon Pea improvement project, as a Research assistant graduating with a MSc. in Plant breeding degree. Between 1986 and 1992 he worked as a breeder and head for the seed production research program at the National Horticultural Research Centre, under the Kenya Agricultural Research Institute (KARI) sponsored by UNDP/FAO horticulture improvement programme.

In 1993 he won a USAID scholarship to study for a PhD at Iowa State University. He worked as a research assistant in the Department of horticulture under the potato transformation and molecular studies project, and graduated in 1996. On his return to Kenya he worked with the USAID/MIAC horticulture development project as a Senior Research Officer in KARI. In 1997 he was appointed officer-in-charge of the Plant Breeders Rights Office.

From 1997 to 1999 he has been involved in forming and operationalising the Plant Breeders Rights Office, reviewing the regulations and eventually accession to the UPOV Convention. He has had extensive training in intellectual property rights in Europe and USA. Apart from Conventional breeding, he is specialised in biotechnology, seed technology, and bio-diversity issues, as well as intellectual property issues. In 1999 he was appointed as the Registrar, Plant Breeders Rights, under the Kenya Plant Health Inspectorate Service (KEPHIS).

Tel. +254 2 4440087
Fax +254 2 448940
E-mail: pvpo@kephis.org / kephis@nbnet.co.ke

ARNOLD VAN WIJK

After completing his MSc in Plant Breeding at the Agricultural University, Wageningen, the Netherlands in 1971, Arnold van Wijk worked from 1971 – 1978 as a breeder of tropical grasses in Kenya. In 1978 he returned to the Netherlands to take up a position as breeder of forage and turf grasses at D.J. van der Have B.V., later called Advanta Seeds. In 1984 he became head of the international grass breeding program of that company. Based on the results of his work in Kenya, Arnold van Wijk obtained a PhD degree of Wageningen University in 1980 on a thesis called "Breeding for improved herbage and seed yield in ***Setaria sphacelata***". He was Director of the International Turfgrass Society, Secretary of Eucarpia Fodder Crops Section and served on various other committees.

In 2000 Arnold van Wijk became head of the cluster Plant Variety Resarch of the Centre for Genetic Resources, the Netherlands in Wageningen and as such responsible for DUS/PBR testing of agricultural and ornamental crops for the Dutch Board for Plant Breeders' Rights and the Community Plant Variety Office. He is course director of an annual international course on Plant Variety Protection, is involved in projects on the implementation and impact of Plant Variety Protection and serves as chairman on two committees of NAK (Dutch General Inspection Service for Agricultural Seeds and Seed Potatoes).

Tel. +31 317 477012
Fax +31 317 418094
E-mail: arndjan.vanwijk@wur.nl
Website: http://www.cgn.wageningen-ur.nl

BERNARD LE BUANEC

Education
- "Ingénieur Agronome" of the "Ecole de Grignon", France, 1966
- Post Graduate in Soil Science, 1967
- Ph.D. in Plant Biology, 1973

Main Occupations

CIRAD-ORSTOM Scientist in Agronomy 1967-1975
1969-1975 Ivory Coast (Head of the Agronomy Dept, 1972-75)

Groupe Limagrain

1976-1979	Production Manager
1980-1984	President and Chief Executive Officer of Mennesson Company: Breeding, production and commercialization of cereals and beet seeds
1985-1993	Senior Vice-President of Groupe Limagrain: Research
1987-1993	Chairman of the Boards, President and CEO of Biocem (France), Biocem Nickerson (UK), Biocem Pacific (Australia): Plant biotechnology companies
1989-1993	Chairman of the Board of Gene Shears (Australia): Joint Venture between CSIRO, Johnson & Johnson and Limagrain

Some Official Positions

FIS/ASSINSEL now ISF

1993-	Secretary General
1986-1993	Scientific Committee of the French National Institute for Agronomic Research (INRA) (member).
1989-1995	Comité pour la protection des obtentions végétales (France) (member).
1990-1994	Conseil supérieur de la recherche et de la technologie (France) (member).
1997-1998	World Bank Panel on Biotechnology and Intellectual Property (member).
1998-2002	Scientific Committee of the French National Institute for Agronomic Research (member).
1998-	Genetic Resources Policy Committee, CGIAR (member).

Some Elected Positions

1986-1990	Maize Section of the International Association of Plant Breeders for the Protection of Intellectual Property (ASSINSEL) (President)
1987-1992	Founder, member of the Steering Committee then Chairman of GIBiP (European Green Industry Biotechnology Platform)
1987-1991	Intellectual Property Group of ASSINSEL (Chairman)
1991-1993	Vice-President, then President of ASSINSEL
2000-	Member of the French Academy of Technologies
2003-	Member of the French Academy of Agriculture

Tel. +41 22 3654420
Fax +41 22 3654421
E-mail: isf@worldseed.org

JOHN GERARD

President, ACCESS Plant Technology, Inc.

Degree: 1961 Purdue University- Ag Education Major

1961-1964: VoAg Instructor, High School- Pine Village, IN

1964-1965: Assistant Manager, Indiana Crop Improvement Association

1965-1970: Manager, Indiana Crop Improvement Association- Wrote MS thesis on Cold Vigor Soybean Testing.

1970-1979: Founder/Owner/President of V.R. Seeds- In 9 years, sales went from 0 to 1,000,000 unit sales of private soybean varieties. Sold V.R. Seeds to Agrigenetics.

1979-1982: Vice-President, Agrigenetics Corporation- Responsible for private label licensing and working with Biotech personnel.

1982-Present: Founder/Owner/Chairman, JGL, Inc.- A soybean and wheat genetics licensing business.

1984-1988: Founder/Owner/President, Plant Science Research, Inc.- A soft red winter wheat breeding company. Sold to Bio Technia, Inc.

1990-1995: Founder/Co-Owner/President, Seed Genetics, Inc.- A corn genetics licensing company. Sold my half of stock to partner.

1995-Present: Founder/Co-Owner/President, ACCESS Plant Technology, Inc.- A plant biotechnology licensing business.

- Past Regional Vice-President ASTA
- Current Chairman ASTA Intellectual Committee
- Current member FIS Intellectual Property Group
- Past President: Indiana Seed Trade Association
- Indiana Crop Improvement Association
- NCCPB
- ASTA: Member Board of Directors

Tel. +1 574 936 3820
Fax +1 574 936 3720
E-mail: jgerard@accessplant.com

OSCAR DOMINGO

Oscar Domingo was born in Buenos Aires -Argentina in October 22 of 1939. He is married with three children and three grand-daughters.

Graduated as Agronomical Engineer in the University of Buenos Aires in 1966 and as Magister Scientiae in the Graduate School in Agricultural Sciences of Argentina in 1971.

He is in seed business since four years before graduation, beginning his professional career in 1962 in a family-owned seed company. Then he worked five years in Dekalb Argentina S A (Argentine subsidiary of Dekalb Co USA , now Monsanto) in the hybrid wheat breeding program. He moved to Northrup King Semillas S A -Argentine subsidiary of Northrup king Co USA, Sandoz, now Syngenta) as Seed Research Director from 1972 to 1988 and Manager of the Marketing Division from 1988 to 1990.

In the last ten years he is one of the Shareholders and Member of the Board of Relmo S A, an Argentina (family-owned) seed company , involved in soybean, wheat and corn seed business.
Mr. Domingo was member of the first Technical Committee of the National Seed Commission in 1979. Now is Chairman of the Technical Forage Crops Committee, and Vice Chairman of the Corn and Sorghum Technical Committee.

From 1967 to 1973 he was Professor of Forage Crops at the Agronomy Faculty of the University of Buenos Aires.

From 1995 to 1999 he was Member of the Board of the Argentine Seed Association and from 1999 to April 2003 he was elected President of such institution.
He is an active golf player.

Tel. +54 2352 428089
Fax +54 2352 431733
E-mail: odomingo@infovia.com.ar

THANDA WAI

Intellectual Property Rights Specialist, Intellectual Property Management Unit, Office of the Deputy Director for Partnerships

Education:

B.Sc. in Cell, Molecular, and Developmental Biology, McGill University, Montreal, Quebec, Canada.

M.Sc. in Cell Biology from the Dept. of Biological Sciences, University of Cincinnati, Cincinnati, Ohio.

Thesis title: A Study in the Packaging of the Vaccinia Virus Chromosome Using Aminomethyltrioxalen (AMT).

Ph.D. jointly from the Dept. of Botany and Plant Pathology and from the Genetics Program, Michigan State University, East Lansing, Michigan.

Dissertation title: Genetic and Physiological Characterization of Naturally-Occurring Multiple Potyvirus Resistance in the Inbred Chinese Cucumber Line TMG-1.

Experience:

Postdoctoral Fellow, Molecular Plant Pathology Laboratory, Agricultural Research Service, USDA, Beltsville, Maryland. Field tested the efficacy of tomato plants that were engineered with various RNA satellites of cucumber mosaic virus (CMV).

Patent Examiner, US Patent and Trademark Office, in general and plant biotechnology, Alexandria, VA, USA, 3 years.

Patent Advisor, Agricultural Research Service, USDA, Albany, California, USA, 2 years.

Intellectual Property Rights Specialist, International Rice Research Institute, Los Baños, Philippines, 2 ½ years.

Tel. +63 2 845 0563
Fax +63 2 845 0606
E-mail: t.wai@cgiar.org

WIPO-UPOV SYMPOSIUM ON INTELLECTUAL PROPERTY RIGHTS IN PLANT BIOTECHNOLOGY

Geneva, October 24, 2003

Opening Address

H.E. MR. ALEJANDRO JARA
Ambassador and Permanent Representative of Chile, Geneva

Ladies and gentlemen,
Friends and colleagues,

It is a pleasure and honor for me to be here with you. I must confess a certain nervousness because I know next to nothing about intellectual property rights and plant biotechnology, but I am not to be held fully responsible for my being here. I have been invited and I have accepted it as a challenge and I am going to learn a lot from you in the course of this Symposium.

WIPO and UPOV have convened this second Symposium on plant biotechnology to examine the role of intellectual property more closely in this specific area at the international, regional and national levels.

This Symposium will specifically focus on how intellectual property rights, i.e., patents and breeders' rights, are effectively used and managed in the field of plant biotechnology.

This requires an understanding of how complex legal frameworks interact from both an institutional and an operational point of view. Therefore, this Symposium has brought together speakers and participants from governments, international organizations, academics and legal experts, as well as companies active in biotechnology and plant breeding.

Speakers will address issues such as the importance of patents and plant breeders' rights in dissemination of technology and development of particular research and business licensing strategies; accessibility of protected inventions and plant varieties for further innovation and breeding will also be covered.

As it was pointed out at the last year's WIPO-UPOV Symposium, biotechnology is a fast-growing area of the world economy, for all countries - developed and developing. This area is not free of its controversies or conflicting views. Some have labeled it a "burning issue." And because of the great interest shown by the participants and the importance they have strongly voiced on this topic, the two Organizations have responded by organizing this second Symposium.

Today's presentations, we hope, will assist us to better understand the role of intellectual property in this field. In particular, the issues raised in last year's Symposium will again be addressed, but in addition, the development of national or regional policy and legislation will be reviewed, as well as the business strategies, to see if we are meeting the current demands of society and that of the users of the intellectual property systems.

Therefore, today's Symposium is divided into four sessions with their focus on:

(1) Plant Biotechnology Developments in the International Framework;
(2) Plant Biotechnology and its Dissemination, as an overview;
(3) Intellectual Property in Plant Biotechnology: National/Regional Experiences;
(4) Management of Intellectual Property Rights.

And at the end, there will be a panel discussion under the heading, "Enhancing the Benefits of Intellectual Property," where more of you from the floor will have a chance to raise questions or make comments.

All of the papers will be posted on WIPO and UPOV Websites immediately after the Symposium.

I should like to express from the outset, our gratitude to our distinguished speakers who have kindly accepted the invitation of WIPO and UPOV. Their knowledge and experience on the topics of the Symposium will no doubt enlighten our discussions.

With this, I declare the "WIPO-UPOV Symposium on Intellectual Property Rights in Plant Biotechnology" open, and move directly on to the first Session.

I must also tell our colleagues, the speakers, that I will be observing a strict time-limit as we all want to have a chance to hear all the speakers and to give also our colleagues from the floor a chance to make comments or ask questions.

I will also refrain from introducing the speakers, since everybody has their profile in the materials handed to you for this Symposium.

SESSION I

Plant Biotechnology Developments in the International Framework

MR. FRANCIS GURRY
Assistant Director General, World Intellectual Property Organization (WIPO)

It is my great pleasure to join Ambassador Jara in welcoming you here this morning on behalf of Dr. Kamil Idris, in his capacity as Director General of WIPO.

WIPO is delighted to be co-hosting this Conference today. For us, it represents an opportunity to explore some of the complex issues relating to intellectual property in the context of plant biotechnology. I share Ambassador Jara's trepidation in approaching these issues, not only because they are inherently complex, but also because, I think it is fair to say, they have developed, at least on the international stage, in a way that leaves much to be desired in terms of the clarity with which the issues have been defined and the relationship of the issues to each other and to other areas of public policy.

For WIPO, plant biotechnology evokes first and foremost the patent system. It may be noted at the outset that, throughout its evolution over the last several hundred years, the patent system has applied in essentially the same way, more or less without exception, to all forms of technology. It is unlike copyright, where there are often technology-specific provisions and sectoral- or industry-specific provisions. It is also unlike plant variety protection, which is limited to a specific subject matter. In view of the technology-neutral evolution of the patent system, does the area of plant biotechnology raise any special questions that require specific attention and a deviation from the general rule of neutrality to technology or sector? The main currents of discussion internationally suggest that there are four such issues and I should like to touch on each of them in outline.

The first of the issues is the well-known question of the availability of protection in this area, an issue which is regulated by Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and, more specifically, by Article 27.3(b). This issue is being reviewed in the TRIPs Council and also received a considerable amount of attention in the WIPO-UPOV Conference held one year ago. Article 27.3(b) leaves a large measure of choice to national systems. Various models are possible at the national level. Plants may be excluded from patent protection, but some form of incentive for innovation must be provided specifically in relation to plant varieties, whether that be through patents or through ***sui generis*** plant variety protection. What seems apparent in relation to the choice available under Article 27.3(b) is that there is a need for more empirical data on the results obtained from the application of different models at the national level, including data on which models seem to be successful and which, if any, seem to generate problems and for what reasons.

Moving from the question of the availability of protection, a second issue that has generated considerable discussion internationally is the different approaches of the patent system, on one hand, and plant variety protection, on the other hand, to the availability of germ-plasm that may be covered by those rights. The patent system tends to take a relatively narrow approach to this question, and allows only a limited exception for the purposes of research, which is, as a general rule, construed narrowly[1]. On the other hand, the plant variety protection system under the

[1] See, as one example of an approach to the research exemption at the national level, ***Madey*** v ***Duke Univ.***, 307 F.3d 1351 (Fed. Cir. 2002), cert. denied 156 L.Ed.2d 656 (2003).

UPOV Convention takes a broader approach to the question and allows a wider range of activity in the interests of experimentation, breeding of other varieties and the use of farm-saved seeds for propagating purposes[2]. But these exemptions and these two approaches are situated in the context of completely different systems. In the case of the patent exemption, it applies to a conceptually non-obvious result. The patent right does not withdraw any existing germ-plasm from use. What is withdrawn from use is germ-plasm that has been the subject of a conceptually non-obvious modification or application. Plant variety protection, on the other hand, is directed to what are, arguably, well-known or obvious techniques, where the nature of the innovation is more incremental and builds more upon the basis of preceding varieties. The level of the innovation warrants a proprietary right that is less extensive.

Does this difference in approach to the operation of the research or experimentation and breeding exceptions matter? In general, there are two responses given to this question around the world. One response, which is to be found to some extent in the European Directive on the Legal Protection of Biotechnological Inventions[3], seeks to compensate for the narrowness of the patent research exception by making available a compulsory licence of the patent "where a breeder cannot acquire or exploit a plant variety without infringing a prior patent". The other response eschews regulation of the relationship between the two sorts of rights and their differences and leaves the interface between the rights to be determined by the market, notably by leaving it to economic agents to negotiate access to dependent or associated rights through voluntary licences. Licensing practices are, in most countries, subject to regulation in the event of abuse of dominant position through antitrust or anti-competitive practice legislation.

The market approach and market mechanisms have the obvious advantage of not being industry- or technology-specific in approach. In this regard, it is pertinent to recall that the quantity of technology dealt with by the patent system is of a completely different order to the quantity of technology that is dealt with by the plant variety protection system. In 1999, for example, there were 4.37 million patents in force around the world, according to the Trilateral Statistical Report[4].

That is a number that is of a completely different order to the number of plant varieties, which I think you will find is more in the vicinity of 50,000 titles in force at any given time, and naturally so, since the patent system applies to all technologies. In similar fashion, the number of patent applications worldwide in the year 2000 represented about 750,000 new inventions (measured by first filings). In view of the magnitude of economic activity represented by patent applications, one needs to exercise the greatest of care before creating specific regulations related to one particular sector or technology.

A third area that has incited considerable attention internationally is the cluster of issues that are related to access to genetic resources and benefit-sharing. These issues are not limited to plant genetic resources, but they have a major application to plant genetic resources.

The first thing that needs to be said about this area is that access to genetic resources is first and foremost a question of physical property. Any regulatory attention, whether of a legislative or an administrative nature, given to the question should in the first place address the question of physical property and physical access. How do intellectual property rights come into the question at all? Well, they become relevant as a consequence of the use of genetic resources to which access has, or may have, been granted. That use may give rise to an invention that is susceptible of protection by an intellectual property right.

Three main questions have been discussed internationally in connection with intellectual property and access to genetic resources. The first of those is whether there should be a sharing of benefits by the owner of an intellectual property right in respect of that right if it involves or is based upon

[2] See Article 15, International Convention for the Protection of New Varieties of Plants ("the UPOV Convention") (1991 Act).
[3] See Article 12 of Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions
[4] Trilateral Statistical Report 2000 available at ***http://www.uspto.gov/web/tws/sr-2.htm***

genetic resources to which access has been given? The Convention on Biological Diversity (CBD) has provisions that require Contracting Parties to "take legislative, administrative or policy measures, as appropriate, … with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources."[5] On the basis of the work of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, the Conference of Parties of the CBD adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.[6] A Second Meeting of the Working Group will take place in December 2003. While the issues are complex, it is apparent that it is very short-sighted to regard intellectual property as a form of plunder of genetic resources. It is, because of licensing, in fact an efficient mechanism for returning benefit to the owner of genetic resources.

A second question that arises in this context is whether intellectual property rights that might be acquired with the use of genetic resources to which access has been given limit the further use of those genetic resources in a way that is harmful to public policy? This is a question that is, in particular, being considered in the context of the International Treaty on Plant Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations (FAO) and the development of the material transfer agreement for the purposes of that treaty. This work is just underway.

A final question in this area is whether the intellectual property system, in general, or the patent system, in particular, is a useful instrument for implementing the policy of legal access to genetic resources? This is the well-known question of disclosure of the origin of genetic resources used in an invention. Should there be a provision in patent law that would require the disclosure of the source or origin of any genetic resources that are used in an invention for which patent protection is applied and, if so, what is the nature of this requirement and what is the nature of any legal remedy that might be applied in the event that the requirement is not complied with? It is very important to contextualise these questions. They are not questions of patent law, but questions of genetic resource policy. At the request of the CBD, formulated in the Bonn Guidelines[7], WIPO prepared a technical study[8] on various issues related to the patent system and the policy of legal access to genetic resources, which has now been approved by the Member States of WIPO for transmission to the next Conference of Parties of the CBD.

There is a final area. It would be very remiss of me not to mention a fourth issue which, like most of these issues, is related to, but not exclusively concerned with, plant biotechnology. It is the question of traditional knowledge. Traditional knowledge can and does exist in relation to plant genetic resources as it exists in other domains and spheres. At WIPO, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has been considering this question very carefully. Recently, the WIPO General Assembly decided to extend the mandate of the IGC. It decided that the IGC's work should continue on all issues, including genetic resources, that have been before the Committee and that its work should focus in the future, in

---

5 Article 15.7, Convention on Biological Diversity

6 Decision VI/24

7 "The Conference of Parties …

4. Invites the World Intellectual Property Organization to prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, ***inter alia***:
   a. Genetic resources utilized in the development of the claimed inventions;
   b. The country of origin of genetic resources utilized in the claimed inventions;
   c. Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;
   d. The source of associated traditional knowledge, innovations and practices; and
   e. Evidence of prior informed consent."

8 Draft Technical Study on Disclosure Requirements related to Genetic Resources and Traditional Knowledge (document WO/GA/30/7Add.1) available at ***http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/index_30.htm***).

particular, on the international dimension of these questions. It further decided that no outcome should be excluded for the work of this Committee. The IGC next meets in March 2004 and its work program over the next two years is expected to be solid and vigorously pursued.

Plant Biotechnology Developments in the International Framework

MR. ROLF JÖRDENS
Vice Secretary-General
International Union for the Protection of New Varieties of Plants (UPOV)

I. INTRODUCTION

1. A year ago, on October 25, 2002, the World Intellectual Property Organization (WIPO) and the International Union for the Protection of New Varieties of Plants (UPOV) organized a Symposium on the "Co-existence of Patents and Plant Breeders' Rights in the Promotion of Biotechnological Developments." The purpose of the Symposium was to address the challenges facing inventors and plant breeders in the light of developments in the world of plant biotechnology and, in particular, genetic engineering.

2. The issue attracted a large degree of attention and provided a unique opportunity to identify measures which could be necessary for the balanced co-existence of patents and plant breeders' rights. In particular, it highlighted: the necessity of well identified measures based on reliable research; clarification of the scope of the research exemption in the national laws; the policy that the industry is likely to follow concerning protection of biotechnological inventions or breeding work; and good cooperation in the fields of patents and plant breeders' rights.

3. In response to the issues raised at that Symposium and, in particular, the need for good cooperation in the fields of patents and plant breeders' rights, UPOV and WIPO recognized the value of considering how these intellectual property rights operate at an international, regional and national level.

4. The purpose of my presentation is to illustrate the impact of the UPOV system in promoting the development of new varieties of plants and to recall some of the key features of the UPOV Convention which enable it to optimize advances in the development of new varieties.

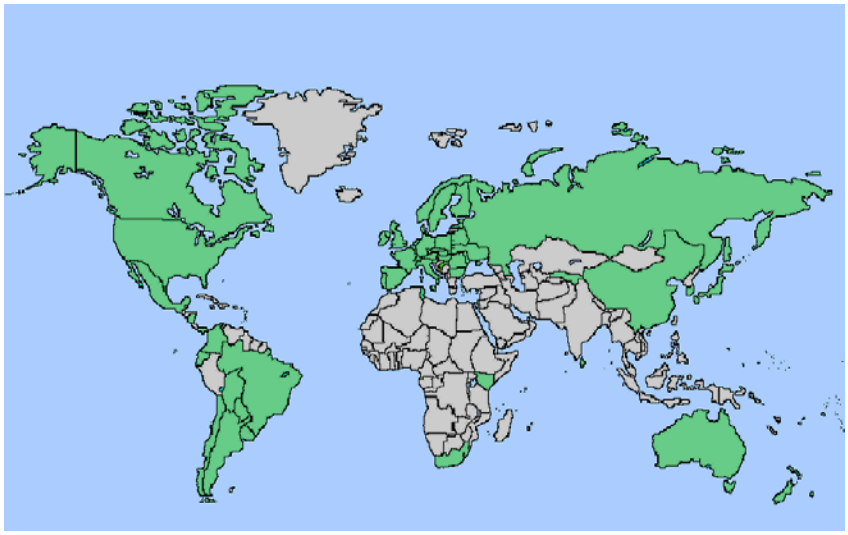
II. IMPACT OF THE UPOV SYSTEM

5. A growing number of States are aware of the need to create a favorable environment for investment in plant breeding, which is recognized as a crucial tool in the development of agriculture and as a basis for overall economic development. The majority of States are opting for a UPOV based ***sui generis*** system, sometimes in parallel to patent protection, for plant varieties. UPOV has now 53 members (Figure 1a). On the one hand, UPOV covers the most important agricultural producers and countries with the largest populations worldwide, but on the other hand, more than half of the UPOV members are from the developing world. In 2003, two States have joined UPOV and five additional States have requested the Council of UPOV to assess the conformity of their legislation on plant variety protection with the UPOV Convention because they have taken a decision to become a member of UPOV.

6. UPOV continues to be the only internationally harmonized and effective ***sui generis*** system of plant variety protection and is continuing to expand. Figure 1b shows States/Intergovernmental Organizations which have initiated the process to accede to UPOV. Statistics provided to UPOV show that around 7,500 new titles of protection, based on principles of the UPOV Convention, have been granted in 2002 (Table 1).

Figure 1a

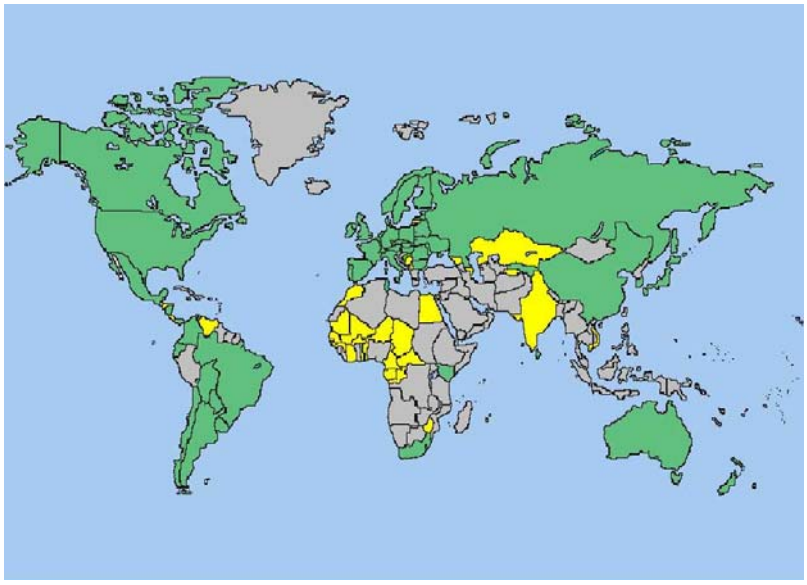
Members of UPOV (August 2003)



States in dark grey (green when printed in color) = UPOV members

Figure 1b

States/Intergovernmental Organizations Having Initiated Accession to UPOV



States/Organizations which have initiated the process to accede to UPOV in light grey (yellow when printed in color)

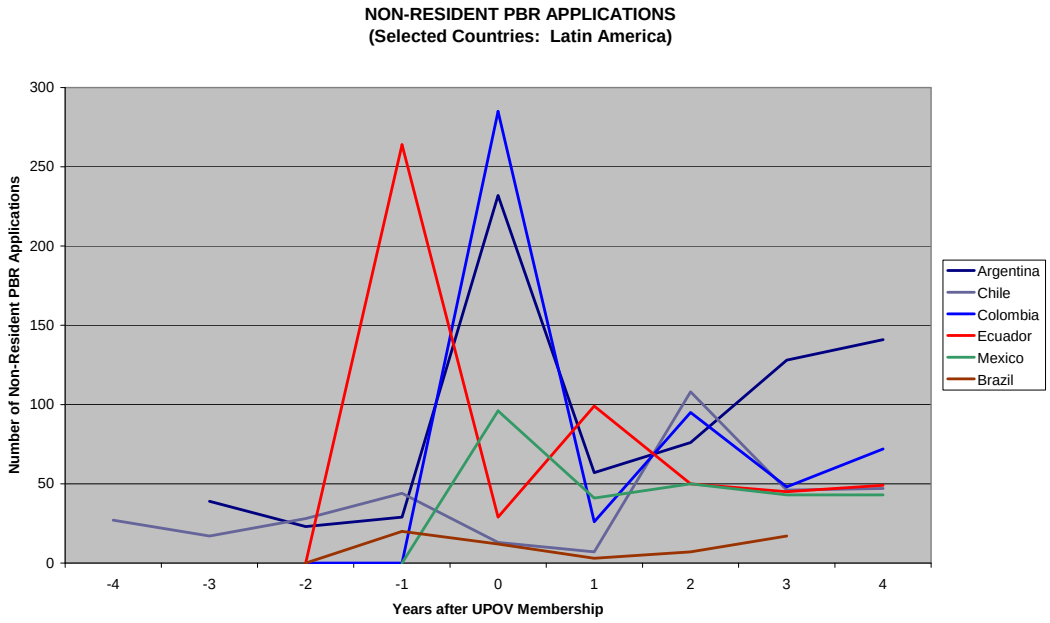
Table 1 Titles of Protection Based on the UPOV Convention

Year	Applications filed by:			Titles issued to:			Titles in force at end of reference year
	Residents	Non-residents	Total	Residents	Non-residents	Total	
1992	4,137	3,128	7,265	2,547	2,032	4,579	24,988
1997	5,645	2,653	8,298	3,122	1,791	5,925	36,152
2002	(6,571)	(3,560)	(10,131)	(5,378)	(2,041)	(7,418)	(51,106)

( ) = provisional figures

7. Introduction of the UPOV system of plant variety protection often results in immediate benefits for a State. In particular, the protection offered encourages foreign breeders to make new varieties available to the farmers, growers and plant producers in that State and thereby to allow the latter to increase their productivity and competitiveness. Furthermore, the breeder's exemption also allows these varieties to be used by local breeders to improve their own breeding programs (Figure 2).

Figure 2: Applications of Non-Residents for Plant Breeders' Rights: Selected Countries in Latin America.



8. A comparable effect to the one in Latin American countries can be observed in other countries e.g. those in transition to a market economy (Figure 3) and various other countries and regions of the world (Figure 4). The immediacy and scale of the impact will depend on factors such as the number of species for which protection is offered and the level of breeding activity which exists in the country.

Figure 3

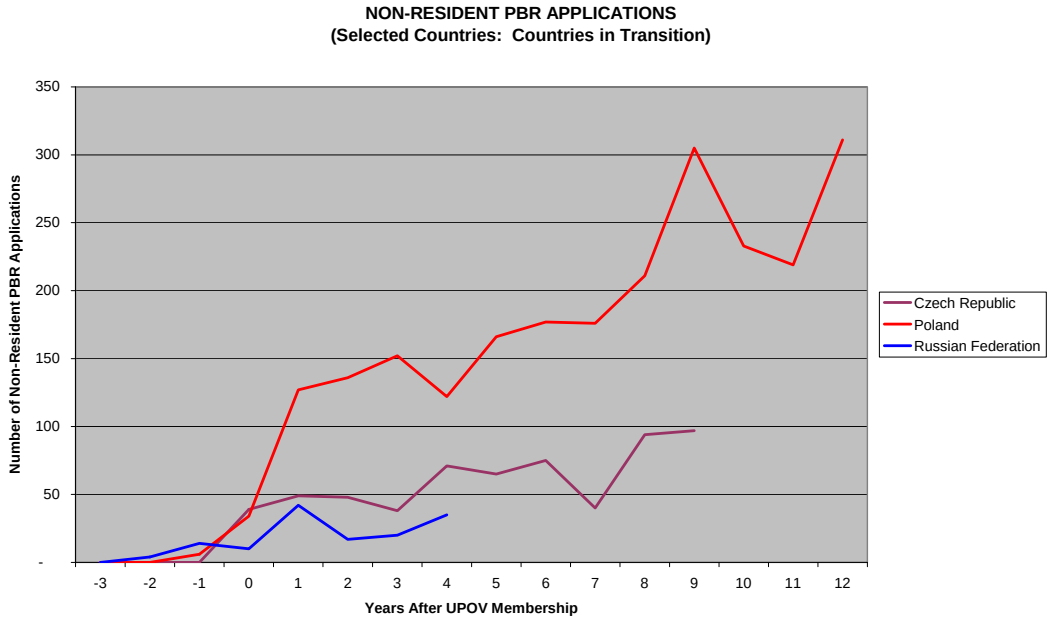
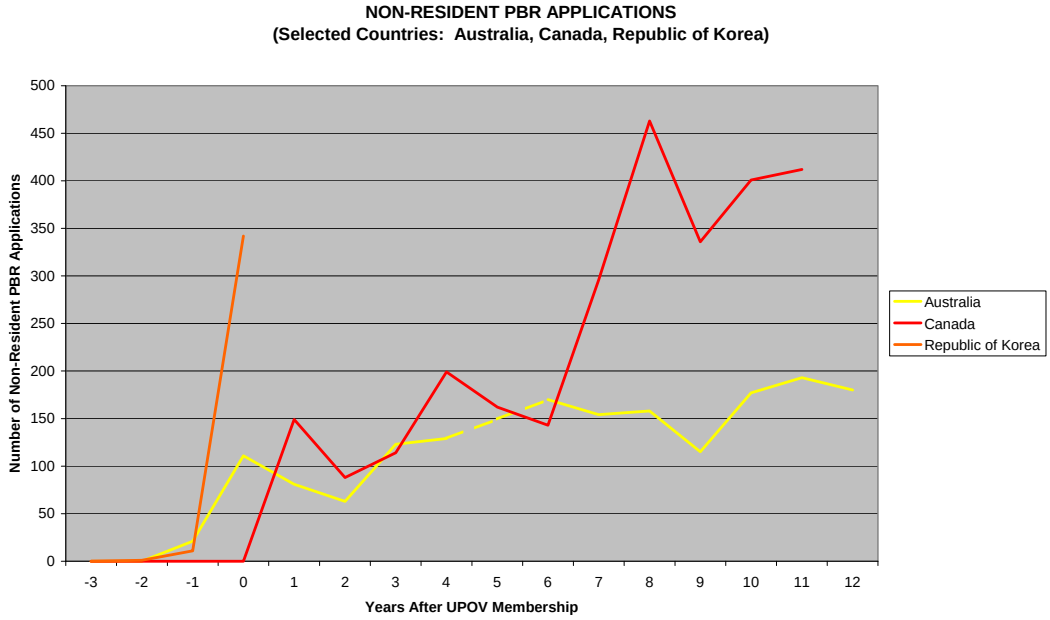


Figure 4



9. Figures 5, 6 and 7 use statistics from the countries featured in Figures 1 to 3, to show that, regardless of the immediacy and scale of the initial impact, the long-term steady growth in the number of titles of protection in force, reflecting the development of new varieties of plants, is a common benefit.

Figure 5

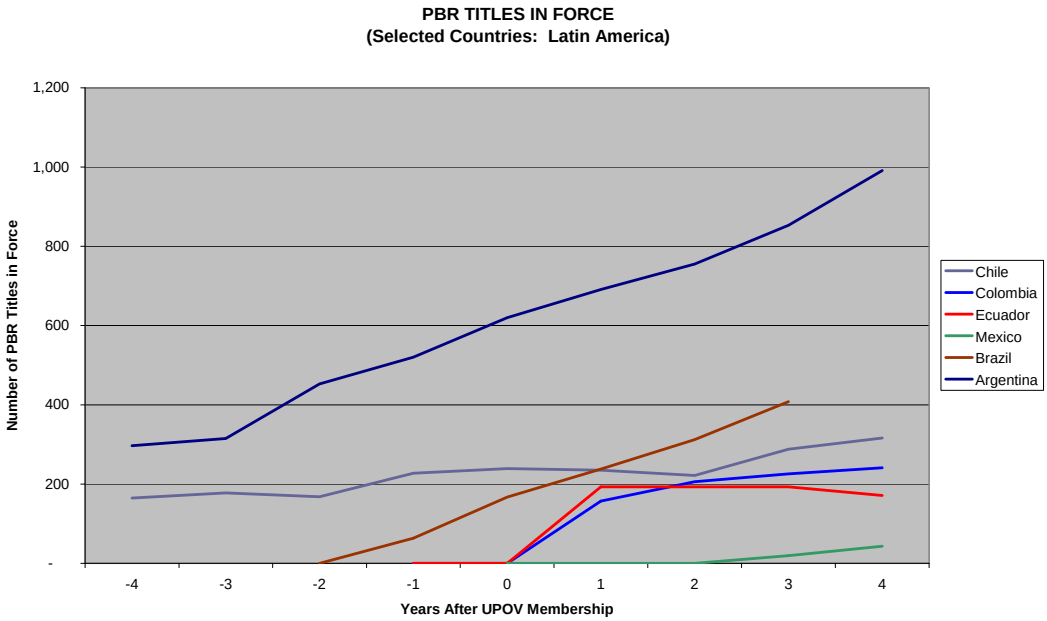


Figure 6

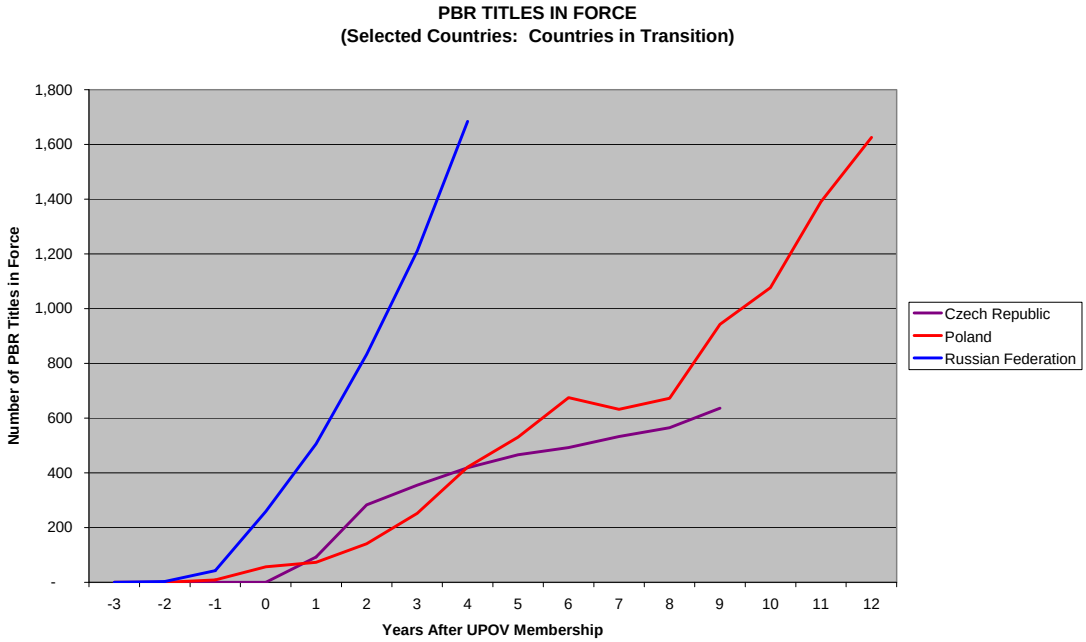
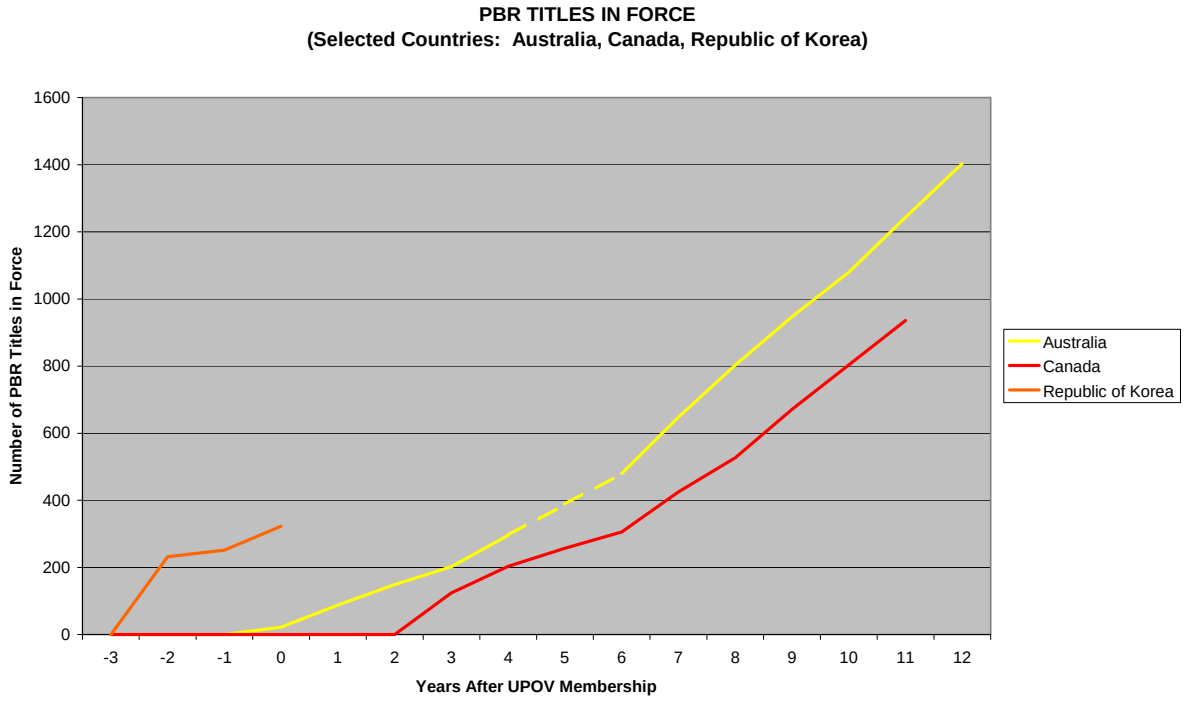


Figure 7



10. UPOV has established a study group which is examining the impact of plant breeders' rights in selected countries, in more detail. An intermediate report on its work will be provided later during this Symposium.

III. Basic Features of the UPOV Convention

Conditions for Protection and Rights Granted

11. The UPOV Convention provides for an effective ***sui generis*** system of plant variety protection. It is particularly adapted to the features of plant breeding and to the requirements of the plant breeders and beneficiaries of new plant varieties, particularly, farmers, growers and producers. The benefits of the UPOV system include:

(a) implementation on a national or regional level does not require the setting up of complex structures;
(b) examination procedures which are harmonized and well-defined;
(c) harmonized application procedures which are straightforward for applicants without legal experience.

New members benefit immediately from 40 years of experience acquired within UPOV. Thus, effectiveness is enhanced and cost of protection is kept low.

12. The basic features have remained essentially unchanged since the Convention was established in 1961. Based on the 1991 Act of the Convention, they may be summarized as follows:

- A natural or legal person who has bred or discovered and developed a variety may apply for a breeder's right in respect of this variety;

- Provided that the variety is designated by a suitable denomination and that the applicant complies with the formal requirements and pays the fees, a breeder's right shall be granted by the relevant authority after it has been assessed that the variety is:

    - novel (commercially new);

    - clearly distinguishable from any other variety of common knowledge;

    - sufficiently uniform and stable in its relevant characteristics.

- A breeder's right, in respect of a protected variety and certain other varieties, implies that, for a fixed period of time, propagation of these varieties and certain related acts require the authorization of the breeder.[1]

- The UPOV Convention stipulates that the breeder's right shall be independent of any measure regulating the commerce of material of the protected variety.

13. The UPOV system of plant variety protection is characterized by certain exceptions which provide a balance between the exclusive right granted to a breeder and provisions to ensure that the overall benefit is maximized.

Compulsory Exceptions

14. The breeder's right does not extend to

- acts done privately and for non-commercial purposes;

- acts done for experimental purposes; and

- acts done for the purpose of breeding other varieties and for the purpose of exploiting these new varieties provided the new variety is not a variety essentially derived from another protected variety (the initial variety). The exploitation of essentially derived varieties requires the authorization of the breeder of the initial variety.

The Breeder's Exemption

15. The latter exception of "acts done for the purpose of breeding other varieties", is a fundamental element of the UPOV system of plant variety protection and is known as the "breeder's exemption." It recognizes that real progress in breeding–which must be the goal of intellectual property rights in this field–relies on access to the latest improvements and new variation. Access is needed to all breeding materials in the form of modern varieties, as well as landraces and wild species, to achieve the greatest progress and is only possible if protected varieties are available for breeding.

---

[1] Article 14(1)(a) of the 1991 Act of the UPOV Convention specifies "… the following acts … in respect of the propagating material of the protected variety shall require the authorization of the breeder:
(i) production or reproduction (multiplication),
(ii) conditioning for the purpose of propagation,
(iii) offering for sale,
(iv) selling or other marketing,
(v) exporting,
(vi) importing,
(vii) stocking for any of the purposes mentioned in (i) to (vi), above."
Under certain conditions, these acts are also covered in respect of harvested material of the protected varieties (Article 14(2)).

16. The breeder's exemption optimizes variety improvement by ensuring that germplasm sources remain accessible to the whole community of breeders. However, it also helps to ensure that the genetic basis for plant improvement is broadened and is actively conserved, thereby ensuring an overall approach to plant breeding which is sustainable and productive in the long term. In short, it is an essential aspect of an effective system of plant variety protection that has the aim of encouraging the development of new varieties of plants, for the benefit of society.

17. The breeder's exemption is of particular relevance for small and medium-sized enterprises and means that barriers to entry into plant breeding are relatively low. This is important since we have seen that in the first instance, after the introduction of the UPOV system on a national level, there is a strong influx of foreign varieties. Local breeders may build on the value of foreign-bred varieties, and produce locally adapted varieties which are an improvement on both foreign-bred and existing local varieties.

18. The Food and Agriculture Organization of the United Nations (FAO), at its 31st Conference, on November 3, 2001, adopted the International Treaty on Plant Genetic Resources for Food and Agriculture. This Treaty (Article 13.2. (d)(ii)) recognizes the concept of the breeder's exemption, in that breeders are excepted from financial benefit-sharing whenever their products are "available without restriction to others for further research and breeding …".

Subsistence Farmers

19. In addition to the breeder's exemption and the research exemption, the UPOV Convention contains another compulsory exception to the breeder's right whereby the breeder's right does not extend to acts done privately and for non-commercial purposes. Therefore, activities of subsistence farmers, where these constitute acts done privately and for non-commercial purposes, are excluded from the scope of the breeder's right and such farmers freely benefit from the availability of protected new varieties.

Optional Exception: Farm-Saved Seed

20. The provision on "farm-saved seed" (also known as the "farmer's privilege") is an optional mechanism provided by the UPOV Convention, under which UPOV members may permit farmers, on their own farms, to use part of their harvest of a protected variety for the planting of a further crop. Under this provision, members of UPOV are able to adopt solutions, which are specifically adapted to their agricultural circumstances. However, this provision is subject to reasonable limits and requires that the legitimate interests of the breeder are safeguarded, to ensure there is a continued incentive for the development of new varieties of plants, for the benefit of society. For example, certain members of UPOV only apply the provision on farm-saved seed to certain species and limit its application using criteria such as the size of the farmer's holding or the level of production. Such measures have the benefit of allowing selected farmers to maximize the benefit of new varieties in a way which does not jeopardize the incentive for breeders to continue the development of new varieties.

Essentially Derived Varieties (EDV): Facilitating Co-existence of Breeders' Rights and Patents

21. The advent of genetic engineering required action when the UPOV Convention was amended in 1991. Whilst, using classical breeding techniques, it takes many years to breed new varieties of most species, genetic engineering offered the prospect of modifying varieties of most species in the laboratory in a matter of months by adding one or more genes. Provided the new varieties were clearly distinguishable from the initial variety, they could, under the terms of the 1978 Act, be protected with no recognition of the contribution of the breeder of the initial variety to the end result. The situation was in contrast to the protection offered by the patent system where the gene in question was the object of patent protection. Thus, if the breeder of the initial variety had wished to add the patented gene to his initial variety to produce a new variety, it appeared that the exploitation of the new variety would fall within the claims of the patent.

22. This situation presented a challenge for policy-makers, who knew that the kinds of improvements generated by classical plant breeding were frequently the result of numerous genes interacting in complex ways, while the kinds of improvements achieved by genetic engineering were typically based on one or a few genes. To optimize plant improvement and encourage sustainable plant breeding development, it was necessary to tailor the UPOV intellectual property system in a way which encouraged both types of activity.

23. The outcome of the ensuing policy debate was the inclusion, in the 1991 Act, of the concept of the essentially derived variety. The essence of this concept is that the scope of the breeder's right for a variety extends to any varieties which are essentially derived from it. If a variety is essentially derived from another variety (the initial variety), for example by inserting a patented genetic element through genetic engineering, it can still be protected if it is new, distinct, uniform and stable, and has a suitable denomination, but for so long as the initial variety remains protected, the essentially derived variety may not be exploited without the authorization of the owner of the initial variety. In this respect, the balance between the plant variety protection system and the patent system is redressed and a new framework is provided within which all parties concerned with plant breeding are encouraged to cooperate.

24. Having stated that the EDV concept establishes a more equal balance between the systems, it is important to note that there is still a significant and important difference between the EDV provision in the UPOV system and the scope of protection conferred by a patent. The EDV provision does ***not*** prevent the breeding of new Variety B (the essentially derived variety); it only requires that the authorization of the owner of Variety A (the initial variety) is obtained to allow the exploitation of Variety B. This means that the essence of the breeder's exemption is retained, i.e. access for breeding is maintained. If the new Variety B represents a significant improvement over other varieties, it is very likely that the owner of Variety A and the patent holder of the genetic element contained in Variety B will come to a mutually beneficial agreement for exploitation of Variety B.

25. The patent system, however, may require that the permission of the holder of the patent on the genetic element is obtained ***before any breeding work can begin***. In such circumstances, it might be more difficult for agreement to be reached between the variety owner and patent holder because the value of the end variety cannot be reliably estimated.

26. In conclusion, it is important to recognize that the essential element of the breeder's exemption, which allows the breeding of new varieties of plants using protected varieties, is not affected by the EDV concept and, thus, the introduction of the EDV concept maintains the access to all varieties for breeding. However, it does provide a mechanism to ensure a suitable reward for plant breeders.

The ability to exercise the breeder's exemption in the case of varieties containing patented inventions

27. The situation outlined relates to a situation where the starting point is a patent holder with a genetic element and a variety owner with a protected variety. It is clear that another situation will arise where there is a protected variety which contains a patented invention—let us say a genetic element for the purpose of discussion. The purpose of the patent is to protect the developer of the genetic element, and the purpose of the plant breeder's right is to protect the developer of the unique combination of plant germplasm forming the variety. However, in certain circumstances, a lack of a similar provision to be breeder's exemption in the patent system might, indirectly, constrain the exercise of this exemption for the protected variety. Later, during the Symposium, we shall hear about attempts to cope with this situation.

IV. Conclusion

28. Data from countries where a UPOV system of plant variety protection has been introduced clearly demonstrate the positive impact for those countries in the form of the introduction of new varieties, which are made available for the benefit of farmers, growers and producers. The key features of the UPOV Convention, including in particular the exceptions contained in the UPOV Convention, result in the opportunity for all stakeholders to benefit from the system in a way which

maximizes overall benefit by facilitating wide access to new varieties, whilst enshrining the incentive for breeders to continue breeding new varieties. Furthermore, the provision of the breeder's exemption provides a particular mechanism to advance the development of new varieties of plants and has been a subject of particular interest concerning the mutual supportiveness of plant breeders' rights and patents. An important aspect of this Symposium will be to hear from industry, legislators and policy-makers how intellectual property rights are being used to fuel advances in plant breeding and any areas where further consideration might prove beneficial.

Plant Biotechnology Developments in the International Framework

MR. ADRIAN OTTEN
Director, Intellectual Property Division,
World Trade Organization (WTO)

Let me thank WIPO and UPOV for giving the WTO the chance to brief you on activities relating to plant biotechnology underway in the WTO.

Of course, the starting point for the work in the WTO in this matter is Article 27.3(b) of the TRIPS Agreement to which Francis has already made reference. This is a permissible exclusion from the normal rule in the TRIPS Agreement that patents should be available without discrimination as to the area of technology. So WTO Members are free to exclude from patentability plants and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties, either by patents or by an effective ***sui generis*** system or by a combination of the two, and the provisions of this sub-paragraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Four years was 1999 and, since that time, the TRIPS Council has been engaged in a review of this provision and I think it is fair to say that that review has covered not only matters that are strictly related to allowable exceptions to patentability, but also matters concerning the relationship with biodiversity and traditional knowledge. In fact, following the Doha Ministerial Conference of the WTO in 2001, the work has been formalized under three headings: review of the provisions of Article 27.3(b), the relationship between the TRIPS Agreement and the Convention on Biological Diversity and protection of traditional knowledge and folklore. For this work, the Council has three overlapping mandates, as set out on the overhead.

You will notice, a reference in paragraph 19 of the Doha Declaration to paragraph 12 of the Doha Declaration. Paragraph 12 is the provision which provides for work to take place on implementation-related issues and concerns that have been raised by developing countries. A number of these specific implementation-related issues and concerns cover matters related to Article 27.3(b), biodiversity, and traditional knowledge and folklore. I might also mention that there are differences of view amongst WTO Members as to the extent to which paragraph 12 work on what we call outstanding implementation issues constitutes part of the new round of trade negotiations, or is outside them until any decision might be taken to bring them into the negotiations.

One of the activities of the TRIPS Council in conducting the review under Article 27.3(b) was to draw up a questionnaire, and to seek replies from Members on the basis of this questionnaire, as to how they are actually implementing Article 27.3(b) at present, both in relation to patent protection and ***sui generis*** protection of plant varieties. We have had replies from 37 Members, that is to say from the European Community and its member States and 22 other Members. Mostly developed countries or transition economy countries, but a number I think 5 developing countries also amongst that group. The Secretariat has attempted to summarize these replies in synoptic tables which I will make available to this Symposium.

I do not have time to go through these replies in any detail, but let me just mention a few points relating to ***sui generis*** plant variety protection systems. Now, all of the Members who responded except for two provide for a ***sui generis*** form of protection for new plant varieties. In the case of all of these countries except for one, the protection clearly conforms to the standard defined in one of the UPOV Acts and, in the other case, protection partially conforms, it seems, to UPOV. As regards the relevant UPOV Act, at the

time that the notifications were made, and this may not be fully up to date, 17 of the replies referred to the 1991 Act and five to the 1978 Act. All of the Members replying provide for some form of farmers' privilege. This work on the questionnaire is still ongoing and we hope for further replies, especially now that for developing countries the transition period has expired and they are applying Article 27.3(b) of the TRIPS Agreement.

In addition to this work, there has been wide-ranging discussion of views and proposals on the three topics that I mentioned and I would just like to flag some of the major points that have come up in this regard. Taking the issue of the patent provisions of Article 27.3(b), you will see from the overhead that amongst WTO Members there are four main types of approach that exist: those who believe that the exceptions to patentability are not really warranted; those who favor leaving Article 27.3(b) as it is, as it finds a good balance; those who think that Article 27.3(b) as it is basically fine, but it would be beneficial to clarify certain of the terms in that Article; and those who believe that Article 27.3(b) should be amended or clarified to actually prohibit the patenting of life forms of plants and animals. So quite a wide spectrum of views as you can see.

On the next overhead I flag a number, but not an exhaustive list, of some of the main points that have come up in the discussion.

- To what extent does Article 27.3(b) require parts of plants and animals, including, for example, genes or DNA sequences to be patentable?

- What is the definition of microorganisms – is it feasible and desirable to attempt to agree on a definition?

- How adequate is the ethical exception to patentability provided for in Article 27.2 of the TRIPS Agreement?

- Is the distinction between discovery and invention - the application of the inventive step rule - being adequately applied worldwide? For example, different views have been expressed about the extent to which genetic materials that have been isolated from nature, but not modified, should be patentable.

- What is the proper definition of prior art and how adequate is the prior art base, especially when it comes to patent applications that involve traditional knowledge?

- How adequate and feasible is it to use the opposition and revocation procedure to deal with situations where patents may be, or may have been, inappropriately granted involving traditional knowledge or genetic material.

Let me now highlight some of the points that have come up in the discussion in regard to ***sui generis*** protection of plant varieties. In all of this discussion, there is a debate amongst WTO Members as to what is the desirability of further clarification of the rules in the TRIPS Agreement which would provide further legal security and clarity, but which, in the minds of some of our Members, might have the effect of limiting national discretion. Now, of course, the issue of the relationship of the TRIPS requirement to provide effective ***sui generis*** protection to UPOV systems of protection has come up, and I do not think there is any question amongst Members that the UPOV system constitutes a form of ***sui generis*** protection, but I also think that it is widely recognized that the TRIPS Agreement does not require WTO Members to necessarily use the UPOV system. The debate has been more about whether use of the UPOV system should be encouraged and, secondly, whether a reference to UPOV might be incorporated at some stage into the TRIPS Agreement, and also about whether the 1978 Act or 1991 Act of UPOV are the most appropriate reference points if the UPOV systems are to be used as a basis for national systems of protection. We have also had a fair amount of discussion as to what should be the characteristics that should be met by a ***sui generis*** system of protection if it is to be considered effective, especially if it departs from the UPOV models, and, further, about the relationship of ***sui generis*** protection to farmers' rights and traditional farming practices, especially in regard to the right to save and exchange seeds, and

compulsory licenses in certain situations, particularly where what could be described as subsistence or non-commercial farming is concerned.
Let me touch on another area of discussion in the work and that concerns the relationship between the TRIPS Agreement and the Convention on Biological Diversity. As you see, there are amongst our Members three broad approaches:

- those who believe there is an inherent conflict between the two;
- those who believe that there is no conflict, that in fact the TRIPS Agreement and the CBD are mutually supportive;
- and those who believe there is no inherent conflict, but there is a case for international action to ensure that the two are implemented in a mutually supportive way.

In regard to this latter point, the main focus of the discussion has been on the disclosure ideas that have already been referred to. A large number of developing countries have put forward proposals along the lines that you can read on this slide that would require Members to require patent applicants to disclose in their applications information on the origin of genetic material and traditional knowledge used in their inventions, evidence of prior informed consent and evidence of fair and equitable benefit-sharing.

In the discussion on these ideas, a number of the points have come up.

- How feasible is such a requirement? How burdensome would it be in relation to the potential benefits?
- What is the adequacy of the approach which would call for the conclusion of contracts based on national legislation between people who want to access and use genetic material and traditional knowledge and the competent authorities in the country of origin?
- What would be the TRIPS consistency of this?

We have had some more recent discussions where some of the developed country Members of the WTO have shown some openness to going perhaps some way down the road to meeting the concerns that have been expressed in these proposals in terms of possibly recognizing the merit of some kind of disclosure requirement in relation to the origin of genetic resources and traditional knowledge, but not as a condition of patentability.

So that is an attempt to summarize the ongoing work in the WTO. As I say, it is ongoing work and I cannot say very much to you at this stage about how it will be carried forward. It seemed likely that, if a substantive Ministerial text had been agreed in Cancun, these issues would have been addressed in broad terms, but as you know such a substantive text was not adopted.

[Annex I follows]

Slide 1

Article 27.3(b) of the TRIPS Agreement

"3. Members may also exclude from patentability:

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

Slide 2

Three mandates

- Article 27.3(b) review provision.
- Paragraph 19 of the Doha Declaration:

"19. We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."

- Outstanding implementing issue.

Slide 3

Patent Provisions of Article 27.3(b)

- Four main positions:
  - remove exceptions to patentability;
  - leave Article 27.3(b) as is;
  - clarify certain terms in Article 27.3(b);
  - amend or clarify to prohibit patenting of life forms.

Slide 4

Issues regarding patentability of inventions involving genetic material and traditional knowledge

- Parts of plants/animals.
- Definition of micro-organisms.
- Ethical exception to patentability (Article 27.2).
- Distinction discovery/invention (inventive step).
- Definition of and adequacy of information on prior art.
- Adequacy of opposition/revocation as a remedy.

Slide 5

WTO OMC

Plant Variety Protection

- Clarification vs national discretion.
- Relationship to UPOV:
  - no obligation to use UPOV;
  - should there be a reference to UPOV;
  - UPOV 1978 or 1991.
- Characteristics of an effective *sui generis* system.
- Relationship to farmers' rights and traditional farming practices.

ato221 - WIPO-UPOV Symp. on IPRs in Plant Biotech., Gva, 24.10.03 5

Slide 6

WTO OMC

TRIPS Agreement and the Convention on Biological Diversity

- Three general views:
  - Inherent conflict:
    - amend TRIPS;
  - No conflict, mutually supportive;
  - No inherent conflict, but potential for conflict:
    - need for international action to ensure implemented in a mutually supportive way.

ato221 - WIPO-UPOV Symp. on IPRs in Plant Biotech., Gva, 24.10.03 6

Slide 7

Disclosure proposal

The TRIPS Agreement should be amended in order to provide that Members shall require that an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition of acquiring patent rights:

(i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention;

(ii) evidence of prior informed consent through approval of authorities under the relevant national regimes; and

(iii) evidence of fair and equitable benefit sharing under the national regime of the country of origin.

ato221 - WIPO-UPOV Symp. on IPRs in Plant Biotech., Gva, 24.10.03 7

Slide 8

Discussion of disclosure proposal

- Feasibility, burdens.
- Adequacy of contracts approach.
- TRIPS consistency.
- Obligation to disclose, but not as a condition of patentability.

ato221 - WIPO-UPOV Symp. on IPRs in Plant Biotech., Gva, 24.10.03 8

[Annex II follows]

WIPO-UPOV Symposium on Intellectual Property Rights in Plant Biotechnology
Geneva, 24 October 2003

EXCERPT FROM SECRETARIAT SUMMARY NOTE ON RESPONSES

TO ILLUSTRATIVE LIST OF QUESTIONS ON

ARTICLE 27.3(B) (IP/C/W/273/REV.1)

The explanatory notes, referred to as Annexes III and IV, can be found in document IP/C/W/273/Rev.1 on the WTO website (http://www.wto.org).

_____

SYNOPTIC TABLE I: PATENT SYSTEM

	AUS	***BGR***	***CAN***	***CHE***	***CZE•***	***EEC***
1. In your territory, is there any basis for denying a patent on an invention consisting of an entire plant or animal that is novel, capable of industrial application, involves an inventive step and has been adequately disclosed?	No*	Yes	Yes*	Yes*	Yes*	Yes
2. If the answer to question 1 is yes, please respond to the following questions:						
(a) Does your patent system exclude entire plants or animals as inventions?	n.a.	No	Yes*	*	No*	No
(b) If your patent system does recognize entire plants and animals as inventions, does it exclude all such inventions from being patentable subject-matter, or does it only exclude certain types of plants or animals? If it excludes only certain types, please identify the categories or characteristics of inventions that are excluded.	n.a. n.a.*	1 Yes*	n.a. No	*, 1 *	1 Yes*	1 Yes*
(c) Is there any other basis in your law that precludes the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step, are capable of industrial application and have been adequately disclosed?						
3. Other than with respect to subject-matter you defined as being ineligible to be patented under question (2), is it possible in your territory to obtain a patent claim defined in any of the following ways?						
(a) A patent claim that is not limited to a specific plant or animal variety.	Yes	*	No	Yes	*	Yes
(b) A patent claim that is expressly limited to a plant or animal variety.	Yes	No*	No	No	*	No
(c) A patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene.	Yes	*	No*	Yes	*	Yes
4. Is it possible to obtain a patent in your territory on a micro-organism that is novel, involves an inventive step and is capable of industrial application?	Yes	Yes	Yes*	Yes	Yes	Yes
5. Is it possible to obtain a patent in your territory on an essentially biological process for the production of a plant or animal (i.e. a process limited to those acts that are necessary for sexual or asexual reproduction of a plant or animal)?	Yes*	No*	No	No*	No*	No*
6. Is it possible to obtain a patent in your territory for subject-matter that is identical to that found in nature (e.g. a plant or animal in its natural state)?	No*	No*	No	No*	No*	*

* See Annex III for further information.

[1] Plant and animal varieties are excluded.

[2] Sexually reproduced plants are excluded.

	AUS	BGR	CAN	CHE	CZE●	EEC
7. Does your patent system include any special provisions to ensure adequate disclosure regarding inventions covered by Article 27.3(b) (for example, micro-organisms)?	Yes*	Yes*	Yes	Yes*	Yes*	

	EST	HKC	HUN	ISL	JPN	KOR
1. In your territory, is there any basis for denying a patent on an invention consisting of an entire plant or animal that is novel, capable of industrial application, involves an inventive step and has been adequately disclosed?	Yes*	Yes*	Yes*	Yes*	No*	Yes
2. If the answer to question 1 is yes, please respond to the following questions:						
(a) Does your patent system exclude entire plants or animals as inventions?	No*	No*	No	No	n.a.	No*
(b) If your patent system does recognize entire plants and animals as inventions, does it exclude all such inventions from being patentable subject-matter, or does it only exclude certain types of plants or animals? If it excludes only certain types, please identify the categories or characteristics of inventions that are excluded.	1	1	No	1*	n.a.	2
(c) Is there any other basis in your law that precludes the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step, are capable of industrial application and have been adequately disclosed?	Yes*	Yes*	No		n.a.	Yes*
3. Other than with respect to subject-matter you defined as being ineligible to be patented under question (2), is it possible in your territory to obtain a patent claim defined in any of the following ways?	Yes	Yes*	Yes	Yes	Yes	Yes
(a) A patent claim that is not limited to a specific plant or animal variety.	No	No*	Yes	No	Yes	Yes
(b) A patent claim that is expressly limited to a plant or animal variety.	Yes	*	Yes	Yes	Yes	Yes
(c) A patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene.						
4. Is it possible to obtain a patent in your territory on a micro-organism that is novel, involves an inventive step and is capable of industrial application?	Yes*	Yes*	Yes	Yes*	Yes	Yes*

	EST	HKC	HUN	ISL	JPN	KOR
5. Is it possible to obtain a patent in your territory on an essentially biological process for the production of a plant or animal (i.e. a process limited to those acts that are necessary for sexual or asexual reproduction of a plant or animal)?	No*	No*	No*	No*	Yes	No*
6. Is it possible to obtain a patent in your territory for subject-matter that is identical to that found in nature (e.g. a plant or animal in its natural state)?	*	*	No	*	No*	No
7. Does your patent system include any special provisions to ensure adequate disclosure regarding inventions covered by Article 27.3(b) (for example, micro-organisms)?		Yes*	Yes*			No

	LTU	NOR	NZL	POL	ROM
1. In your territory, is there any basis for denying a patent on an invention consisting of an entire plant or animal that is novel, capable of industrial application, involves an inventive step and has been adequately disclosed?	Yes*	Yes*	No*	Yes	No
2. If the answer to question 1 is yes, please respond to the following questions:					
(a) Does your patent system exclude entire plants or animals as inventions?	No*	n.a.	n.a.	No	n.a.
(b) If your patent system does recognize entire plants and animals as inventions, does it exclude all such inventions from being patentable subject-matter, or does it only exclude certain types of plants or animals? If it excludes only certain types, please identify the categories or characteristics of inventions that are excluded.	*1	n.a.	n.a.	1	n.a.
(c) Is there any other basis in your law that precludes the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step, are capable of industrial application and have been adequately disclosed?	Yes*	No	n.a.	n.a	n.a.

	LTU	NOR	NZL	POL	ROM
3. Other than with respect to subject-matter you defined as being ineligible to be patented under question (2), is it possible in your territory to obtain a patent claim defined in any of the following ways?					
(a) A patent claim that is not limited to a specific plant or animal variety.		No	Yes	No*	No
(b) A patent claim that is expressly limited to a plant or animal variety.		No	Yes	No*	Yes*
(c) A patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene.	*	No	Yes	Yes/ No*	No
4. Is it possible to obtain a patent in your territory on a micro-organism that is novel, involves an inventive step and is capable of industrial application?	Yes*	Yes	Yes	Yes*	Yes
5. Is it possible to obtain a patent in your territory on an essentially biological process for the production of a plant or animal (i.e. a process limited to those acts that are necessary for sexual or asexual reproduction of a plant or animal)?	No*	No	Yes	No*	Yes
6. Is it possible to obtain a patent in your territory for subject-matter that is identical to that found in nature (e.g. a plant or animal in its natural state)?	No*	No*	No*	No*	No*
7. Does your patent system include any special provisions to ensure adequate disclosure regarding inventions covered by Article 27.3(b) (for example, micro-organisms)?	Yes*	Yes*	No*	Yes*	Yes

	SVK	SVN	THA	USA	ZAF	ZMB
1. In your territory, is there any basis for denying a patent on an invention consisting of an entire plant or animal that is novel, capable of industrial application, involves an inventive step and has been adequately disclosed?	Yes*	No	Yes*	No	Yes	Yes
2. If the answer to question 1 is yes, please respond to the following questions:						
(a) Does your patent system exclude entire plants or animals as inventions?	No*		Yes*	n.a.	No	No
(b) If your patent system does recognize entire plants and animals as inventions, does it exclude all such inventions from being patentable subject-matter, or does it only exclude certain types of plants or animals? If it excludes only certain types, please identify the categories or characteristics of inventions that are excluded.	*,1		n.a.	n.a.	*, 1	n.a.
(c) Is there any other basis in your law that precludes the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step, are capable of industrial application and have been adequately disclosed?	Yes*		*	n.a.	Yes*	Yes*
3. Other than with respect to subject-matter you defined as being ineligible to be patented under question (2), is it possible in your territory to obtain a patent claim defined in any of the following ways?						
(a) A patent claim that is not limited to a specific plant or animal variety.	*	Yes		Yes	No	Yes
(b) A patent claim that is expressly limited to a plant or animal variety.	No*	Yes		Yes	No	Yes
(c) A patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene.	*	Yes		Yes		Yes
4. Is it possible to obtain a patent in your territory on a micro-organism that is novel, involves an inventive step and is capable of industrial application?	Yes	Yes	Yes*	Yes	Yes	Yes
5. Is it possible to obtain a patent in your territory on an essentially biological process for the production of a plant or animal (i.e. a process limited to those acts that are necessary for sexual or asexual reproduction of a plant or animal)?	No*	Yes	No*	No*	No	

	SVK	SVN	THA	USA	ZAF	ZMB
6. Is it possible to obtain a patent in your territory for subject-matter that is identical to that found in nature (e.g. a plant or animal in its natural state)?	No*	Yes*	No*	No*	No*	
7. Does your patent system include any special provisions to ensure adequate disclosure regarding inventions covered by Article 27.3(b) (for example, micro-organisms)?			No*	Yes*	n.a.	No

SYNOPTIC TABLE II: PLANT VARIETY PROTECTION SYSTEMS

	AUS	BGR	CAN	CHE	CZE•	EEC
1. Do the laws applicable to your territory provide for a sui generis form of protection for a new plant variety?	Yes	Yes	Yes	Yes	Yes	Yes
2. If the answer to question 1 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?	Yes	Yes	Yes	Yes	Yes	Yes
3. If the answer to question 2 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).	1991	1991	1978	1978*	1991*	1991
4. If sui generis protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder:						
(a) acts performed for research or experimental purposes, or to develop new varieties of plants?	No	No	No	No*	No	No
(b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics?	Yes*		No	No*	Yes	Yes
(c) acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmer's land?	No*	No*	No	No*	No*	No*
If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?	No*		No	No	Yes*	Yes*
5. Would acts done privately and for non-commercial purposes require the authorization from the right holder?	No	No*	No	No*	*	
6. Does your legislation provide for other exceptions to the rights conferred?	Yes*	Yes	Yes		*	

* See Annex IV for further information.

	AUS	BGR	CAN	CHE	CZE•	EEC
7. Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for sui generis protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection)?	*	Yes*	Yes*	Yes*	Yes* (1/4/6)	Yes*
8. To be entitled to rights under sui generis plant variety protection does one have to be the person who bred, or discovered and developed the variety, or his successor in title?	Yes	Yes	Yes		*	
9. Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the expressed characteristics of plant varieties derived from such genes or germplasm?	No	No*	No	No	No	No
10. What are the conditions that your law require for protection?[1]	d,u, s,n[1]	d,u,s,n,pd[1]	d,u,s,n,pd[1]		d,u,s,n,pd[1]	
11. What is the duration of protection?	25/20*	30/25*	18*		25/30*	

	EST	HKC	HUN	ISL	JPN	KOR
1. Do the laws applicable to your territory provide for a sui generis form of protection for a new plant variety?	Yes	Yes	No	Yes*	Yes	Yes
2. If the answer to question 1 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?	Yes	Yes*	Yes	Yes	Yes	Yes
3. If the answer to question 2 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).	1991	1991*	1978	1991	1991	1991

[1] d=distinctness; u=uniformity; s=stability; n=novelty; pd=proper denomination

	EST	HKC	HUN	ISL	JPN	KOR
4. If sui generis protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder:						
(a) acts performed for research or experimental purposes, or to develop new varieties of plants?	No*	No*	n.a.	No*	No	No
(b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics?	Yes*	Yes*	n.a.	Yes*	Yes*	Yes
(c) acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmer's land?	No*	Yes*	n.a.	No*	No*	No
If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?	Yes*	No*	n.a.	Yes*	No	No
5. Would acts done privately and for non-commercial purposes require the authorization from the right holder?	No*	No*	n.a.	No*		No
6. Does your legislation provide for other exceptions to the rights conferred?		Yes*	Yes			Yes
7. Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for sui generis protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection)?	Yes* (1/4/6)	Yes* (1/4/6)	Yes*	Yes* (1/4/6)	Yes*	Yes*
8. To be entitled to rights under sui generis plant variety protection does one have to be the person who bred, or discovered and developed the variety, or his successor in title?		Yes*	Yes			Yes
9. Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the expressed characteristics of plant varieties derived from such genes or germplasm?	*	*	No	No	No	No
10. What are the conditions that your law require for protection? [1]		d,u,s,n*,1	d,u,s,n,pd[1]			d,u,s,n,pd[1]
11. What is the duration of protection?		20/25*	15/18*			25/20*

	LTU	MAR	NOR	NZL	POL	ROM
1. Do the laws applicable to your territory provide for a sui generis form of protection for a new plant variety?	Yes	Yes	Yes	Yes	Yes	Yes
2. If the answer to question 1 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?	Yes*	Yes	Yes	Yes	Yes	Yes*
3. If the answer to question 2 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).	1991	1991*	1978*	1978	1991	1991
4. If sui generis protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder:						
(a) acts performed for research or experimental purposes, or to develop new varieties of plants?	No*	No*	No*	No	No	No
(b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics?	No*	Yes*	No*	No	No	Yes
(c) acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmer's land?	No*	No*	No	No		No
If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?	Yes*	No*	No	No		No*
5. Would acts done privately and for non-commercial purposes require the authorization from the right holder?	No*	No*		No	No	No
6. Does your legislation provide for other exceptions to the rights conferred?	Yes*	Yes*		Yes*	Yes	Yes*
7. Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for sui generis protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection)?	Yes* (1/4/6)	Yes*	Yes*	Yes*	Yes*	Yes*
8. To be entitled to rights under sui generis plant variety protection does one have to be the person who bred, or discovered and developed the variety, or his successor in title?	Yes*	Yes*		Yes*	Yes	Yes*

	LTU	MAR	NOR	NZL	POL	ROM
9. Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the expressed characteristics of plant varieties derived from such genes or germplasm?	*		No	No*	*	No
10. What are the conditions that your law require for protection? [1]	d,u,s,n*,1	d,u,s,n,pd[1]		d,u,s,n[1]	d,u,s,n,pd[1]	d,u,s,n,pd[1]
11. What is the duration of protection?	25/30*	20/25/30*		23/20*	30/25*	30/25*

	SVK	SVN	THA	USA	ZAF	ZMB
1. Do the laws applicable to your territory provide for a sui generis form of protection for a new plant variety?	Yes	Yes	Yes	Yes*	Yes	No*
2. If the answer to question 1 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?	Yes	Yes	*	Yes	Yes	n.a.
3. If the answer to question 2 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).	1991*	1991	*	1991	1991*	n.a.
4. If sui generis protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder:						
(a) acts performed for research or experimental purposes, or to develop new varieties of plants?	No	No	No*	No*	No	n.a.
(b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics?	Yes	Yes	No*	Yes	No	n.a.
(c) acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmer's land?	No	No	No*	No*	No	n.a.
If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?	No	Yes*	Yes	No		n.a.
5. Would acts done privately and for non-commercial purposes require the authorization from the right holder?			No*	No	No	n.a.
6. Does your legislation provide for other exceptions to the rights conferred?			Yes*		Yes	n.a.

	SVK	SVN	THA	USA	ZAF	ZMB
7. Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for sui generis protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection)?	Yes* (1/4/6)	Yes*	*	Yes*	No*	n.a.
8. To be entitled to rights under sui generis plant variety protection does one have to be the person who bred, or discovered and developed the variety, or his successor in title?				Yes	Yes*	n.a.
9. Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the expressed characteristics of plant varieties derived from such genes or germplasm?	No	No*	*	No*	*	n.a.
10. What are the conditions that your law require for protection? [1]			d,u,s,n*,1		d,u,s,n[1]	*
11. What is the duration of protection?			12/17/27*	25/20*	25/20*	n.a.

SECTION II

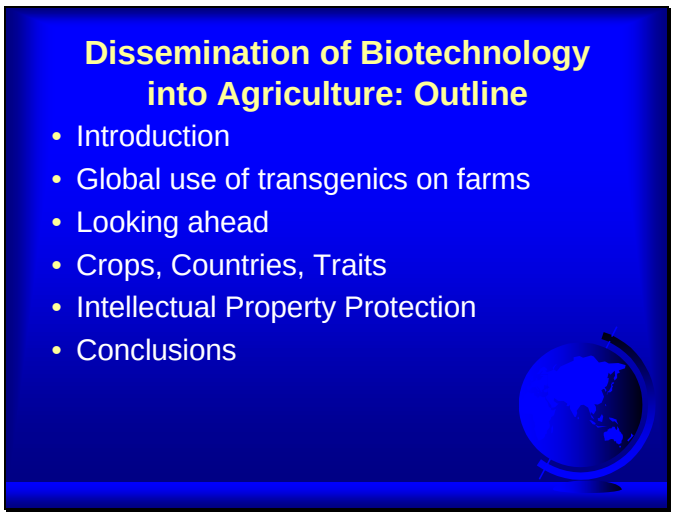
PLANT BIOTECHNOLOGY AND ITS DISSEMINATION

Dissemination of Biotechnology into Agriculture

MR. STEPHEN SMITH
Germplasm Security Coordinator, Pioneer Hi-Bred International Inc.
Johnston, United States of America

Slide 1

Slide 2

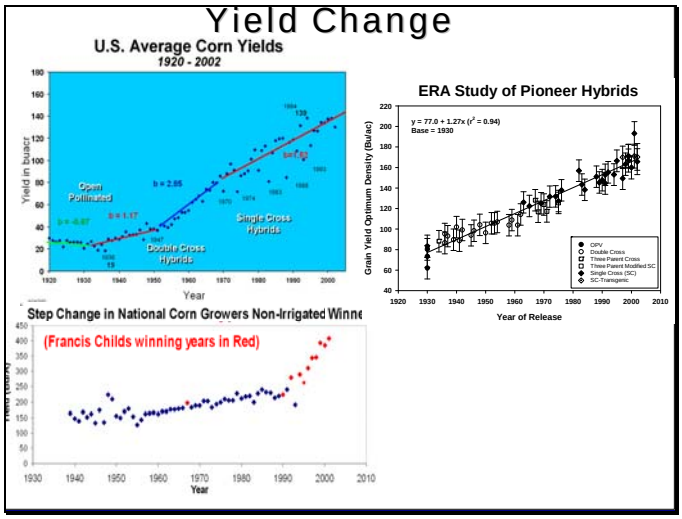


Slide 3

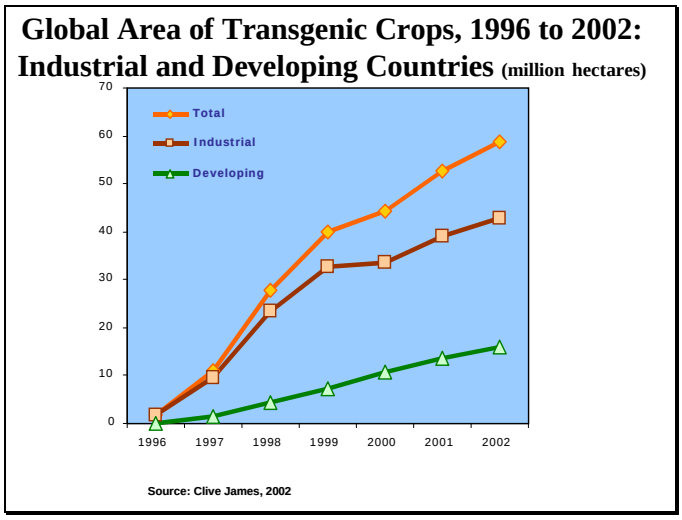
Introduction

- Agriculture is the original biotechnology
- Agriculture fundamental to culture, health, quality of environment, biodiversity
- Seed: a superb vehicle for disseminating innovation and underpinning benefits
- Effective IP critical to encourage investments and promote genetic diversity
- Biotechnology: far more than transgenes
- Development of improved germplasm critical

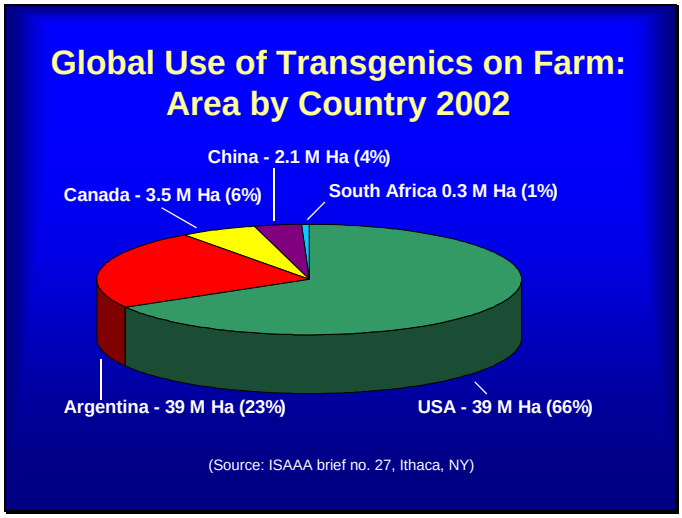
Slide 4



Slide 5

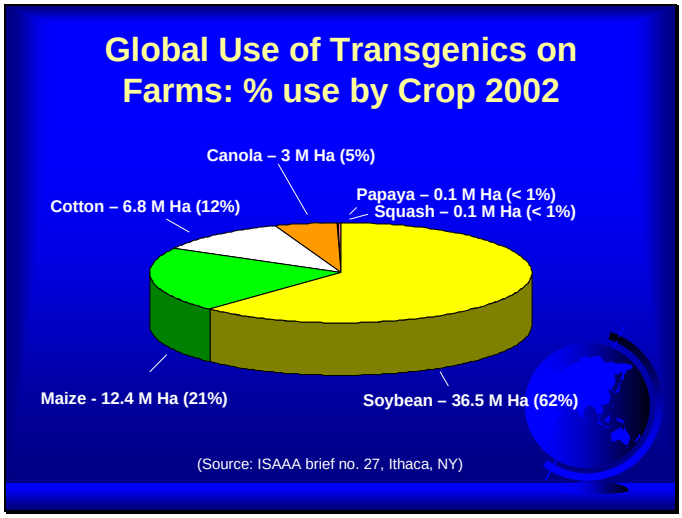


Slide 6

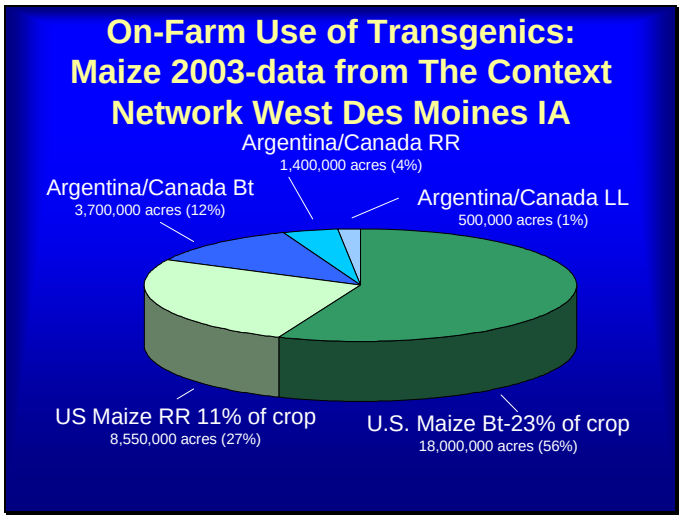


Slide 7

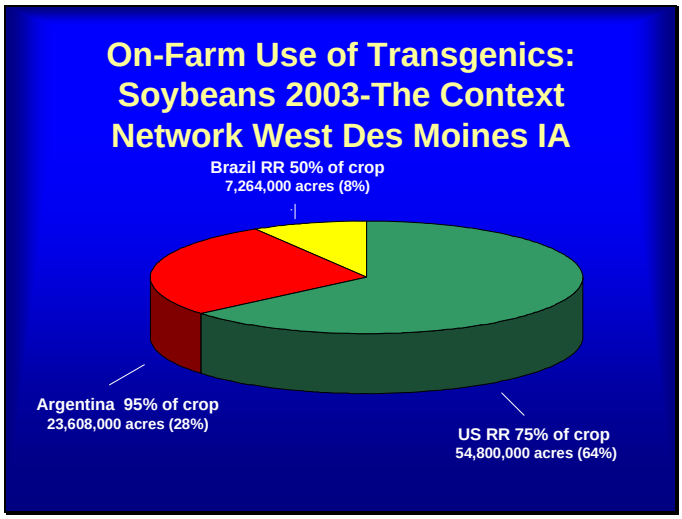
Slide 8



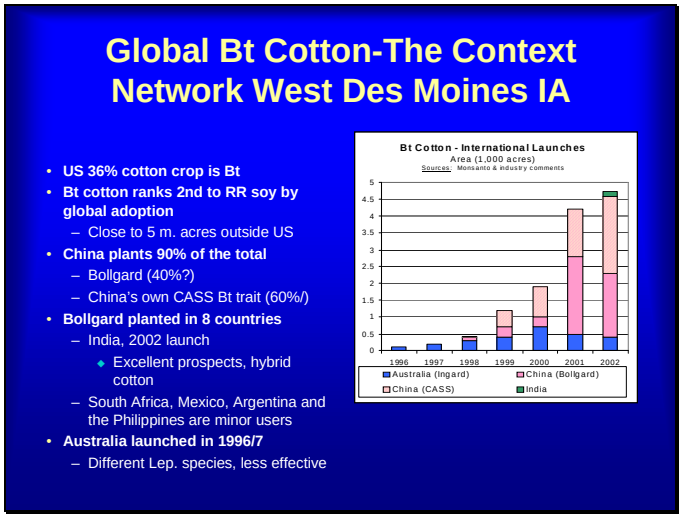
Slide 9



Slide 10



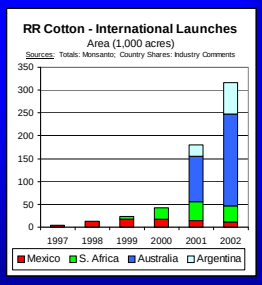
Slide 11



Slide 12

Global RR Cotton-The Context Network West Des Moines IA

- US 54% of crop is RR
- In **Mexico**, RR cotton has been planted on a small acreage from 1997 on
  - Mexico is a very minor cotton producer
- In **South Africa**, RR cotton was launched in the 1998-9 season.
  - The country has around 150,000 acres, but by 2001/2 RR/Bollgard stacked cotton had been adopted on 28% of that total.
- In **Australia**, RR cotton was commercialized in the 2001/2 season
- In **Argentina**, RR cotton was also approved ahead of the 2001/2 planting season.



Farm Labor Cost Issue

- Herbicide-tolerance traits for China, & India, Uzbekistan?

Slide 13

Looking Ahead

- Climates change
- Farm cultivation/husbandry practices change
- Pests and diseases evolve
- Need more effective use of soil and water
- Need to increase productivity, including in harsh environments
- Un-ending need for better adapted varieties
- Improved germplasm and traits are needed

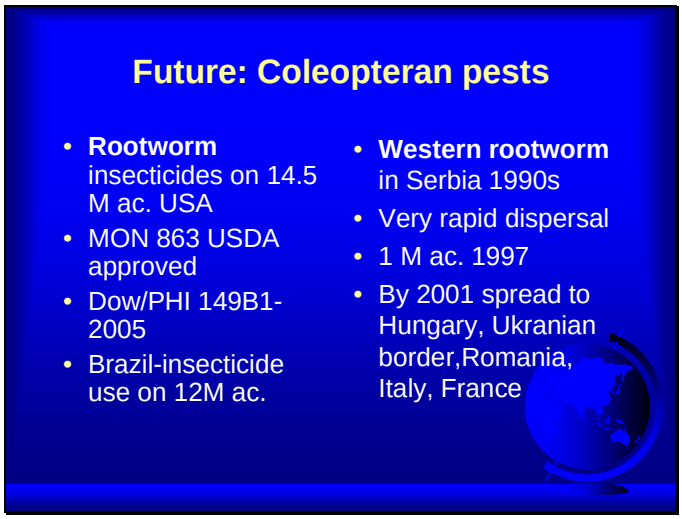
Slide 14

Looking Ahead

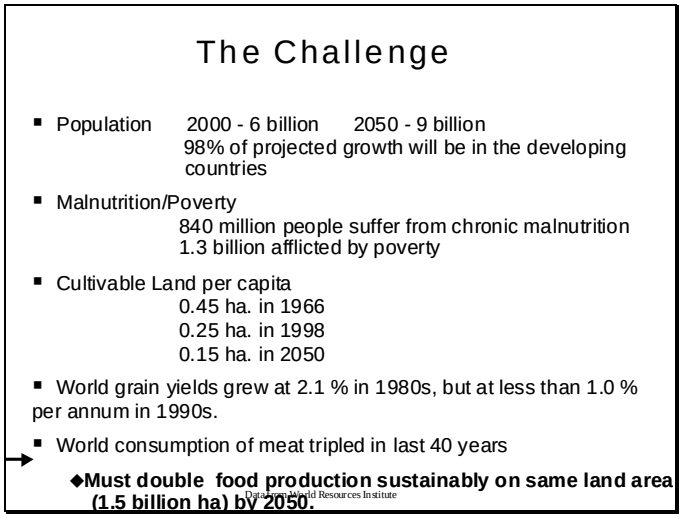
- Capitalizing on scientific discovery in cultivar development—new tools facilitate access
- Adds complexities and costs to Research and Product Development
- IP is a prerequisite to support trait and germplasm development
- Encourage use of new genetic diversity rather than repeated narrowing use of old base
- Compulsory licenses (e.g. breeder exemption under patent law) undermine research investments, narrow genetic base

Slide 15

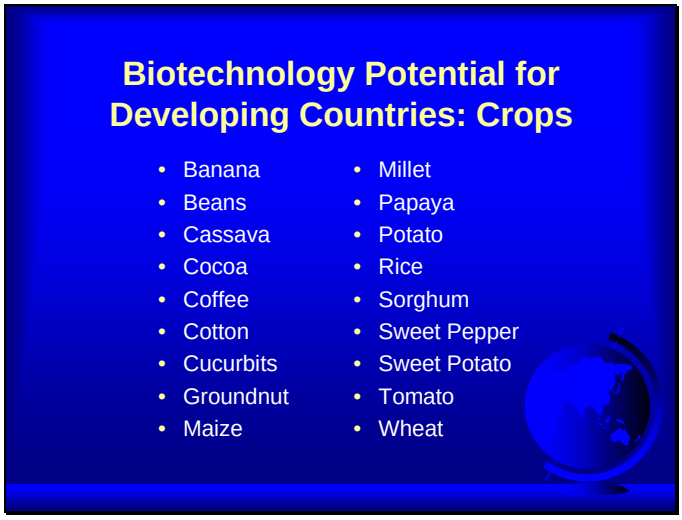
Slide 16



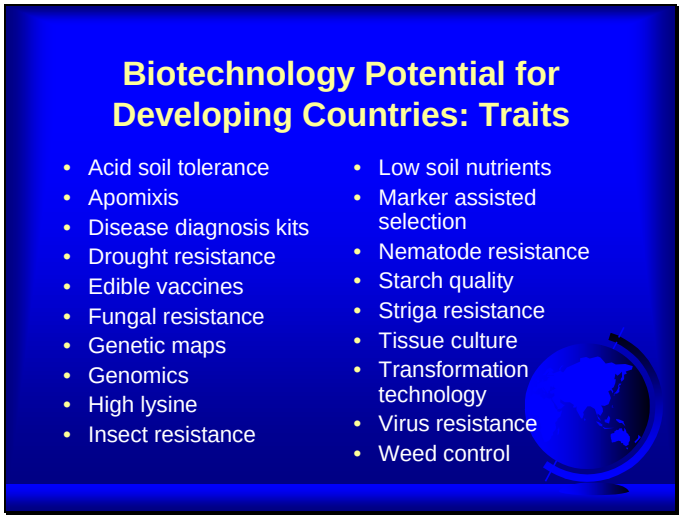
Slide 17



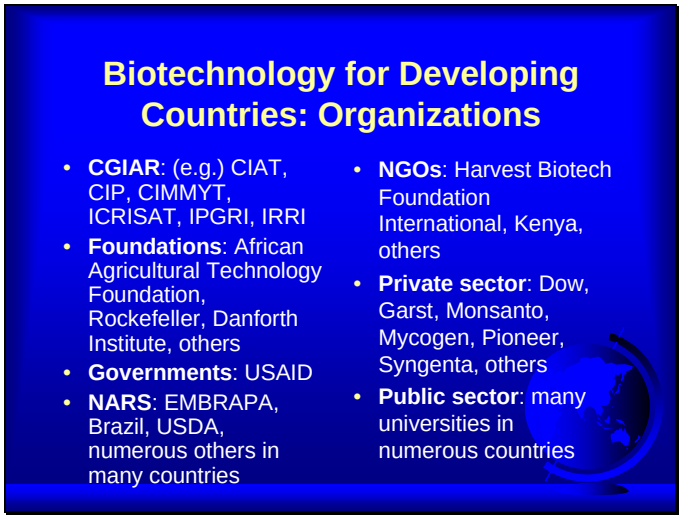
Slide 18



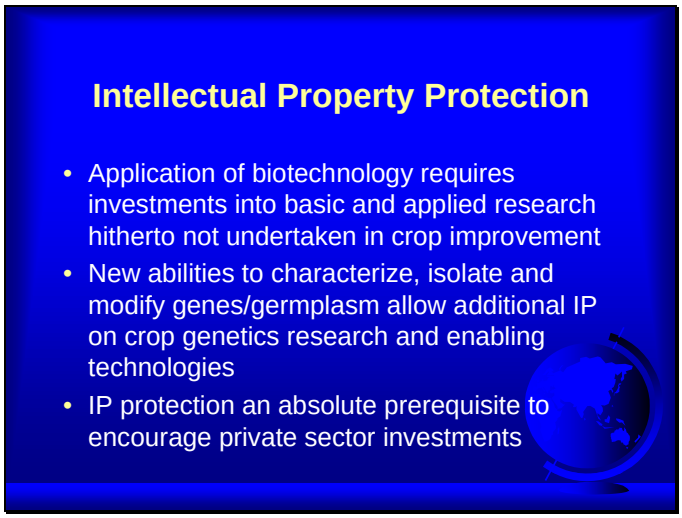
Slide 19



Slide 20



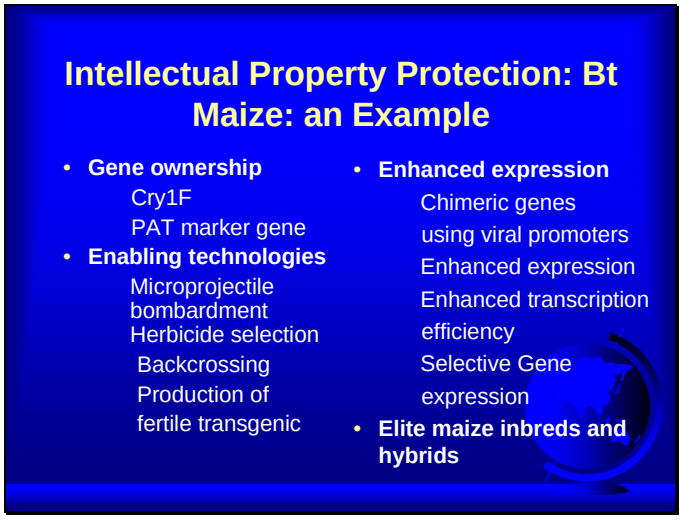
Slide 21



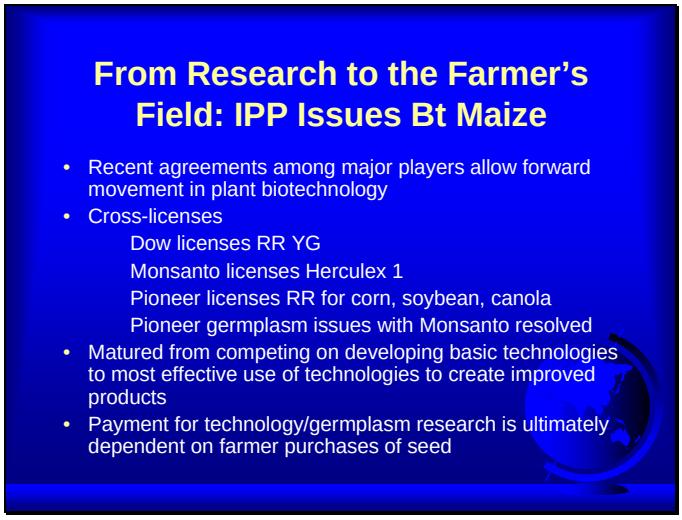
Slide 22

Slide 23

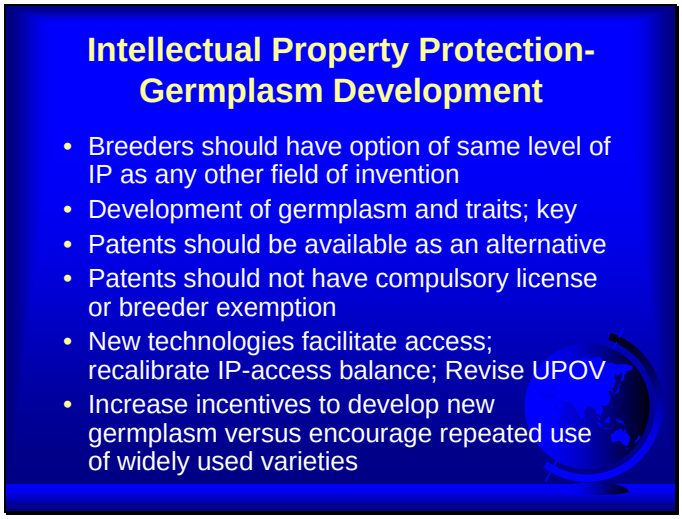
Slide 24



Slide 25



Slide 26



Slide 27

Conclusions and Future Prospects

- Increase knowledge and capabilities through research
- Increase productivity and positive environmental impacts of agriculture
- Need strong public and private sectors
- More effective IP for germplasm development
- Bridge gaps between research plots and farmers fields
- Conservation and evaluation of genetic resources for future use

Slide 28

Dissemination to Culture and the Human Spirit

- " When I got home I heard John Barbirolli conducting Beethoven's Seventh Symphony. What was agriculture for except that such a thing as that symphony and the playing of it should be made possible? To make bread so that it shall be possible for mankind to have more than bread; to listen to a Beethoven, a Sibelius, a Tchaikovsky, uttering some far message of paradox and joy".

John Stewart Collis : The Worm Forgives the Plough, Penguin Modern Classics, 1973.

Slide 29

Acknowledgements

- Eric Barbour
- Joanne Barton
- Mark Cooper
- David Ertl
- Tim Helentjaris
- Enno Krebbers
- Tony Nevshemal
- Bill Niebur
- Antoni Rafalski
- Howie Smith
- Scott Tingey
- Dwight Tomes

Creating, Protecting and Using Crop Biotechnologies Worldwide in an Era of Intellectual Property

PROFESSOR PHILIP PARDEY
Science and Technology Policy, Department of Applied Economics,
University of Minnesota, St. Paul, United States of America

1. Introduction

Most crops are grown in places where they did not occur naturally—they were introduced, either incidentally or intentionally. In this way the development and dissemination internationally of new and improved seed varieties has been the basis for productivity improvement in agriculture since crops were first domesticated about 10 millennia ago. Initially the movement of plant material involved farmers carrying seed as they migrated to new areas. Columbus returned from his voyage to the New World in the latter part of the 15th century laden with new plants that ushered in an extended era of state-sponsored expeditions to gather and evaluate plant materials the world over. For most of that time, new crop varieties were largely treated as common property, shared freely among farmers and countries and generating billions of dollars of benefits worldwide.[1]

The era of free and unencumbered access to new crop varieties appears to be passing. This has implications beyond the movement and marketing of new crop varieties; it affects their creation as well. Scientific crop breeding, drawing on rediscovered Mendelian Laws of Heredity, began in earnest about a century ago. For many countries, varietal innovations continue to rely heavily on introduced germplasm, making the international spillovers of germplasm, breeding techniques, and know-how integral to these crop improvement efforts. While substantial germplasm (much in the form of landraces and other primary plant materials) flowed from poorer countries into the rich ones, so too did enhanced germplasm subsequently move back to the poorer parts of the world. This reverse flow appears to have accelerated as the Green Revolution took hold, beginning in the 1960s, as developing-country farmers took up improved varieties in a big way and as local breeding efforts screened and adapted these varietal spillins to better deal with local agroecological realities and production constraints.

Throughout all these changes, crop improvement has been, and largely remains, a ***cumulative*** or ***sequential innovation process—***new varieties build directly on the selection and breeding efforts of farmers and scientists of yesteryear. A new twist has come with the advent of modern biotechnology tools. Now the genetic makeup of new varieties are altered by the "conventional or classical" genetic manipulation techniques practiced formally by scientists for the past 100 years (and less formally by farmers for eons prior to that), or by bioengineered techniques involving the purposeful insertion of gene fragments into plants from other

[1] While personal or corporate intellectual property rights for plant biotechnology are recent phenomena within most countries, attempts at asserting national property rights over breeding materials internationally are nothing new (Boettiger et al. 2003). Monopolization of valuable markets has long been accomplished by nation-states prohibiting access to breeding materials. Examples include the Dutch monopolization of the European tea supply (Juma 1989), the Italian prohibition on rice seed export famously violated by Thomas Jefferson (Fowler 1994; Root and de Rochemont 1976), and more recently Ethiopia's ban on the export of some coffee tree varieties (Fowler and Mooney 1990). These cases are, however, atypical; in general, traders, collectors, and breeders have had free access to landraces and farmers' varieties from around the world. For a review of the evidence on the benefits arising from crop-improvement research, see Alston et al. (2000).

plants or other organisms using genomic and transformation technologies developed within the past two decades.[2] Like the crop varieties themselves, the tools of crop manipulation are increasingly encumbered by intellectual property, making the future of crop-improvement inextricably tied to the future of the biotechnologies increasingly used to manipulate them.

Whether these changing market, scientific, and intellectual property regimes will help or hinder efforts to develop and disseminate varietal technologies in the future, and especially the crop innovations required by the developing world, is an open question. In this paper we survey and report newly compiled evidence on the research and, especially, the intellectual property landscapes regarding plant biotechnologies as a step toward resolving these questions.

2. Crop Biotechnology Creation

Crop biotechnologies are not necessarily used or protected where created. Here we investigate the location and structure of the relevant R&D sectors as a basis for analyzing the patterns of intellectual property rights in the resulting crop innovations and their uptake worldwide.

Research Spending. In 1995 about half a trillion (nearly $500 billion, 1993 prices) U.S. dollars was invested in all public and privately financed science worldwide—around 85 percent of it conducted in rich countries (Pardey and Beintema 2001). Agricultural research accounted for $33 billion of this total or nearly 7 percent of all private and public spending on science.

The public share of agricultural investment was substantial, but is now flagging. Worldwide, public investments in agricultural research nearly doubled in inflation-adjusted terms over the past two decades, from an estimated $11.8 billion in 1976 to nearly $22 billion in 1995. Yet for many parts of the world, growth in spending during the 1990s slowed dramatically. In the rich countries, public investment grew just 0.3 percent annually between 1991 and 1996 compared with 2.3 percent per year during the 1980s. In Africa, there was no growth at all. In Asia, the 4.4 percent annual growth figure compared with 7.5 percent the previous decade.

The distribution of spending on agricultural research has shifted as well. In the 1990s, for the first time, developing countries as a group spent more on public agricultural research than the developed countries. Among the rich countries, $10.2 billion in public spending was concentrated in just a handful of countries. In 1995 the United States, Japan, France and Germany accounted for two thirds of this public research, about the same as two decades before. Just three developing countries—China, India, and Brazil—spent 44 percent of the developing world's public agricultural research money in 1995, up from 35 percent in the mid-1970s.
By the mid-1990s about one third of the $33 billion total public and private agricultural research investment worldwide was private (Table 1). But little of this research takes place in the developing world. The overwhelming majority ($10.8 billion, or 94 percent of the global total in 1995) is conducted in developed counties, where private research is over half of all expenditures. In developing countries, the private share of research is just 5 percent, and public funds are still the major source of support.

[Table 1: ***Private and Public Agricultural R&D Investments, circa 1995***]

[2] All crops are genetically modified, making the mnemonic "GMOs" misleading in ways that seem to have profoundly affected peoples' perceptions about the latest set of crop-improvement techniques. Among the continuum of genetic modification methods, Drew and Pardey (2003) distinguish between classically bred crops using techniques like hybridization that became commonplace among scientific breeders beginning a century ago, and varieties whose DNA has been manipulated with bioengineering techniques like the ballistic gun or agrobacterium mediated transformations of DNA that form the forefront of present crop improvement methods. Confounding efforts to neatly classify crop varieties, some modern varieties are conventionally bred but incorporate herbicide tolerant genes identified using modern genomic methods.

Private agricultural research is displacing public research generally, and specifically in areas like commercial crop breeding for the seeds of crops with high commercial value. This tendency is especially pronounced in countries like the United States where private agricultural R&D was 90 percent of public spending in 1960, growing to 133 percent by 1996, the latest year for which comparable public-private data are available. Private investments, fueled by agricultural biotechnology research, gravitate to techniques which promise large markets, are protected by intellectual property rights, and are easily transferable across agroecologies. These included food processing and other post-harvest technologies and chemical inputs including pesticides, herbicides and fertilizers. Hence, while private research is much more geographically concentrated than public research, many of its fruits may be more easily transferred across borders and agroecological zones. Even so, private research is far less likely in products or methods with small markets, weak intellectual property protection, and limited transferability, precisely the situations in which most poor farmers are found.

Research Intensities and Stocks of Knowledge. One way to gauge the commitment of agricultural research funds, public or private, is to compare them to national agricultural output, rather than measuring them in absolute terms. This relative measure captures the ***intensity*** of investment in agricultural research as a percentage of agricultural GDP, not just the ***amount*** of total research spending. In 1995, as a group, developed countries spent $5.43 on public and private agricultural R&D for every one hundred dollars of agricultural output compared with just 66 cents per hundred dollars of output for developing countries. The eightfold difference in total research intensities illustrates the size of the technological gap in agriculture between rich and poor countries. Moreover, the situation is growing worse. The difference in public research intensity ratios was 3.5–fold in the 1970s, compared with 4.3–fold now (an even wider gap would have opened up if private spending was also factored in).

These trends may actually understate the scientific knowledge gap. Science is a cumulative endeavor, with a snowball effect. Innovations beget new ideas and further rounds of innovation or additions to the cumulative stock of knowledge. The sequential and cumulative nature of scientific progress and knowledge is starkly illustrated by crop-improvement. It generally takes 7–10 years of breeding to develop a uniform, stable, and superior variety (with improved yield, grain quality, or other attributes). But breeders of today build on a base of knowledge built up by breeders of yesteryear. The cumulative nature of this process means that past discoveries and related research are an integral part of contemporary agricultural innovations. Conversely, the loss of a variety (or the details of the breeding histories that brought it about) means the loss of accumulated past research to the present stock of knowledge. Providing adequate funding for research is thus only part of the science story. Putting in place the policies and practices to ***accumulate*** innovations and increase and preserve the stock of knowledge is an equally important and almost universally unappreciated foundation.[3]

Estimates of the stocks of scientific knowledge arising from public and private research conducted in the United States and Sub-Saharan Africa have been developed by Pardey and Beintema (2001). Historical research spending (running from 1850 for the United States and 1900 for Africa and allowing for a gradual diminution of the effect of distant past R&D spending on money measures of the current stock of knowledge) was compared with the gross domestic agricultural product for 1995. The accumulated stock of knowledge in the United States was ten times more than the amount of agricultural output produced in that year. In other words, for every $100 of agricultural output there existed a $1,000 stock of knowledge to draw upon. In Africa the stock of knowledge in 1995 was actually less than the value of African agricultural output. The ratio of the U.S. knowledge stock relative to U.S. agricultural output in 1995 was nearly 12 times higher than

[3] Discoveries and data that are improperly documented or inaccessible (and so effectively exist only in the minds of the relevant researchers) are lost from the historical record when researchers retire from science. These "hidden" losses seem particularly prevalent in cash-strapped research agencies in the developing world, where inadequate and often irregular amounts of funding limit the functioning of libraries, data banks and genebanks, and hasten staff turnover. There can also be catastrophic losses, tied to the political instability that is a root cause of hunger. Civil strife and wars cause an exodus of scientific staff, or at least a flight from practicing science.

the corresponding amount for Africa. Stocks of knowledge measures provide a better basis for evaluating the developed versus developing country capacities for actually carrying out crop biotechnologies, and in fact the overall differences may understate the effective gaps for this advanced area of agricultural R&D. These gaps also underscore the immensity, if not the outright impossibility, of playing "catch-up," in addition to the need to transfer knowledge across borders and continents.

Biotechnology Trials. Absent meaningful data on "crop-related biotechnology research" spending, the only indication of the location of crop biotechnology research is data on the number of field trials conducted internationally.[4] Pardey and Beintema (2001) compiled data on the number of field trials conducted on bioengineered crops from 1987 through December 2000 grouped by the regions in the world where the trials were conducted (Table 2).[5] According to these data, a total of twenty seven countries conducted trials on 14 different crops and 183 different "events."[6]

[Table 2: ***Field Trials of Bioengineered Crops by Regions of the World***]

Eighty four percent of the world's trials were conducted in rich countries; two thirds of the total was in the United States and Canada alone. This points to a biotechnology-research gap between rich and poor countries that is even more pronounced than the gap in overall agricultural R&D spending (wherein 64 percent of global agricultural R&D was conducted in rich counties). Two fundamental factors may account for much of the marked spatial asymmetry in agricultural biotechnology research: specifically, who conducts the research, and the nature of the science itself. First, as indicted in Table 2, the preponderance of these biotechnology trials are conducted by private firms and most of the world's private agricultural R&D (about 94 percent, Table 1) takes place in rich counties. Second, this type of cutting-edge research requires access to highly skilled scientists, well functioning scientific infrastructure that provides ready access to reagents and a myriad of laboratory equipment and supplies, along with technical information, and the appropriately trained support staff to help carry out the research. Even though most of the trials are conducted by private firms, the sophistication of the research involved and its pace of change mean that "applied" aspects of the biosciences are likely to receive significant spillovers from on-going basic research, and from accumulated stocks of scientific knowledge arising from past research, both elements that are much more readily supplied in rich than poor countries. Indeed, it is the localized spillovers from university research (often involving tacit knowledge embodied in the scientific and technically trained people that form part of university communities) that influences the location of industrialized R&D (Adams 2001).[7]

3. An Economic Primer on Intellectual Property Rights

Research and development (R&D), like almost all other aspects of life, is an economic activity. Who pays for the research, who performs what research where, and who gains and looses (and by how much) as a

[4] Precisely what is meant by "crop-related biotechnology research" is difficult to determine. "Biotechnology" can run the whole gambit from conventional breeding, through culturing methods, to genomic and bioengineering (including transgenic) techniques. In addition, and as discussed regarding the patent data reported below, many biotechnology techniques developed with spending directed to the health sciences, for example, have agricultural applications as well.

[5] As indicators of the level of bioengineering research effort, these data must be taken with a grain of salt. To meaningfully assess the distribution of transgenic crops being tested in the ground, one would like the notion of "field trial" to be standardized across countries. One option is to count each location as a separate instance. But in the United States, for example, a "location" can have many sites. For example, test 01-024-26n in the APHIS database contains Pennsylvania as one location, but there are 313 sites comprising a total of 1,838 acres. Likewise, Canada lists field trials conducted at multiple sites within a province as one field trial, but it is not clear if all the data for all the other countries are reported similarly.

[6] An event involves the insertion of a specific gene in a particular crop, resulting in the expression of a trait in that crop. For example, insertion of the Bt cry1(c) protein producing gene into a particular cotton variety is considered an event.

[7] See also Graff, Rausser, and Small (2003).

consequence are all influenced by economic incentives. The degree to which innovators can appropriate the fruits of their endeavors lies at the heart of the incentives to invest, giving rise to pervasive policies worldwide to assign property rights to innovations in an effort to better align private incentives with social interests.

The conventional rationale for protecting intellectual property by patents or other means is to provide some proprietary or "monopoly" rights to an invention—albeit circumscribed and exclusionary in nature—in exchange for public disclosure of the details of the invention (Nordhaus 1969). What is disclosed may be useful for further innovation. But the monopoly right also encourages invention directly, and the social value of the right tends to include surplus above the private value. Thus, the (private and social) benefits of patents include wide diffusion of the creation of aspects of new or advanced technologies. The costs are transitory (for the life of a patent) and entail higher-than-otherwise prices or constrained choices of innovations subject to some monopolistic behavior. However, this conventional, static, one-off view of invention does not fully reflect the dynamic nature of a large part of research and development.

Much technological change comes in the form of cumulative innovation processes, whereby the fruits of innovation frequently materialize as the embodiment of a sequence of prior innovations. While strong patent protection may stimulate the earlier-than-otherwise development of a research tool, it can also delay or deter follow-on innovation due to the transaction costs of negotiating a license or merger and the ability to prevent competitors from introducing similar technology (Merges and Nelson 1990, Heller and Eisenberg 1998). Thus the ***dynamic cost*** of a patent within a cumulative innovation scheme—which includes the accumulated costs of delayed follow-on inventions—is an important policy consideration that is often neglected when counting the conventional (i.e., static) social cost of a patent (Koo and Wright 2002).

A special case of cumulative innovation involves the development of a research tool, that is a product or process whose only value is as an input to follow-on innovations. In agricultural biotechnology, a research tool can be a patent on a DNA sequence modified to enhance the expression of a trait such as insect-resistance, while the follow-on innovation may be a new transgenic variety of cotton. Since the patentee of a research tool can capture revenue only through direct production of the follow-on innovations, efficient compensation of the patentee, through licensing, joint ventures, or other means, is critical in providing the incentive to innovate research tools. In addition, these efficient mechanisms also reduce the transaction costs incurred by those contracting for use of the rights, thereby encouraging the utilization of research tools by follow-on innovators.

One way of reducing dynamic costs and encouraging technology transactions is to clarify property rights. The Bayh-Dole Act of 1980 and subsequent legislation, which allowed U.S. universities, other non-profit institutions, and government labs to patent and exclusively license federally funded inventions, was intended to achieve this purpose. Firms are often unwilling to invest significantly in developing and disseminating innovations lacking clearly defined property rights. This point was clearly captured by the 1945 Report of the U.S. House of Representatives, which stated that "…what is available for exploitation by everyone is undertaken by no one (cited from Jaffe 2000, p.534)." The main objective of the Bayh-Dole Act is to foster markets for the transfer of technology, and there is some evidence the Act has achieved these aims (Jensen and Thursby 2001). However, the Bayh-Dole Act is most effective when inventions require heavy expenditure in downstream technology and product development, which is not the case for all technologies. In addition, some have argued that the Act may actually constrain and delay the flow of fundamental scientific knowledge (as "prior art" concerns impede open scientific discourse through seminars and the professional literature) and shift the emphasis of university research from fundamental basic research toward more applied research that is potentially more rewarding financially for the university (or its research faculty) but not necessarily for society as a whole over the longer run (Mazzoleni and Nelson 1998).

The impact of a patent system also depends on the type of technology itself. Agriculture seeds have special attributes, most significantly their almost costless reproducible nature, which merit special attention. Under plant variety protection schemes, farmers may legally save and reuse (and sometimes sell) seeds in following

seasons, so that seed firms are faced with only the residual demand for their seeds in subsequent seasons. This problem, together with the difficulty of monitoring and enforcing property rights to seed, makes its legal protection less valuable than other forms of protection on other products. Private seed markets have responded to the appropriability problem by developing hybrid varieties or pursuing genetic use restriction technologies (GURTS), both of which prevent seeds from effectively reproducing, a form of "biological" rather than legal property protection.

What evidence is there that intellectual property rights (IPRs) stimulate inventive activity? Although there are no readily measurable markets for IPRs in which the benefits and costs of patents, for example, can be easily evaluated, a few studies have sought to measure the overall inventive effects of patents. Findings from survey studies suggest that innovators rely primarily on other means (like trade secrets or first-mover advantages) rather than patent protection to appropriate the returns from their innovative investment, with the exception of pharmaceuticals (Levin et al. 1987, Cohen et al. 2000). Some have estimated the private value of patent protection using patent data, concluding that the distribution of patent-rights values is sharply skewed, with most of the value concentrated in a small number of patents (Lanjouw et al. 1998). Using European patent renewal data, Schankerman (1998) estimated that the private value of patent protection was about 15-25 percent of the related R&D expenditure, suggesting a small impact of patent rights on innovative behavior.

Most empirical studies, all using U.S. data, have generally found weak or indeterminate empirical evidence to suggest that plant breeders' rights are effective in stimulating investments in varietal-improvement research (Perrin et al. 1983, Knudson and Pray 1991, Alston and Venner 2002). Some point out that plant variety protection does not provide patent-like ***ex ante*** investment incentives, nor generate substantial ***ex post*** licensing and enforcement activity (Janis and Kesan 2002). Alston and Venner (2002) found that varietal rights for wheat in the United States had little measurable impact on the rate of technical change in that crop, and may simply have served as a marketing tool.

Given evidence of the general lack of appropriability from patent or plant variety protection, why do innovators continue to apply for IP protection? Even accepting the claims that practicing patents may not be the primary means by which large firms recoup their R&D investments, it can still be an important incentive mechanism for smaller new entrants and the venture capital firms that often fund them. Patent portfolios may be critical to obtaining venture capital or to maintaining control of the technology while downstream innovation is pursued or production and sales capabilities are established (Kitch 1977, Mazzoleni and Nelson 1998). In addition, firms (large and small alike) use patents to block products of their competitors, and as bargaining chips when negotiating cross-licensing agreements, as is the case of the semiconductor industry (Hall and Ziedonis 2001). Strategic patenting behavior that relies on larger patent portfolios is consistent with rising rates of patenting and high patent-to-R&D spending ratios, even absent any perceived increase in the appropriable value of patents. For some developing countries with newly introduced plant variety rights such as China, a surge in PVP applications may be explained by an over-optimistic view of the prospective value of varietal rights even though the current size of the seed market and the cost and effectiveness of protection do not seem to economically justify the extent of protection presently being sought (Koo et al. 2003).

4. Crop Biotechnologies as Property

Creating new crop biotechnologies is one thing, protecting the intellectual property embodied in them is an altogether (but not unrelated) other thing, with its own set of economic costs and benefits. Notwithstanding the incentive-to-innovate arguments broached in the previous section, one view is that intellectual property rights over plant biotechnologies in rich and poor countries leads to a lock-out phenomenon: the growth in intellectual property is restricting access to proprietary research results in ways that curtail the freedom to operate for research conducted in or on behalf of poor countries, to the detriment of developing-country food-security prospects. This view is commonly held, absent evidence on the international pattern of intellectual property protection, or a clear understanding of the effect this has on the rate and direction of

inventive activity, the use to which these inventions are put, and the trade in agricultural products arising from this research. What follows is a first pass at describing the IPR evidence for plant biotechnologies internationally.

Plant Variety Protection

Global trends. Table 3 shows the pattern of applications for plant breeders rights (PBRs) since 1971 for 36 countries grouped into four per-capita-income classes. More than 136,000 PBR applications have been lodged worldwide since 1971.[8] During the 1970s and 1980s, rich countries accounted for 92 to 96 percent of the total applications. Their share throughout the 1990s declined to average 77 percent in 2001-02. PBR applications filed in upper-middle-income countries—including Argentina, Brazil, Chile, Czech Republic, Hungary, Poland, Slovakia, South Africa, and Uruguay—grew steadily since the early 1970s, while reported PBR applications in lower-middle-income countries—that now includes Bulgaria, Colombia, Romania, and the Russian Federation—began increasing a decade later.

[Table 3: ***Plant Breeders Rights Applications—Countries Grouped by Per Capita Income, 1971-2002.***]

The shifting geographical pattern of plant varietal protection arises for several reasons. The growth in the total number of applications for high-income countries is largely due to an increase in the rate of applications per country per year. Most high-income countries had PBR legislation in place for most of the period reported here. In contrast—and setting aside some initial "start-up" blips in PBR applications—, the majority of middle-income countries showed no general tendency to increase their rates of application over time.[9] In fact some countries in this group experienced a decline in application rates. For this group, the preponderance of growth was due mainly to an increase in the number of countries offering plant breeders rights (3 countries in 1971, 5 in 1985, 8 in 1990 and 13 in 2002).[10] An exception was the lower-middle-income countries where there was a particularly marked jump from 131 applications during 1991-1995 to 2,437 applications during 1996-2000. Applications lodged in the Russian Federation (which reports applications beginning in 1994) grew rapidly to 825 in 2001, and there were much smaller but still sizable increases in Colombia and Bulgaria as well during the late 1990s. Increasing rates of protection may reflect legal-cum-economic as well as institutional factors. One would expect applications to increase over time as awareness of the existence and effectiveness of PBRs in a particular country increased and as the economic costs of applying for and evaluating applications declined with improved bureaucratic procedures.[11]

---

8 Some applications were lodged before 1970, but the number is small compared with the totals reported in Table 3.

9 Koo et al. (2003) describe a start-up phenomenon in China when it began issuing PBRs in April 1999, where an initial blip in applications was taken to reflect pent up demand for these anticipated rights being satisfied. Note, China is not included in the UPOV series reported here.

10 Plant breeders' rights have been available in many rich countries for at least the past three decades. Germany, for example, has issued plant breeders rights since at least the 1950s and likewise for a few other European countries. The United States began issuing plant variety protection certificates (PVPCs) in 1971 for sexually reproduced plants: asexually reproduced plants (like grape vines, fruit trees, strawberries, and ornamentals that are propagated through cuttings and graftings) have had recourse to intellectual property protection since 1930 when the Plant Patent Act was passed. Many middle-income counties passed PVP legislation during the 1990s in compliance with their ***sui generis*** obligations to offer the intellectual property rights over plant varieties enshrined in article 27(3)b of the 1995 Trade-Related Aspects of Intellectual Property (TRIPS) agreement in the World Trade Organization (WTO). An indication of the geographical extent of plant breeders' rights is the listing of member countries of the International Union for the Protection of New Varieties of Plants (UPOV). At its inception in 1961, UPOV had 5 member countries (Belgium, France, Germany, Italy, and Netherlands, all of them high-income countries), growing to 20 countries by the end of 1992, then increasingly rapidly to 53 countries—21 high income, 27 middle income and 5 low income—as of September 2003. Notably, under the TRIPs agreement, the "least developed" countries (a WTO designation) are exempt from complying with article 27(3)b until 2005.

11 In addition, some countries have expanded the scope of crops eligible for protection overtime. In China, for instance, a total of 10 species were eligible for protection in September 1999, growing to 30 species by March 2002 (including 5

Notably, the number of plant breeders rights sought in low-income countries is negligible. Since 1971 they accounted for just 145 (0.106 percent) of the global total of 136,234 recorded PBR applications, with almost 85 percent of these rights being sought in the Ukraine alone. The principal proximate cause of this situation is the lack of rights on offer in poor-countries. More fundamentally, it reflects a range of economic influences regarding the costs and benefits of securing breeders rights in a particular jurisdiction.

To capture this cost-benefit calculus, Koo et al. (2003) use an option value model to characterize the crop breeders' decision to apply for and retain varietal protection. While the costs of gaining and securing plant variety protection are known with reasonable surety, the sequence of future returns from a varietal right is highly uncertain for many reasons. There are uncertainties about the size of the appropriable seed market for a given crop, the probability of commercial success of the protected variety, and the extent of enforcement of assigned property rights. Where required, breeders make periodic (often annual) renewal decisions, preserving the right to pay renewal fees and exercise their exclusionary rights in future periods. Thus applying for, and subsequently renewing, PVP rights is a way of reserving the rights to potential future revenues, even if revenues in the short term are negligible. Thus the expected value of holding plant variety rights consists of the current returns captured from the coming year and the option to renew the right in the subsequent year.

Decisions taken by individual breeders to obtain PBRs in a particular jurisdiction, and the factors that affect those decisions, are directly relevant for efforts to account for variations across countries in the total number of PBRs sought. Specifically, other things being equal, countries with weaker ***effective*** property rights (be they related to plant biotechnologies or crop varieties in particular, or more broadly, including the rights encompassed by commercial contract law) and those with smaller sized seed markets are likely to have less PBR applications than countries with larger seed markets and more effective property rights.

To test this notion, we regressed the total number of PBR applications for 42 countries (i = 1,…., 42) during the period 1997-2001, $PBRT_i$, against the total value of crop production in 2002, VC_i, the per capita income of each country in 2002, PCI_i, and the period of time in years since varietal rights applications were first lodged, PT_i. The value of crop production was deemed indicative of the value of the corresponding seed markets,[12] per capita income was used as an instrumental variable measuring the effectiveness of PBRs, while the number of years since varietal rights were first on offer proxied the transactions costs involved in securing and maintaining rights (the longer the PBR legislation has been operative, presumably the lower the costs). Our regression results are reported in Table 4. Choice of functional form is always problematic, so we tried two commonly used forms. Regression (1) is a double-log specification, wherein both the dependent and all the independent variables were logged, and regression (2) is a semi-log specification wherein only the right-hand side variables are logged.

[Table 4: ***Plant Variety Rights Applications—Regression Results***]

Obvious omitted variable and other empirical issues caution against over-interpreting these results. But they are nonetheless suggestive, not least because well over 40 percent of the cross-country variation in total PBR applications (as indicated by the error sums of squares, R^2) is accounted for by the included variables. Greater numbers of varietal rights applications are associated with more valuable seed markets and more effective IPR protection (as indexed by the per capita income variable, ***PCI***). Even after controlling for differences in market size and IPR effectiveness, lowering the transactions costs involved in applying for protection (as proxied by ***PT***) also generates statistically significant increases in PBR applications.

---

major cereals, 2 oil crops, 2 roots and tubers, 10 vegetables and fruits and 11 flowers and grasses but excluding cotton).

12 For those countries in which we had overlapping data, regressing the value of crop production against the proximate value of seed sales (obtained from ISF 2003) revealed a reasonably strong association—specifically a correlation coefficient of 0.72.

Foreign PBR Applications. The UPOV data on varietal rights applications allows us to distinguish between domestic and foreign applicants. Overall, 33 percent (16,548 of a total of 48,675) of the applications filed during 1997–2001 were lodged by foreigners, an indication of the extent of potential spillovers of varietal improvement research done in one locale on seed market and production developments elsewhere in the world. Just on two thirds of the total foreign applications were filed in rich countries and only one percent in low-income countries. Middle-income countries make up the balance, with 26 percent of the foreign applications being lodged in upper-middle income countries.

The ***intensity*** of foreign participation in domestic varietal rights markets differs markedly. Looking regionally, 61 percent of the PBR applications in upper middle-income countries were lodged by foreigners, 32 percent of the low-income applications are foreign, as are 31 percent of the applications in high-income countries and 22 percent of those lodged in lower-middle income countries. The country-by-country participation of foreigners is even more variable. For example, 84 percent of the applications in Switzerland are foreign as are 82 percent of the Canadian applications. For the United States the share is 54 percent, and lower in other European countries (e.g., 37 percent in the United Kingdom, 16 percent in the Netherlands and Germany, and 11 percent in France). Foreigners account for 23 percent of the PBR applications lodged in Japan.

Regressions (3) and (4) in Table 4 were run to assess if there was any systematic sources of variation in the foreign intensity of national PBR applications using the same variables we used to account for cross-country variation in total PBR applications. Between 22 and 25 percent of the variation in foreign intensity ratios was explained by our variables. All the explanatory variables had the expected signs, with the size of the domestic seed market being the statistically most significant explanator of the degree to which foreigners participate in local PBR markets.

European and United States Trends. Worldwide, seed sales are estimated to be $30 billion annually (ISF 2003). While the economic value of seed markets within the European Union (about $5.2 billion in total) are a little less than U.S. seed sales ($5.7 billion), there have been three times more PBR applications lodged throughout Europe than the United States since 1971 (Table 5). This may partly reflect the different forms of varietal protection effectively on offer in Europe versus the United States. Plant varieties have been subject to utility patents in the United States since 1985, whereas utility patents for plant varieties in Europe is still not an established practice (Henson-Apollonio 2002). Overall, there are more than twice as many plants for which protection is sought under the 1930 U.S. Plant Patent Act as PVP applications, trending toward a higher proportion of plant patent versus PVP applications over time. Another explanation is the historical practice of multiple applications for the same variety among different national jurisdictions in Europe, whereas only one application is required per variety in the United States.

[Table 5: ***Plant Breeders Rights Applications in the European Union and the United States***]

Four countries—the Netherlands, France, Germany and the United Kingdom—account for most of the European applications. Adding applications lodged with the Community Plant Variety Office (CPVO) to those filed nationally, the Netherlands accounted for 35 percent of the European total, France 22 percent, Germany 16 percent and the United Kingdom 8 percent.[13] The number of PBR applications filed with the CPVO has

[13] Prior to April 27, 1995 when the Community Plant Variety Office (CPVO) was established, a breeder seeking protection for a variety throughout the European Union was required to submit an application to each of the member states. Now with a single application to the CPVO, a breeder can be granted varietal protection rights throughout the European Union. This European-wide system—CPVO members currently include Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, and the United Kingdom—operates in parallel with respective national systems, although the owner of a variety cannot simultaneously exploit both a community plant variety right (CPVR) and a national plant breeders right in relation to that variety. Individuals or companies from member states of UPOV, but not a member of the European Union, can

increased over time, offsetting declines in the number of applications lodged with national protection offices. In 1996, there were 1,385 applications lodged with the CPVO and a total of 2,766 applications made to individual national systems. By 2000, almost equal numbers of PBR claims were filed with the CPVO and the respective national offices (about 2,000 applications each), and in 2001 CPVO applications (2,158) exceeded those filed with national offices (1,864)(UPOV 2002).

About 85 percent of the PVP applications made in the United States since 1971 were filed by private companies (Table 6). Universities accounted for 11 percent of the total overall, with comparatively few applications from private foundations or government agencies such as the U.S. Department of Agriculture. Just four private firms—Dupont (including Pioneer HiBred), Seminis, Monsanto, and Delta and Pineland—accounted for 31 percent of the total PBR applications since 1971. The only two public entities to appear among the top 15 applicants are the Texas and Minnesota agricultural experiment stations (ranked 8th and 9th respectively), with up to 150 applicants accounting for the remaining 57 percent of the total. Notably the pattern of PVP applications has become less, not more, concentrated over time. The top four applicants overall accounted for the same share in 1981-90 as in 2001-02, while the share of the 16th and lower ranked applicants grew from 54 to 62 percent.

[Table 6: ***US Plant Variety Protection Certificate Applications by Applicant***]

Regarding the types of crops for which varietal protection is sought, oil and cereal crops—in descending order of importance, soybeans, wheat and corn—accounted for 55 percent of the U.S. total since 1971, while vegetable crops and grasses made up another 30 percent (Table 7). Ornamental plants accounted for only 2 percent of the U.S. total. This contrast with European patterns of protection, where 60 percent of the PBR applications lodged with the CPVO since 1995 were for ornamental plants, 23 percent for agricultural crops, and 10 percent for vegetables (Table 8). However, if 88 percent of the U.S. plant patents were for clonally propagated ornamentals (a feasible share), the types of material for which protection is sought in the United States would be in line with European practices.

[Table 7: ***US Plant Variety Protection Certificate Applications by Crop Category***]

[Table 8: ***CPVO Plant Breeders Rights Applications by Type of Crop, 1996-2002***]

Biotechnology Patenting Patterns

An initial foray into examining the international dimensions of patent activity in biotechnology and specific sectors, such as agriculture and health, is presented in Figure 1. Numbers of patent applications submitted to the World Intellectual Property Organization (WIPO) under the Patent Cooperation Treaty (PCT) (Panel a) and patents granted by the European Patent Office (EPO) (Panel b) are plotted against the year published. For this analysis, patent documents were selected on the basis of the International Patent Classification (IPC) scheme used by the patent offices. Data were obtained for documents satisfying criteria for "biotechnology" and further sub-divided into "agricultural biotechnology" and "health biotechnology."[14] The numbers of the two sub-divisions add to more than for biotechnology as some documents fit into both categories. While initially agricultural biotechnology patent documents exceeded health related documents both at EPO and WIPO, the

also apply, provided that an agent domiciled in the Community has been nominated. The duration of CPVR protection is 25 years for most crops, and 30 years for potato, vine and tree varieties.

[14] For this work, "biotechnology" refers to "the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services", a definition used by the OECD (see "Statistical definition of biotechnology" 12 June 2002 in the Biotechnology, Statistics section of www.oecd.org)

situation reversed in 1999. Furthermore, the spectacular rise in patent filings in the late 1980s and through the 1990s appears to be leveling off.

[Figure 1: ***Biotechnology Patents***]

The data presented here contrast with recently reported analyses of Graff et al. (2003) who noted drops in patent grants in plant biotechnology at the EPO after peaking in 1994-1995. The differences may be due to disparities in the definition of plant or agricultural biotechnology. Their definition comprises a description of the scope of technologies, such as genetic engineering of plants, plant genes, and plant breeding methods. They appear to choose only those documents having one of a small subset of IPC codes and specific technology keywords. In contrast, our definition encompasses many aspects of plant biotechnology, including genetic modification of plants, biocides, organismal or enzymic-based methods for preservation of foods, microbiological treatment of water and soil, compositions containing micro-organisms or enzymes, and processes using micro-organisms or enzymes. The definitional differences are highlighted by the order of magnitude difference in the number of documents that satisfy the criteria. For example, in 2000, we obtained 8,859 PCT patent filings and 5,097 EP patent grants for inventions concerning agricultural biotechnology compared with around 625 PCT applications and 50 EP patent grants for the narrower area of "plant biotechnology" reported by Graff et al. (2003).

The percentage of PCT applications in agricultural biotechnology has been on the rise. In 1985, agricultural biotechnology applications were 4.0 percent of the total submitted. By 1990, they were 7.5 percent of the total, and in 2000 had risen to 9.7 percent of the total. In 2000, ag-biotech patents granted in EPO were 18.5 percent of the total granted. Clearly further examination of patent activity with an eye to the commercial and public good consequences encompassing the changing geographical and institutional origins of biotechnology innovations on a global scale, and their spillovers or transfer to other countries, will be sensitive to the patents included in the source set of documents.

5. Crop Biotechnology Use

The evidence on the worldwide dissemination of contemporary, bioengineered crop technologies is usefully viewed in the context of the diffusion of the classically bred crop varieties that preceded them.

Classically Bred Crop Varieties

Worldwide, around 95 percent of major cereal production gains during the past four decades came from increased yields, which have more than doubled since 1961 (Runge et al. 2003). Increasing yields result from increased use of inputs such as agricultural chemicals (including fertilizers, herbicides, and pesticides), irrigation water, and improved crop varieties. In the developed world at least, the growth in crop yields began picking up pace several hundred years ago. Looking in detail at developments in U.S. wheat varieties since 1800, Olmstead and Rhode (2002), for example, estimated that roughly one-half of the U.S. growth in labor productivity in that crop between 1839 and 1909 was attributable to biological innovations. Pardey et al. (1996) showed that wheat varietal change in the United States accelerated during the 20th century—an average of 5.1 commercially successful wheat varieties were introduced each year from 1901 to 1970, the rate jumped to 21.6 varieties per year during the period 1971 to 1990. Moreover, the creation of these new varieties continued to rely heavily on foreign germplasm. By the early 1990s, one-fifth of the total U.S. wheat acreage and virtually all the spring-wheat cropped in California were sown to varieties with CIMMYT ancestry.[15]

[15] CIMMYT is the Spanish acronym for the International Maize and Wheat Improvement Center based in El Batán, Mexico. Pardey et al. (1996) estimated that the improved genetic makeup of wheat varieties between 1970 and 1993 was worth almost $43 billion (1993 prices) to the United States—equivalent to 10.6 percent of the present value of

There are still long lags between committing R&D dollars and realizing the returns on that investment. Even in the United States it took decades to build up the genetic resource base and train and deploy the scientists skilled in classical genetic manipulation techniques before reaping the really big dividends during the latter half of the 20th century. In the developing world, scientific crop breeding lagged well behind. Beginning in the 1950s and 1960s, improved varieties became increasingly available to farmers and yields rose: wheat went from 1 ton per hectare or less in China and India in the mid-1960s to over 2.5 tons in India, and almost 4 tons in China, by the late 1990s. Table 9 shows the rapid spread of modern rice, wheat and maize varieties throughout the developing world. Asia embraced these new varieties most rapidly, while adoption lagged in Sub-Saharan Africa. A striking feature of these data, however, is the limited uptake of scientifically bred crop varieties throughout most of the developing world as late as 1970. When virtually all the cropped acreage in rich countries was sown to scientifically bred rice and wheat varieties, less than one-third of the developing world's rice acreage and just one-fifth of its wheat acreage were planted to modern forms of these crops.

[Table 9: Share of Area Planted to Modern Varieties of Rice, Wheat, and Maize]

For these three food staples much of the crop improvement research involved publicly funded and conducted research. The big innovation of the 1960s and 1970s for rice and wheat was the development and release of increasing numbers of semi-dwarf varieties by national and international research agencies bred using plant material and crop transformation techniques that were entirely public domain. Almost all the resulting improved varieties were made available without personal or corporate intellectual property rights. The public sector performed most of the research, and in few jurisdictions were IPRs over the varieties themselves or the techniques used to transform them even a legal option at that time.

For corn the story is a different. While publicly bred varieties were, and remain, a feature of this crop, the private sector presence is much more pronounced. Hybrid corn technologies that took off in the United States in the 1930s (and later elsewhere) offered significant protection for the intellectual property embodied in them. This made it possible for breeders to appropriate a larger share of varietal benefits than was possible for the self-replicating forms of varietal transformations featured in rice and wheat.[16] For hybrid corn varieties, as long as the in-bred lines were kept secret (and laws were in place in the United States and elsewhere to help preserve these trade secrets), the cost of imitation was prohibitively large enabling inventors to appropriate significant shares of the benefits stemming from their efforts.

Table 9 indicates the developing-country uptake of modern maize varieties has also been substantial, but less extensive than the move to improved forms of rice and wheat worldwide. This could partly be due to the greater proprietary (and private sector) nature of maize varietal changes, but a whole host of other influences could be operative as well. About 86 percent of the improved acreage world wide is sown to hybrids, the rest to open pollinated varieties.

Varietal Spillovers. While the agroecological specificities of much agricultural R&D—and especially many crop biotechnologies—limits the geographical scope of agricultural innovations, there is overwhelming evidence that spatial spillovers of technologies have played a pivotal part in productivity improvements worldwide. In reviewing the economic studies of this phenomenon, Alston (2002) concluded that interstate or international R&D spillovers might account for half or more of the total measured productivity growth.

---

wheat production during this period—, and that up to $13.6 billion of that total benefit was attributable to varietal spillins from CIMMYT alone.

[16] Hybrid technologies were also pursued for rice and wheat but less extensively so. Knudson and Ruttan (1988) document efforts to develop hybrid wheats in the United States. Hybrid rice is grown extensively in China, beginning in the mid-1960s. Since then, the area under hybrid rice has increased steadily to about 23 percent in 1981 and 61 percent in 2001 (Fan et al. 2003). Notably, profit potentials were not a contributing factor to the development of this technology in China where the research was a government undertaking.

Spillovers of crop varietal technologies have flowed in all sorts of directions. Looking at the spillins to the United States of varietal improvement research done at the international research centers, specifically CIMMYT in Mexico and IRRI in the Philippines, Pardey et al. (1996) estimated that the U.S. economy gained at least US$3.4 billion and up to US$14.6 billion—depending on the benefit attribution methods deployed—from 1970 to 1993 from the use of improved wheat varieties developed by CIMMYT. In the same 23-year period, they found that the U.S. economy realized at least US$30 million and up to US$1 billion through the use of rice varieties developed by IRRI.

In more recent research, Pardey et al. (2002) quantified the benefits from crop improvement research in Brazil and attributed them between the Brazilian national agricultural research agency (Embrapa), other public and private agencies operating in Brazil, and spillovers from the CGIAR and the United States. They found that 64 percent of the total benefits from varietal improvement for upland rice in Brazil (which had a present value of US$1,683 million in 1999 dollars over 1984-2003), were from non-Embrapa sources. Likewise, 67 percent of the total benefits from varietal improvement research for edible beans (which had a present value of US$677 million in 1999 dollars over 1985-2003) came from non-Embrapa sources, mostly within Brazil, whereas 77 percent of the total benefits from varietal improvement research for soybeans (which had a present value of US$12,473 million in 1999 dollars over 1981-2003) was due to non-Embrapa sources, with 22 percent of the benefits attributable to spillins from the United States.

Bioengineered Crop Varieties

Where the crop varieties and bioengineered traits embodied in them perform well and been given approval for commercial use, the rate of uptake has been rapid (although contrary to some claims, not entirely unprecedented, even for biological innovations used in agriculture).[17] James (2002) estimates that 58.7 million hectares were planted to bioengineered crops worldwide in 2002, an increase from 52.6 million hectares in the previous year and well up on the 2.8 million hectares planted in 1996.[18]

Despite this growth, the geographical, crop, and technological scope of bioengineered crops is still small. In 2002, the preponderance of the area under these crops consisted of bioengineered soybean (62 percent of the total bioengineered cropping area sown to this crop): 21 percent of the area was sown to bioengineered maize, 12 percent to cotton, and 5 percent to canola. Just 4 countries accounted for 99 percent of the global total in 2002 (Figure 2). Two-thirds of this global total was planted in the United States, 22 percent in Argentina, 6 percent in Canada, and 3 percent in China. Two traits dominate the picture—herbicide tolerance (mainly in soybeans and canola) and insect tolerance (mainly in corn and cotton)—with some limited use of bioengineered viral resistance in papaya and squash.

[Figure 2: ***Area Sown to Bioengineered Crops Worldwide***]

Figure 2 shows that the developing-country share of global bioengineered crop area has grown: from 14 percent of the world total in 1997 to about 27 percent in 2002. Notably, it is plantings in just four countries—soybeans in Argentina, and cotton in China, South Africa, and for the first time in 2002, India—that accounts for the lion's share of the developing-country bioengineered acreage. Finding bioengineered traits that deal successfully with local production constraints is one thing, expressing them in specific crop varieties that compete well locally against landraces and conventionally bred varieties of the same crop (absent the bioengineered trait) is an altogether other thing. Not surprisingly, the bioengineered traits are being grown in

[17] Griliches (1957) studied the uptake of hybrid corn technologies in the United Sates and showed that Iowa, for example, went from 0 to 50 percent of the state's corn acreage sown to hybrid varieties in just 6 years (1932 to 1938), reaching 90 percent by 1940.

[18] The Flavr-Savr™ tomato, genetically engineered to delay softening so the tomato could ripen on the vine and retain its "fresh picked" flavor was the first bioengineered crop to be grown commercially (in 1994).

developing-country areas that are agroecologically similar to the rich countries for which the traits were first developed, and in most cases involve the identical crop varieties.[19] This is precisely where the spillover costs are smallest (consisting mainly of local screening and regulatory approval costs along with the costs of marketing the technology). That is, disseminating these particular bioengineered crop varieties involves only adaptive or imitative technology development costs beyond the initial discovery costs—a much smaller cost than inventing entirely new bioengineered traits and successfully expressing those traits in locally superior varieties of locally important crops.

The site-specificity of many agricultural biotechnologies arises from agroecological aspects, which defines the size of the relevant market in a way that is much less common in other industrial R&D. As Alston and Pardey (1999) described, one way to think of this is in terms of the unit costs of making local research results applicable to other locations (say, by adaptive research), which must be added to the local research costs. Such costs grow with the size of the market.[20] Economies of size, scale, and scope in research mean that unit costs fall with size of the R&D enterprise, but these economies must be traded off against the diseconomies of distance and adapting site-specific results (the costs of "transporting" the research results to economically "more distant" locations). Thus, as the size of the research enterprise increases, unit costs are likely to decline at first (because economies of size are relatively important) but will eventually rise (as the costs of economic distance become ever-more important).

Given the United States dominates the world totals, its trends are worth scrutinizing. Table 10 shows the trend in bioengineered acreage in the United States since 1996, differentiating among crops and technology types. Ranked in terms of total acreage, the world and U.S. crop relativities for 2002 are the same—soybeans dominate, followed by corn then cotton. However, the intensity of use of bioengineered versus classically bred crops differs between the Unites States and the rest of the world.

[Table 10: Bioengineered Cropping Patterns in the United States]

The United States uniformly makes more intensive use of bioengineered crops than the rest of the world (Figure 3). While 77 percent of the U.S. canola crop was sown to bioengineered varieties in 2002, the corresponding rest-of-world share was 28 percent. Likewise, bioengineered soybeans covered 71 percent of the U.S. soybean acreage and only 28 percent of the rest-of-world soybean area.[21] For cotton the corresponding shares were 71 percent for the United States and 11 percent for the rest of the world; for corn it was 34 percent for the United States and 1.4 percent elsewhere. This reflects both technology and market realities. While the dominant bioengineered traits (to date targeting mainly budworm/boll weevil complexes in cotton, European stem borers in corn, and Roundup® and Liberty Link® resistance in soybeans and canola) have yield enhancing or cost reducing consequences for rest-of-world farmers, they are especially consequential for U.S. producers. And, given their earlier regulatory approval in the United States, these traits are now incorporated into a myriad of locally optimized crop varieties.

---

[19] For example, all the officially approved Monsanto/DeltaPine bioengineered cotton varieties grown in China are the same varieties grown in the United States, while most of the bioengineered Chinese varieties are based on older DeltaPine varieties introduced into China in the 1940s and 1950s (Pray et al. 2002). Likewise the transgenic cotton varieties grown in Mexico are from the United States (Traxler et al. 2003), and in South Africa, NuCotn 37-B, an American variety, is widely used (Thirtle et al. 2003).

[20] A close analogy can be drawn with spatial market models of food processing in which processing costs fall with throughput but input and output transportation costs rise with throughput so that when the two elements of costs are combined a U-shaped average cost function is derived (e.g., Sexton 1990).

[21] In some U.S. states, the share of 2002 soybean acres planted to Roundup Ready® soybeans approached 90 percent (Marra, Pardey and Alston 2003).

[Figure 3: Bioengineered Cropping Intensities—United States vs Rest-of-the-World, 2002]

6. Summing Up

In this paper we showed that the preponderance of research conducted on bioengineered crops is carried out in rich countries (which is where the overwhelmingly large share of biotechnology acreage is still to be found), and much of the product development work is done by private firms. Moreover, most of the bioengineered traits and the specific crop varieties that are planted in developing countries are spillovers from, or adaptive modifications of, rich-country research. Only when we achieve a reasonable rate of inventor appropriability of the returns to the technologies that are applicable in less-developed countries, combined with an economic infrastructure that facilitates adoption of those technologies, can we expect a significant private-sector role to emerge in the poorer parts of the world.

We also drew attention to the comparatively low rates of investment in public agricultural R&D in developing countries, where government revenues may be comparatively expensive (because it is comparatively expensive to raise government revenues through general taxation measures), or have a comparatively high opportunity cost.[22] Many less-developed countries are characterized by under-investment in a host of other public goods, such as transportation and communications infrastructure, schools, hospitals, and the like, as well as agricultural science. These other activities, like agricultural science, might also have high social rates of return.[23]

Even among the rich countries of the world, most have not had very substantial private or public agricultural science industries; so why should we expect the poorest countries of the world to be more like the richest of the rich in this regard? [24] The lion's share of the public (as well as private) investment in agricultural science has been undertaken by a small number of countries, and these have also been the countries that have undertaken the lion's share of scientific research, more generally.[25] An important consideration is economies of size, scale, and scope in research, which influence the optimal size and portfolio of a given research institution. In some cases the "optimal" institution may efficiently provide research for a state or region within a nation, but for some kinds of research the efficient scale of institutions may be too great for an individual nation (e.g., see Byerlee and Traxler 2001). Many nations may be too small to achieve an efficient scale in much if any of the relevant elements of their interests' in crop biotechnology research, except perhaps in certain types of adaptive research.

Historically there have been large spillovers of improved varieties (and the technology and know-how embodied in them) among countries. However, as Alston and Pardey (2003) emphasize, we cannot presume that the rich countries of the world will play the same roles as in the past. In particular, countries that in the

[22] Alston and Pardey (2003) develop these and related ideas in more detail.

[23] As Alston and Pardey (2003) point out, there are also political factors at play here. In rich countries, agriculture is a small share of the economy and any individual citizen bears a negligible burden from financing a comparatively high rate of public investment in agricultural R&D (for instance, in the United States expenditure of $2 billion on agricultural R&D amounts to less than $10 per person per year). The factors that account for high rates of general support for agriculture in the industrialized countries can also help account for their comparatively high public agricultural research intensities. In many less-developed countries, where agriculture represents a much greater share of the total economic activity, and where per capita incomes are much lower, a meaningful investment in public agricultural research might have a much more appreciable impact on individual citizens—and the problem is that this burden is felt now, while the payoff it promises may take a long time to come, and will be much less visible when it does.

[24] As noted by Pardey and Beintema (2001), the geographical concentration among countries of particular classes of research—for instance research into agricultural chemicals or machinery—is even greater than that for agricultural R&D in total.

[25] Pardey and Beintema (2001) report that the United States conducted 42 percent of the world's total investment in all science in 1995.

past relied on technological spillovers from the North may no longer have that luxury available to them in the same ways or to the same extent. This change can be seen as involving three elements:

- The types of technologies being developed in the rich countries may no longer be as readily applicable to less-developed countries as they were in the past (the agenda in richer countries is shifting away from areas like yield improvement in major crops to other crop characteristics and even to non-agricultural issues);

- The private presence in rich country agricultural R&D has increased and many biotech companies are not as interested in developing technologies for many less-developed country applications, and even where they have such technologies available, often they are not interested in pursuing potential markets in less developed countries, for a host of reasons;

- Those technologies that are applicable and available are likely to require more substantial local development and adaptation, calling for more sophisticated and extensive forms of scientific research and development than in the past (for instance, more advanced skills in modern biotechnology or conventional breeding may be required to take advantage of enabling technologies or simply to make use of less-finished lines that require additional work to tailor them to local production environments).

In short, different approaches may have to be devised to make it possible for less-developed countries to achieve equivalent access, to tap into technological potentials generated by rich countries; and in many instances less-developed countries may have to extend their own R&D efforts farther upstream, to more fundamental areas of the science.

Some argue that strengthening intellectual property regimes in poorer countries is one way of stimulating investments in developing-country R&D as well as efforts to commercialize crop technologies developed elsewhere. Others argue that the number and breadth of patents, plant breeders' rights and other forms of intellectual property is already hindering the R&D required to tackle food security concerns of poor countries. Binenbaum et al. (2003) studied the situation for the 15 staple food crops of the world and concluded there was undue concern that intellectual property rights were currently limiting the freedom to operate for research on developing-country food staples. This paper reinforced the IP evidence they assembled for some key enabling technologies used in agriculture—IPRs concerning crop biotechnologies are overwhelming concentrated in rich-country jurisdictions, meaning poor-country research can proceed largely unencumbered by any intellectual property restraints. Binenbaum et al. (2003) also showed that bilateral trade in food staples from poor- to rich-country jurisdictions—where the IP was presumptively in force—was meager (and limited to just a few crops from a few poor countries), meaning the results of this research can be disseminated and used with few if any IP impediments if the intent is to feed and cloth poor people in poor countries.

As things stand today, the constraints to conducting modern crop biotechnology research in developing countries appear to lie largely beyond IP concerns. Market considerations limit substantial private interests for many crops in many developing countries, and the intensity of public investments is generally low for reasons that do not seem likely to change soon.[26] Intellectual property rights may have a role to play in stimulating efforts to commercialize crops in developing countries, especially helping to harness spillin technologies developed elsewhere, but, at least in the nearer term, they will be no substitute for rich and poor country governments alike reinvesting in the R&D required to maintain and continue adding to the crop yields necessary in the decades ahead.

[26] Some even see a scientific apartheid taking shape, with large parts of the developing world being left behind or denied the prospects science has to offer for growth, development, and prosperity (Serageldin 2001).

References`

Adams, J.D. "Comparative Localization of Academic and Industrial Spillovers." NBER Working Paper No 8292. Washington D.C.: National Bureau of Economic Research, May 2001.

Alston, J.M. "Spillovers." ***Australian Journal of Agricultural and Resource Economics*** 48(3)(September 2002): 315-346.

Alston, J.M. and P.G. Pardey. "Developing Country Perspectives on Agricultural R&D—New Pressures for Self Reliance?" chapter 2 in P.G. Pardey, J.M. Alston and R.R. Piggott. eds. ***Agricultural R&D Policy in the Developing World***. Washington D.C.: International Food Policy Research Institute, 2003 in process.

Alston, J.M. and R.J. Venner. "The Effects of the US Plant Variety Protection Act on Wheat Genetic Improvement." ***Research Policy***, 31 (2002): 527-542.

Alston, J.M., M. C. Marra, P.G. Pardey, and T.J. Wyatt. ***A Meta Analysis of Rates of Return to Agricultural R&D: Ex Pede Herculem?*** Washington D.C.: IFPRI Research Report No 113, 2000.

Alston, J.M. and P.G. Pardey. "The Economics of Agricultural R&D Policy." Chapter 2 in J.M. Alston, P.G. Pardey, and V.H. Smith, eds. ***Paying for Agricultural Productivity***, Baltimore: Johns Hopkins University Press, 1999.

Binenbaum, E., C. Nottenburg, P.G. Pardey, B.D. Wright, and P. Zambrano. "South-North Trade, Intellectual Property Jurisdictions, and Freedom to Operate in Agricultural Research on Staple Crops." ***Economic Development and Cultural Change***. 51(2)(January 2003): 309-336.

Boettiger, S. G. Graff, P.G. Pardey, E. van Dusen, and B.D. Wright. "Intellectual Property Rights for Plant Biotechnology: International Aspects." Chapter in P. Christou and H. Klee eds. ***Handbook of Plant Biotechnology*** Chichester: John Wiley and Sons, 2003 forthcoming.

Byerlee, D. "Modern Varieties, Productivity, and Sustainability: Recent Experience and Emerging Challenges." ***World Development*** 24 (4)(1996): 697–718.

Byerlee, D. and P. Moya. ***Impacts of International Wheat Breeding Research in the Developing World, 1966–90.*** Mexico City: ***Centro Internacional de Mejoramiento de Maiz y Trigo*** (CIMMYT), 1993.

Byerlee, D., and G. Traxler. "The Role of Technology Spillovers and Economies of Size in the Efficient Design of Agricultural Research Systems." Chapter 9 in J.M. Alston, P.G. Pardey, and M. J. Taylor eds. ***Agricultural Science Policy: Changing Global Agendas***. Baltimore: Johns Hopkins University Press, 2001.

Cohen, W. A., R.R. Nelson R.R., and P.P. Walsh. "Protecting their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or not).", NBER Working paper No. 7552, Washington D.C., National Bureau of Economic Research, 2000.

Community Plant Variety Office (CPVO). ***Annual Report, 2001***. Community Plant Variety Office, Paris, 2002

Drew, J. and P.G. Pardey. "Genetic Manipulation of Agricultural Crops—Looking Long Run." University of Minnesota, Department of Applied Economics Working Paper, in progress, 2003.

Fan, S., C. Chan-Kang, K. Qian, and K. Krishnaiah. "National and International Agricultural Research and Rural Poverty: The Case of Rice Research in India and China." EPTD Discussion Paper No. 100. Washington, D.C.: International Food Policy Research Institute, forthcoming 2003.

Fernandez-Cornejo, J. and W.D. McBride. ***Adoption of Bioengineered Crops***. Agricultural Economic Report no. 810. Washington D.C: Economic Research Service, USDA, May 2002.

Fowler, C. Unnatural Selection: Technology, Politics, and Plant Evolution. Yverdon, Switzerland: Gordon and Breach, 1994.

Fowler, C., and P. Mooney. ***Shattering: Food, Politics, and the Loss of Genetic Diversity.*** Tucson: University of Arizona Press, 1990.

Graff, G., G.C. Rausser, and A.A. Small. "Agricultural Biotechnology's Complementary Intellectual Assets." ***Review of Economics and Statistics*** 85(2)(2003):349-363.

Griliches, Z. "Hybrid Corn: An Exploration in the Economics of Technological Change." ***Econometrica*** 25(4)(1957): 501-522.

Hall, B.H. and R.H. Ziedonis, "The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979-1995." ***Rand Journal of Economics***, 32(1)(2001): 101-128.

Heisey, P. W., M. Lantican, and H. J. Dubin. Assessing the benefits of international wheat breeding research: An overview of the global wheat impacts study. Part 2 in P. L. Pingali, ed. ***CIMMYT 1998–9 World Wheat Facts and Trends: Global Wheat Research in a Changing World: Challenges and Achievements***. Mexico City: ***Centro Internacional de Mejoramiento de Maiz y Trigo*** (CIMMYT), 1999.

Heller, M. and R. Eisenberg. "Can Patents Deter Innovation? The Anticommons in Biomedical Research." ***Science***. 280(1998): 698-701.

Henson-Apollonio, V. "Patent Protection for Plant Material." Paper presented at WIPO-UPOV Symposium on the Co-Existence of Patents and Pant Breeders' Rights in the Promotion of Biotechnology Developments" Geneva, October 25, 2002. Available at http://www.upov.org/en/documents/Symposium2002/pdf/wipo-upov_sym_02_4.pdf Accessed on January 2003.

International Seed Federation (ISF). "Estimated values of the commercial markets for seed and planting material for some countries." Switzerland, Available at www.worldseed.org/statistics.html. Accessed September 2003.

Jaffe, A.B. "The U.S. Patent System in Transition: Policy Innovation and the Innovation Process." ***Research Policy***; 29(4-5)(April 2000): 531-57.

James, C. ***Global Status of Commercialized Transgenic Crops***. Ithaca: International Service for the Acquisition of Agri-Biotech Applications, various years

Janis, Mark D. and Jay P. Kesan. "U.S. Plant Variety Protection: Sound and Fury…?" ***Houston Law Review***, 39(3)(2002): 727-778.

Jensen, R. and M. Thursby. 2001. "Proofs and Prototypes for Sale: The Licensing of University Inventions." ***American Economic Review***, 91(1): 240-259.

Juma, C. 1989. ***The Gene Hunters: Biotechnology and the Scramble for Seeds***. New Jersey: Princeton University Press.

Kitch, E.W. "The Nature and Function of the Patent System." ***Journal of Law and Economics***, Vol. 20 (1977), pp. 265-290.

Knudson, M.K. and C.E. Pray. "Plant Variety Protection, Private Funding, and Public Sector Research Priorities." ***American Journal of Agricultural Economics***, 73 (1991): 882-886.

Knudson, M.K. and V.W. Ruttan, "Research and Development of a Biological Innovation: Commercial Hybrid Wheat." ***Food Research Institute Studies*** 21(1)(1988): 45-68.

Koo, B. and B. Wright. "Economics of Patenting a Research Tool." EPTD Discussion Paper No.88. Washington D.C.: International Food Policy Research Institute, 2002.

Koo, B., P.G. Pardey, K. Qian, and Y. Zhang. "The Economics of Generating and Maintaining Plant Variety Rights in China." EPTD Discussion Paper No. 100. Washington, D.C.: International Food Policy Research Institute, February 2003.

Lanjouw, J, A. Pakes, and J. Putnam. "How to Count Patents and Value Intellectual Property: The Uses of Patent Renewal and Application Data." ***Journal of Industrial Economics*** 46(4)(1998): 405-32.

Levin, R., A.K. Klevorick, R.R. Nelson, and S.G. Winter. "Appropriating the Returns from Industrial Research and Development." ***Brookings Papers on Economic Activity***. 3. 783-820, 1987.

Marra, M.C., P.G. Pardey, and J.M. Alston. "The Payoffs to Transgenic Field Crops: An Assessment of the Evidence." ***AgBioForum*** online 5(2)(2003), available at <http://www.agbioforum.org./v5n2/v5n2a02-marra.htm>.

Mazzoleni, R. and R.R. Nelson "The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate." ***Research Policy*** 27 (1998): 275-86.

Merges, R.P. and R.R. Nelson "On the Complex Economics of Patent Scope." ***Columbia Law Review*** 90 (1990): 839-916.

Morris, M.L. "Overview of the World Maize Economy." in M.L. Morris ed. ***Maize Seed Industries in Developing Countries***. International Maize and Wheat Improvement Center, Mexico. 1998.

Morris, M.L. ***Impacts of International Maize Breeding Research in Developing Countries, 1966-98.*** International Maize and Wheat Improvement Center, Mexico. 2002.

Nordhaus, W. ***Invention, Growth and Welfare: A Theoretical Treatment of Technological Change***. Cambridge Massachusetts: MIT Press, 1969.

Olmstead, A.L. and P.W. Rhode. "The Red Queen and the Hard Reds: Productivity Growth in American Wheat, 1800-1940." ***Journal of Economic History*** 62(4)(December 2002): 929-966.

Pardey, P.G., J.M. Alston, C. Chan-Kang, E.C. Magalhães, and S.A. Vosti. "Assessing and Attributing the Benefits from Varietal Improvement Research: Evidence from Embrapa, Brazil." EPTD Discussion Paper No. 95. Washington, D.C.: International Food Policy Research Institute, August 2002.

Pardey, P.G. and N.M. Beintema. ***Slow Magic: Agricultural R&D a Century After Mendel***, Food Policy Report. Washington, D.C.: International Food Policy Research Institute, October 2001.

Pardey, P.G., J.M. Alston, J.E. Christian and S. Fan. ***Hidden Harvest: U.S. Benefits from International Research Aid***, Food Policy Report, Washington, D.C.: International Food Policy Research Institute, September 1996.

Perrin, R.K., K.A. Kunnings, and L.A. Ihnen. ***Some Effects of the US Plant Variety Act of 1970.*** Economics Research Report no. 46, North Carolina State University, Raleigh, NC, 1983.

Pray, C.E., J. Huang, R. Hu and S. Rozelle. "Five Years of Bt Cotton in China—The Benefits Continue." ***Plant Journal*** 31(4)(2002): 423-30.

Root, W., and R. De Rochemont. ***Eating in America: A History***. New York: William Morrow and Company, 1976.

Runge, F.C., B. Senauer, P.G. Pardey, and M.W. Rosegrant. ***Ending Hunger in our Lifetime: Food Security and Globalization***. Baltimore: John Hopkins University Press, 2003.

Schankerman, M. "How Valuable Is Patent Protection? Estimates by Technology Field." ***RAND Journal of Economics*** 29(1)(1998): 77-107.

Serageldin, I. 2001. "Changing Agendas for Agricultural Research." chapter 2 in J.M. Alston, P.G. Pardey, and M. J. Taylor. eds. ***Agricultural Science Policy: Changing Global Agendas***. Baltimore: Johns Hopkins University Press.

Sexton, R.J. "Imperfect Competition in Agricultural Markets and the Role of Cooperatives: A Spatial Analysis." ***American Journal of Agricultural Economics*** 72 (August 1990): 709-720.

Thirtle, C., L. Beyers, Y. Ismael, and J. Piesse. "Can GM-Technologies Help the Poor? The Impact of Bt Cotton in Makhathini Flats, KwaZulu-Natal." ***World Development*** 31(4)(2003):717-32.

Traxler, G. S. Godoy-Avila, J. Falck-Zepeda, and J. Espinoza-Arellano "Transgenic Cotton in Mexico: Economic and Environmental Impacts." Chapter in N. Kalaitzandonakes ed. ***Economic and Environmental Impacts of First Generation Biotechnologies***, Kluwer Academic: New York, 2003.

UPOV. "Plant Variety Protection Statistics." International Union for the Protection of Plant Varieties. Geneva, 2002.

UPOV. Plant Variety Database CD 2003/02. International Union for the Protection of Plant Varieties. Geneva, 2003.

USDA, National Agricultural Statistical Service (NASS). "Acreage Reports" downloaded from http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bba. Washington D.C.: U.S. Department of Agriculture, National Agricultural Statistical Service, 2003.

World Bank. ***World Development Indicators 2002***. Washington D.C.: World Bank, 2002.

Table 1***: Private and Public Agricultural R&D Investments, circa 1995***

	Expenditures			Shares		
	Public	Private	Total	Public	Private	Total
	(*million 1993 international dollars*)			(*percent*)		
Developing countries	11,469	672	12,141	94.5	5.5	100
Developed countries	10,215	10,829	21,044	48.5	51.5	100
Total	*21,692*	*11,511*	*33,204*	*65.3*	*34.7*	*100*

Source: Pardey and Beintema (2001).

Note: Drawing together estimates from various sources meant there were unavoidable discrepancies in what constitutes "private" and "public" research. For example, the available data for Asia includes nonprofit producer organizations as part of private research, whereas Pardey and Beintema opted to include research done by nonprofit agencies as part of public research in Latin America and elsewhere when possible.

Table 2: Field Trials of Bioengineered Crops by Regions of the World

	Number of Approved Events/crops[a]			Field Trials[a]			
				Number of		Share of	
	Countries	Events	Crops	Countries	Trials	Global total	Private in-country total
						(percentage)	
Developed Countries	19	160	14	20	9,701	84.2	na
United States	1	49	14	1	6,337	55	83.4
Canada	1	49	4	1	1,233	10.7	63.9
All others	17	62	5	18	2,131	18.5	na
Developing Countries	8	23	4	19	1,822	15.8	na
Argentina	1	7	3	1	393	3.4	90.1
China	1	5	4	1	45	0.4	na
All others	6	11	3	17	1,384	12	na
Total	*27*	*183*	*14*	*39*	*11,523*	*100*	*na*

Source: Pardey and Beintema (2001).

Note: na stands for not available.

a. Data through to December 2000 where available. For the United States and Canada, and perhaps other countries, a single "trial" may consist of tests conducted at multiple (maybe many) different sites.

Table 3*: Plant Breeders Rights Applications—Countries Grouped by Per Capita Income, 1971-2002*

Income group	1971-1975	1976-1980	1981-1985	1986-1990	1991-1995	1996-2000	2001-2002	Total
					(*counts*)			
Number of Applications								
High income country (21)[a]	1,491	6,607	10,865	20,431	31,362	34,276	12,981	118,013
Upper middle income country (9)	66	206	402	1,658	3,555	5,493	2,515	13,895
Lower middle income country (4)	25	34	57	57	131	2,437	1,440	4,181
Low income country (2)	-	-	-	1	27	117	-	145
Total	*1,582*	*6,847*	*11,324*	*22,147*	*35,075*	*42,323*	*16,936*	*136,234*
Application rates					(*counts per year*)			
High income country (21)	298	1,321	2,173	4,086	6,272	6,855	6,491	3,688
Upper middle income country (9)	13	41	80	332	711	1,099	1,258	434
Lower middle income country (4)	5	7	11	11	26	487	720	131
Low income country (2)	-	-	-	0	5	23	-	5
Total	*316*	*1,369*	*2,265*	*4,429*	*7,015*	*8,465*	*8,468*	*4,257*
Share of Total					(*percentage*)			
High income country (21)	94	96	96	92	89	81	77	87
Upper middle income country (9)	4	3	4	7	10	13	15	10
Lower middle income country (4)	2	0	1	0	0	6	9	3
Low income country (2)	0	0	0	0	0	0	0	0
Total	*100*	*100*	*100*	*100*	*100*	*100*	*100*	*100*

Source: Authors compiled from data obtained from UPOV (2003).

a. Bracketed numbers indicate number of countries in each income class based on the classification by the World Bank (2002).

Table 4*: Plant Variety Rights Applications—Regression Results*

	Dependent variable Total PBR (PBRT)		Dependent variable Foreign PBR (PBRF)	
Variable Name/Definition	log(PBRT)	PBRT	Log(PBRF)	PBRF
Regression number	(1)	(2)	(3)	(4)
VC/log value of crop production (US$)	0.544 (0.122)**	475.7 (119.9)**	0.294 (0.175)*	152.2 (50.4)**
PCI/log GDP per capita (US$)	0.267 (0.367)	755.5 (350.6)*	0.470 (0.513)	291.1 (147.4)*
PT/History of PVP implementation (years)	0.044 (0.017)**	28.96 (16.57)*	0.053 (0.024)**	4.908 (6.968)
Constant	-5.676 (4.224)	-14040.5 (4153.0)**	-5.179 (6.075)	-4822.1 (1746.2)**
Number of observations	35	35	35	35
F value	11.27	9.32	4.12	4.8
Adjusted R^2	0.475	0.423	0.215	0.251

Source: Authors calculations.
Note: Standard errors in parenthesis.
* indicates significantly different from zero at the 10 percent level of confidence.
** indicates significantly different from zero at the 5 percent level of confidence.

Table 5: *Plant Breeders Rights Applications in the European Union and the United States*

Country/region	Before 1970	1971-75	1976-80	1981-85	1986-90	1991-95	1996-2000	2001-02	Total
				(*counts*)					
European Union[a]	**598**	**843**	**4,369**	**6,374**	**13,254**	**20,290**	**19,232**	**7,471**	**72,431**
Netherlands	140	213	518	1,369	4,252	6,838	4,278	1,386	18,994
France	-	-	2,151	2,046	3,206	3,395	2,326	686	13,810
Germany	212	244	436	1,007	2,275	3,042	1,306	472	8,994
UK	2	6	8	6	500	2,365	1,334	359	4,580
Italy	-	-	-	-	-	1,349	384	67	1,800
Others	244	380	1,256	1,946	3,021	3,301	960	121	11,229
CPVO[b]	-	-	-	-	-	-	8,644	4,380	13,024
United States	**3,495**	**1,313**	**1,587**	**2,039**	**3,111**	**3,594**	**5,609**	**1,908**	**22,656**
Plant Variety Protection	-	600	614	934	1,228	1,505	1,943	562	7,386
Plant Patent	3,495	713	973	1,105	1,883	2,089	3,666	1,346	15,270

Source: Authors compiled from data obtained from the US Patent Statistics Report and Technology Assessment and Forecast Report for the US Plant Patent, the US Plant Variety Protection Office Crop Database for the US plant variety protection, UPOV (2003) for data of European Union countries, and CPVO (2002) for CPVO data.

a. Footnote 13 includes a list of the countries included in this total.

b. CPVO stands for Community Plant Variety Office. See CPVO (2002) for further details. Around 35 percent of these applications are lodged from the Netherlands, 16 percent from Germany, 14 percent from France, 19 percent from elsewhere in the European Union and 16 percent from outside the European Union since it was first implemented in 1995.

Table 6: ***US Plant Variety Protection Certificate Applications by Applicant***

	Counts of PVP applications					Share of PVP applications				
	1971-80	1981-90	1991-00	2001-02	Total	1971-80	1981-90	1991-00	2001-02	Total
	(*number of applications*)					(*percentages*)				
Types of institutions										
Private	1,027	1,900	2,941	436	6,304	85	88	85	78	85
University	138	229	358	84	809	11	11	10	15	11
Foundation	43	19	96	18	176	4	1	3	3	2
Public	6	14	53	24	97	0	1	2	4	1
Total	*1,214*	*2,162*	*3,448*	*562*	*7,386*	*100*	*100*	*100*	*100*	*100*
Top 15 applicants										
Dupont	36	165	508	102	811	3	8	15	18	11
Seminis	110	208	281	36	635	9	10	8	6	9
Monsanto	132	252	204	33	621	11	12	6	6	8
Delta and Pine Land Company	18	32	129	10	189	1	1	4	2	3
Advanta	48	83	48	3	182	4	4	1	1	2
Exelixis	38	89	42	-	169	3	4	1	0	2
Turf-Seed, Inc	5	53	67	3	128	0	2	2	1	2
Texas Agricultural Experiment Station	11	20	36	7	74	1	1	1	1	1
Minnesota Agricultural Experiment Station	5	17	29	7	58	0	1	1	1	1
W. Atlee Burpee Company	49	6	1	-	56	4	0	0	0	1
Del Monte Corporation	-	2	53	-	55	0	0	2	0	1
Pickseed West Inc.	5	24	19	4	52	0	1	1	1	1

	Counts of PVP applications					Share of PVP applications				
	1971-80	1981-90	1991-00	2001-02	Total	1971-80	1981-90	1991-00	2001-02	Total
	(*number of applications*)					(*percentages*)				
Stoneville Pedigreed Seed Company	13	11	19	8	51	1	1	1	1	1
Cebeco	2	18	28	1	49	0	1	1	0	1
FFR Cooperative	11	13	25	-	49	1	1	1	0	1
Others	731	1,169	1,959	348	4,207	60	54	57	62	57
Total	*1,214*	*2,162*	*3,448*	*562*	*7,386*	*100*	*100*	*100*	*100*	*100*

Source: Authors' calculations based on data from US Plant Variety Protection Office Crop Database.

Note: Data reported based on all mergers and acquisitions activities as of November 2002.

a. Includes applications lodged jointly with Monsanto (which total 176 through to end of 2002).

Table 7: ***US Plant Variety Protection Certificate Applications by Crop Categories***

Crop	Counts					Share				
	1971-80	1981-90	1991-00	2001-02	Total	1971-80	1981-90	1991-00	2001-02	Total
	(*number of applications*)					(*percentages*)				
Oilcrops	367	587	957	140	2,051	30	27	28	25	28
Cereal	210	508	1,062	200	1,980	17	23	31	36	27
Vegetable	209	410	453	65	1,137	17	19	13	12	15
Grass	175	341	489	80	1,085	14	16	14	14	15
Pulses	146	198	224	32	600	12	9	6	6	8
Ornamental plants	42	40	69	5	156	3	2	2	1	2
Roots	-	-	116	31	147	0	0	3	6	2
Fruit	19	30	40	6	95	2	1	1	1	1
Spices	28	30	17	1	76	2	1	0	0	1
Tobacco	14	14	19	1	48	1	1	1	0	1
Others	4	4	2	1	11	0	0	0	0	0
Total	*1,214*	*2,162*	*3,448*	*562*	*7,386*	*100*	*100*	*100*	*100*	*100*

Source: Authors' calculation based on data from US Plant Variety Protection Office Crop Database.

Table 8: *CPVO Plant Breeders Rights Applications by Type of Crop, 1996-2002*

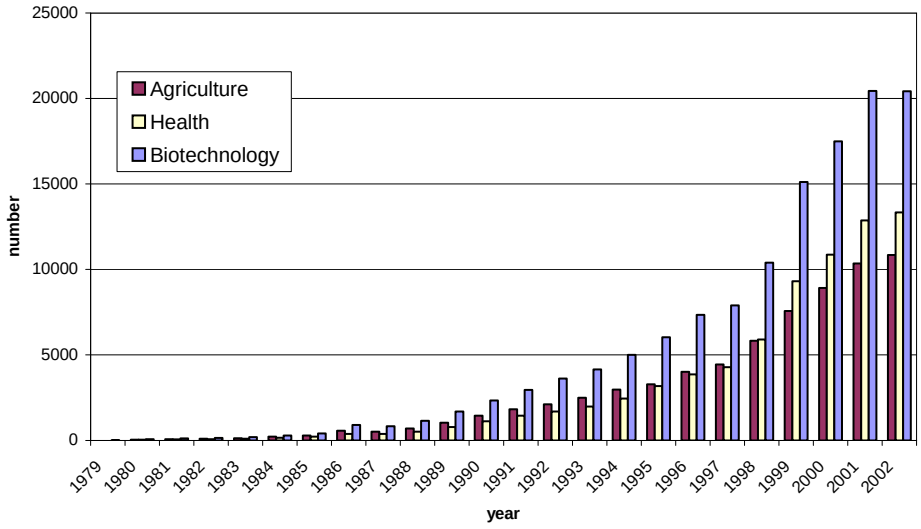
Species	1996	1997	1998	1999	2000	2001	2002	Total
Number of Applications				(*counts*)				
Agricultural crops	365	343	404	407	406	440	415	4,104
Vegetable crops	123	148	214	181	244	181	177	1,833
Ornamental plants	834	953	1,100	1,194	1,266	1,415	1,504	10,636
Fruits	61	77	104	95	95	117	125	973
Others	2	9	13	4	2	5	1	44
Total	*1,385*	*1,530*	*1,835*	*1,881*	*2,013*	*2,158*	*2,222*	*17,590*
Share of Total				(*percentage*)				
Agricultural crops	26	22	22	22	20	20	19	23
Vegetable crops	9	10	12	10	12	8	8	10
Ornamental plants	60	62	60	63	63	66	68	60
Fruits	4	5	6	5	5	5	6	6
Others	0	1	1	0	0	0	0	0
Total	*100*	*100*	*100*	*100*	*100*	*100*	*100*	*100*

Source: CPVO (2002).

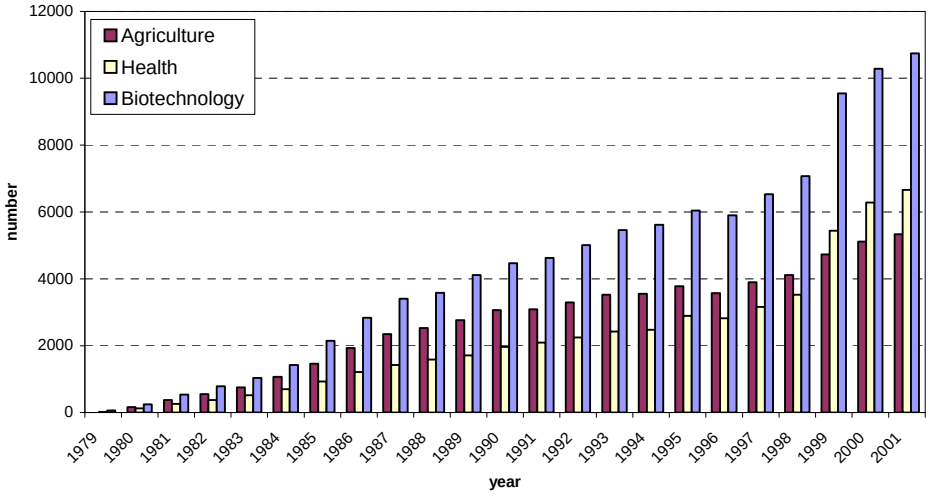
Note: Totals in right hand column include applications lodged in 1995-2002***.***

Figure 1: ***Biotechnology Patents***

Panel (a) PCT Applications



Panel (b) EP-B Grants



Source: Compiled by authors from CAMBIA-IP Resource database

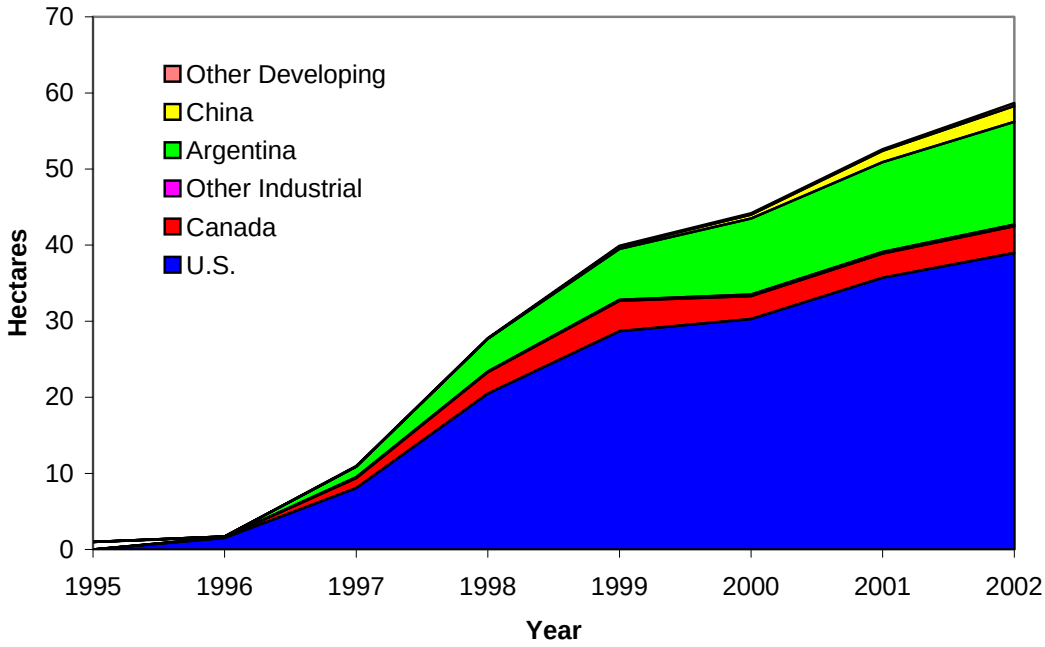
Table 9***: Share of Area Planted to Modern Varieties of Rice, Wheat, and Maize***

	Rice			Wheat				Maize	
Regions	1970	1983	1991	1970	1977	1990	1997	1992	1996
				(***percentage of area planted***)					
Sub-Saharan Africa	4	5	n.a.	5	22	52	66	37	46
West Asia/North Africa	0	11	n.a.	5	18	42	66	26	n.a.
Asia (excluding China)	12	48	67	42	69	88	93	42	64
China	77	95	100	n.a.	n.a.	70	79	97	99
Latin America	4	28	58	11	24	82	90	49	45
All Developing Countries	30	59	74	20	41	70	81	58	62

Source: For rice and wheat, Runge et al. (2003) based on data from Byerlee and Moya (1993), Byerlee (1996), Heisey, Lantican, and Dubin (1999). For maize, Morris (1998), and Morris (2002).

Note: n.a. indicates not available. Modern varieties of rice and wheat refer mainly to semi-dwarf varieties; for maize it includes hybrid and improved open pollinated varieties.

Figure 2: ***Area Sown to Bioengineered Crops Worldwide***



Source: Authors based on data from James (various years).

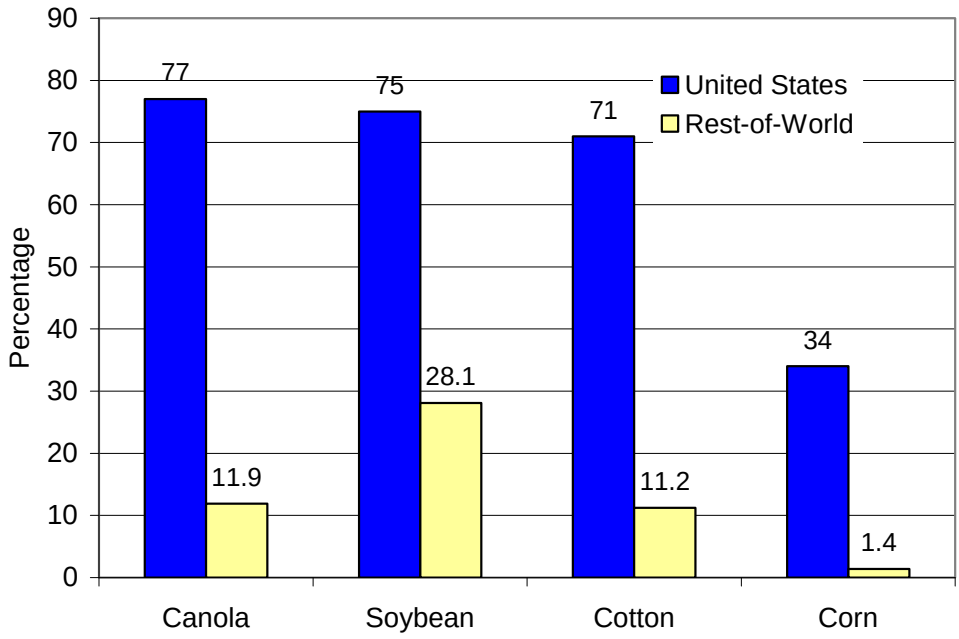
Table 10: ***Bioengineered Cropping Patterns in the United States***

	1996	1997	1998	1999	2000	2001	2002	2003
				(thousands of acres)				
Bioengineered acres								
Corn	3,536	9,547	22,704	26,249	19,895	19,696	26,878	31,626
Bt corn	1,125	6,097	15,432	20,055	14,324	13,635	17,392	19,767
Herbicide-tolerant	2,411	3,450	7,272	6,194	4,775	5,303	7,115	8,697
Stacked	-	-	-	-	796	758	1,581	3,163
Soybean								
Herbicide-tolerant	4,728	12,045	32,142	41,169	40,231	50,391	55,319	59,659
Cotton	2,413	3,521	5,561	11,066	9,487	10,880	9,909	10,165
Bt cotton	2,097	2,071	2,173	4,804	2,333	2,050	1,814	1,949
Herbicide-tolerant	316	1,450	3,388	6,262	4,044	4,888	5,025	4,456
Stacked	-	-	-	-	3,110	3,784	3,071	3,759
				(percentages)				
Bioengineered share								
Corn	4.4	11.9	28.1	33.9	25	26	34	40
Bt corn	1.4	7.6	19.1	25.9	18	18	22	25
Herbicide-tolerant	3	4.3	9	8	6	7	9	11
Stacked	0	0	0	0	1	1	2	4

	1996	1997	1998	1999	2000	2001	2002	2003
				(thousands of acres)				
Soybean								
Herbicide-tolerant	7.4	17	44.2	55.8	54	68	75	81
Cotton	16.8	25.5	43	74.4	61	69	71	73
Bt cotton	14.6	15	16.8	32.3	15	13	13	14
Herbicide-tolerant	2.2	10.5	26.2	42.1	26	31	36	32
Stacked	0	0	0	0	20	24	22	27

Source: Fernandez-Cornejo and McBride (2002) for years prior to 2000. All other years from USDA, NASS (2003).

Figure 3: ***Bioengineered Cropping Intensities—United States vs Rest-of-the-World, 2002***



Source: Authors based on data from USDA, NASS (2003) and James (2002).

Note: Data represent share of respective crop acreage in each region sown to bioengineered varieties.

Dissemination of Plant Biotechnology- An African Perspective

MR. ALEXANDER OCHEM
Research Assistant, Molecular Biology, International Center for Genetic Engineering and Biotechnology (ICGEB), Trieste, Italy

Introduction

The most important applications of plant biotechnology in Africa are those targeted at solving some of the continent's long-standing problems such as increased food production, poverty alleviation and improvement of the continent's public health services. Dissemination of plant biotechnology, on the other hand, requires that the tools of this novel technology are made available also to the low-scale farmers.

Genetic engineering techniques adopted in modern plant biotechnology effect transfers of genetic material between various organisms with the following aims:

- developing plant varieties with requisite properties to survive and thrive under the climatic conditions prevalent in the specific regions (resistance to heat, drought, acidity, salinity and pests);
- development of higher yielding plant varieties that guarantee the environmentally sustainable production of larger quantities of food and possibly, at lower production costs;
- production of plant varieties endowed with more nutritious constituents than the wild type species to boost the quality of the available food supply;
- development of fruit crop varieties with delayed ripening properties to reduce post-harvest loss due to fruit over-ripening;
- engineering novel plant varieties for the preservation and fostering of environmental biodiversity.

The need for plant biotechnology in Africa

In Africa, the objectives of plant biotechnology assume a higher degree of importance due to the continent's harsh climatic conditions and where, in some areas such as southern Africa, many years of drought have further dwindled the already poor farm yields thus, exacerbating the problem of food supply shortages. However, in order to assess the extent to which Africa needs biotechnologically improved crops and the dissemination of the requisite techniques to boost its food production capacity, it is important to review some statistical facts about the Continent and about its position in the arena of global food production.

- With a population of over 750 million, Africa holds 13% of the world's population in a total landmass corresponding to 20% of the world landmass. But 40% of Africa is desert land leaving only 12% of arable land for the African population, and only 6% of this arable and permanent cropland is irrigated compared to an average 33% for Asia.
- The rate of population growth in Africa out-balances the rate of increase in food production. In fact, according to a recent UN study, by 2020 the demand for cereals in Sub-Saharan Africa is forecast to outweigh the region's production by as much as 27 million metric tons.

- Farm work and the processes of food production in Africa remain predominantly manual. Furthermore, recurrent yearly poor harvests has fuelled the phenomenon of rural to urban youth migration, thus depleting rural farm work-force, and relegating the arduous task of food production to the uneducated elderly, women and children. It is thus not surprising that agriculture in Africa shows the lowest yield among all the developing regions of the world. Consequently, Sub-Saharan Africa is the only developing region where per capita food-grain output has effectively declined over the past four decades.

- Africa is the poorest continent with 40% of the population living on less than USD 1 a day, despite being one of the most richly endowed. In fact, the continent includes 25 of the world's 30 poorest countries, and Sub-Saharan Africa is host to 32 of the 48 least developed countries.

- Health care services are most inadequate in Africa than anywhere else, making the Continent a fertile habitat for numerous illnesses. According to the United Nations Economic Commission for Africa (ECA) Executive Secretary, "on the major health problems of our time, Africa leads the world. Fully 80% of infectious diseases are found in Africa. Malaria alone kills two million people and reduces the GDP of Sub-Saharan Africa by one percent every year"(Amoako, K.Y. 2003). Certainly, the importance of efficient public health care services to adequate food production in any nation cannot be over-emphasized since the sick would produce very little food while the dead would produce none.

From the foregoing consideration, Africa desperately and urgently requires agricultural biotechnology in order to dramatically boost its capacity to produce abundant environmentally sustainable and nutritious food. More importantly, the tools of plant biotechnology and crop improvement should be made available to low-scale farmers. This would be effective dissemination of plant biotechnology. But notwithstanding this glaring necessity, agricultural biotechnology in Africa has fared rather poorly.

The principal cause for this poor performance of plant biotechnology in Africa is the persistent minimal investment in agricultural research and development by the governments of most African countries. In fact, as at the year 2001, only in the Republic of South Africa has agricultural biotechnology been practiced at the commercial level.

African countries depend heavily on foreign aid for agricultural research and development. In fact, many of the continent's agro-biotech institutions are founded and funded essentially by international or donor organizations. Unfortunately, many indigenous food-crops that feed a large percentage of the African population (such as yams, millet, sorghum and cassava), represent little commercial interest to the multinational companies that invest in R&D. Thus, the extension of modern biotechnology tools to the improvement of these food crop species have been minimal, and in some cases, non-existent.

Agricultural biotechnology in Africa has also been hindered by the global debate on the safety of genetically modified foods. Many African countries have therefore, been resistant to adopting these technologies principally to protect their international trading interests.

In order to reverse this trend and participate more actively in agricultural research and development in Africa, the Executive Secretary of the ECA, Mr. Amoako has outlined the duties of national governments in Africa necessary to bring about success in biotechnology and enhance food production in the Continent. He wrote, "If Africa is not to miss the biotechnology revolution, then governments have to take the lead. Governments throughout Africa simply must refocus attention on agriculture".

Status of plant biotechnology in Africa

The most important successes in plant biotechnology in Africa include the development and commercial production of Bt crops (Bollgard® cotton and YieldGard® maize) in South Africa, and the development of new rice varieties dubbed NERICA (NEw RIce for AfriCA) at WARDA in Western

Africa. WARDA is an intergovernmental research organization comprising 17 West African countries. Engineered by genetic crosses between African and Asian rice species, NERICA combines the high-yielding properties of Asian rice with the multiple stress resistance that characterize African rice varieties. Yield increases with this genetically improved rice range from 25% up to 250% (Monty, J. 2000).

Both Bollgard® cotton and YieldGard® maize are engineered for pest resistance, and farmers who planted these transgenic crops recorded substantial yield increases over those planting the non treated species (Bennet 2001). Planting Bt cotton in the Makhatini flats of northern Kwazulu Natal in South Africa helped to eliminate the need for insecticide sprays during the 2001 planting season. In an independent study in which 100 Makhathini farmers were interviewed, it was found that farmers who adopted and planted Bt cotton in 1998 and 1999 benefited from the new technology according to all the assessment measures used (Ismael ***et al*** 2001). Besides helping to reduce the overall number of hours spent in their farms, many small-scale cotton farmers in South Africa who planted transgenic cotton experienced an average 27% net income increase in the 2001 planting season. Thus, planting transgenic cotton contributed significantly to poverty alleviation through increased income earnings for the farmers in South Africa.

Important varieties of NERICA, developed at WARDA in Ivory Coast, include species suitable for cultivation in acid soils in which phosphate fertilizers are substituted with local rock phosphate. Others are low land varieties resistant to viruses, to drought and to iron toxicity, while other varieties carry resistance genes to rice blast fungus and to the yellow mottle virus. Some of these varieties are currently being distributed for large-scale cultivation. Two other NERICA varieties include the SAHEL 108, endowed with a short life cycle thereby allowing for annual double cropping, and the CISADANE resistant to the gall midge (a mosquito-like insect whose larvae bore rice shots). The CISADANE was a product of the International Institute for Tropical Agriculture (IITA) in Nigeria.

Scientists at the ISAAA and KARI both in Kenya have developed virus resistant sweet potatoes. Field trials for these transgenic sweet potato varieties started in 2001 (KARI 2001), and the commercial production would lead to substantial recovery of edible food in a zone where up to 50% of yearly farm yields are generally lost to degradation by the virus.

Other achievements in plant biotechnology in selected African countries, although essentially still at the laboratory level include the following:

(adapted from Brink, J.A***. et al*** 1998)

North Africa

Morocco
Micropropagation of forest trees, date palms. Development of disease-free and stress tolerant plants. Molecular biology of date palms and cereals. Field tests for transgenic tomatoes.

Tunisia
Abiotic stress tolerance and disease resistance. Genetic engineering of potatoes. Tissue culture of date palms, prunus rootstocks and citrus. DNA markers for disease resistance.

West Africa

Cameroon
Plant tissue culture of Theobroma cacao (cocoa tree), Hevea brasiliensis (rubber tree), Coffea arabica (coffee tree), Dioscorea sativa (yam) and Xanthosoma mafutta (cocoyam). Use of ***in vitro*** culture for propagation of banana, oil-palm, pineapple, cotton and tea.

Nigeria
Micropropagation of cassava, yam, banana and ginger. Long-term conservation of cassava, yam and banana, and medicinal plants. Embryo rescue for yam. Transformation and regeneration of cowpea, yam, cassava and banana. Genetic engineering of cowpea for virus and insect resistance. Marker

assisted selection of maize and cassava. DNA fingerprinting of cassava, yams, banana, pests, and microbial pathogens. Genome linkage maps for cowpeas, cassava, yams and banana.

Senegal

Well established Microbial Resources Center (MIRCEN) programme that serves the region of West Africa in microbial-plant interaction. Production of rhizobial and mycorhizal-based biofertilizers for rural markets. Well established ***in vitro*** propagation of Faidherbia albida, Eucalyptus canaldulensis, Sesbania rostrate, Acacia senegal, in co-operation with several international agencies.

East & Central Africa

Burundi
In vitro production of ornamental plants - orchids, tissue culture of medicinal plants, micropropagation of potato, banana, cassava and yam.

Democratic Republic of Congo
In vitro propagation of potato, soybean, maize, rice and multipurpose trees, e.g. Acacia auriculiforius and Leucaena leucocefhala. Production of rhizobial-based biofertilizers in experimental stage. Tissue culture of medical plants, e.g. Nuclea latifolia, Phyllanthus niruroides.

Kenya
Production of disease-free plants and micro-propagation of pyrethrum, bananas, potatoes, strawberries, sweet potato, citrus, sugar cane. Micropropagation of ornamentals (carnation, alstromeria, gerbera, anthurium, leopard orchids) and forest trees. ***In vitro*** selection for salt tolerance in finger millet. Transformation of tobacco, tomato and beans. Transformation of sweet potato with proteinase inhibitor gene. Transformation of sweet potato with Feathery Mottle Virus, Coat protein gene (Monsanto, ISAAA5, USAID6, ABSP7, KARI8). Tissue culture regeneration of papaya. ***In vitro*** long-term storage of potato and sweet potato. Marker assisted selection in maize for drought tolerance and insect resistance. Well-established MIRCEN providing microbial biofertilizers to countries in the East African region.

Uganda
Micropropagation of banana, coffee, cassava, citrus, granadella, pineapple, sweet potato and potato. ***In vitro*** screening for disease resistance in banana. Production of disease-free plants of potato, sweet potato and banana.

Southern Africa

Madagascar
Tissue culture programme supporting conventional production of disease-free rice and maize plantlets, and medicinal plants. Production of biofertilizers to boost production of groundnut (Arachis hypogea), bambara groundnut (Vigna subterranea).

South Africa

Genetic engineering
- Cereals: maize, wheat, barley, sorghum, millet, soybean, lupins, sunflowers and sugarcane.
- Vegetables and ornamentals: potato, tomato, cucurbits, ornamental bulbs, cassava and sweet potato.
- Fruits: apricot, strawberry, peach, apple, table grapes, banana.

Molecular marker applications
- Cultivar identification – potatoes, sweet potato, ornamentals, cereals and cassava.
- Markers for disease resistance in wheat, forestry crops.

Tissue culture

- Production of disease free plants – potato, sweet potato, cassava, dry beans, banana and ornamental bulbs.
- Micropropagation of potato, ornamental bulbs, rose rootstocks.
- chrysanthemum, strawberry, apple rootstocks, endangered species, coffee, banana, avocado, blueberry and date palm.
- Embryo rescue of table grapes, sunflower and dry beans.
- Long term storage - potato, sweet potato, cassava and ornamental bulbs.
- Forest trees, medicinal plants and indigenous ornamental plants.

Zimbabwe

Genetic engineering of maize, sorghum and tobacco. Micropropagation of potato, cassava, tobacco, sweet potato, ornamental plants and coffee.

In all these countries as well as in other African countries, sustained public financial support will be required over the decades to move research in plant biotechnology from the laboratory or field trials to the commercial production of these transgenic crops. Only then will the benefits of crop improvement by genetic engineering be made available to those who need them most: the low-scale farmers.

Conclusions

Africa lags dramatically behind all other regions of the world in the overall application of agricultural biotechnology and food production. In order to avert the dangers posed by under-nutrition, governments of African countries must invest in agricultural R&D for crop improvement through genetic manipulation. The major tasks for achieving this goal lie on the collective hands of Africans in accordance with the African proverb that "the owner of the house sits where the roof leaks."

Positive signals emerging in this direction include the creation of the African Centre for Crop Improvement (ACCI) at the University of Natal, South Africa to train African PhD's in the breeding and biotechnology of African crop species adapted to the African environment, and in Nigeria where the government currently budgets several millions of US dollars for biotechnology development. If other African countries could adopt similar measures, according to their individual capabilities, then the future for the Continent would certainly shift from that of the present state of economic stagnation, social unrest and general strife to that of fulfilled promises of technological advancement, adequate and nutritious food security, economic prosperity and general welfare for the citizens.

I would like to conclude my presentation reminding those who campaign against the introduction of genetically improved crops in the food chain in Africa that one cannot rationally argue with the hungry on the potential health risks that may result from being overfed. If African countries fail to feed the present generation of their citizens due to fears of the potential future dangers deriving from GM foods, there would probably not be any future generations of Africans to protect from such dangers.

SESSION II: DISCUSSIONS

Mr. Huib GHIJSEN, Global Manager Germplasm Protection,
Oilseeds Department, Bayer BioScience N.V., Gent, Belgium

I have a general question to some speakers from WIPO and the other speakers concerning the TRIPS Agreement. What I find interesting is the discussions now going on relating to the issues that are concerning the patenting of biotech inventions and plant varieties. One of the things that strikes me in the granting of patents worldwide is that there are still strong differences in the various national patent systems concerning the description of prior art as was referred to by the WIPO speaker and the opposition procedures. I think that also the discussion in relation to the disclosure in origin - these things play a role because it sometimes or often happens that patents are granted for knowledge that already exist but have not been put on paper. I wonder whether there is any discussion about harmonizing within WIPO or the Patent Cooperation Treaty (PCT) these issues, for instance, will the prior art problem be solved and also if, after granting of a patent, it appears that this patent was not rightfully granted on account of the claims being too wide, which leads to the lock-up phenomenon that has been referred to, that proper opposition procedure can be undertaken by any party, whether it is an interested party or not, as exists in some countries, but not in other countries.

Mr. Anthony TAUBMAN, Acting Director and Head, Traditional Knowledge Division, Office of Legal and Organization Affairs and PCT System, WIPO

It is a very interesting and complex question that cuts across a lot of our work, I think. Just to put in a nutshell two key elements that may be relevant. One concerns the practical availability of prior art, so that prior art concerning genetic resources and traditional knowledge is literally on the screen of the patent examiners when relevant patent applications are being considered. Within the WIPO Intergovernmental Committee there is a great deal of work that is being done to enhance the practical availability of such material. We have a number of detailed documents that I can share with any participant who would like to go into it in some depth. Concerning the legal questions, one proposal in the context of the Draft Substantive Patent Law Treaty is indeed to harmonize the international standard of prior art in the way that was discussed and once again, that material is certainly readily available for any interested participant.

Mrs. Carmen Amelia M. GIANNI, Director of Legal Affairs, National Secretariat of Agriculture, Livestock, Fisheries and Food, Ministry of Production, Buenos Aires

It has been said that the purpose of biotechnology is to ensure that it reaches the people and the farmers and thereby making up for lack of foodstuffs and doing away with world hunger. It has also been said that there are countries such as the United States of America and Argentina, that have managed to spread transgenic crops on a major scale over the last few years. Is it not through UPOV and the breeder's exemption in relation to protection of the breeders' rights, which the representative of Pioneer proposes to eliminate, that enables these technologies to be transferred to other countries. Wouldn't it be that it is the patent system, which creates monopolies in agriculture, which is not the most appropriate system for the further development of new technologies for plants in developing countries.

H.E. Mr. Alejandro JARA, Ambassador and Permanent Representative of Chile (Chairman)

Thank you for your question which is the focal issue of this Symposium. Probably this is a question that we will try to take up throughout this Symposium. Would any of the panelists like to address the question now?

Mr. Stephen SMITH, Germplasm Security Coordinator, Pioneer Hi-Bred International Inc., Johnston, United States of America (Speaker)

Thank you very much for your question and it is very important. We should bear in mind that it is important to create improved products and that they are put to use on farms for the benefit of farmers and people who need the food. For the private sector, for us to be able to take the risk to invest, it is important to have effective intellectual property protection so that there may be some opportunity to have returns for those investments. However I acknowledge, and I said in my talk, that there are areas of the world that the private sector cannot reach, and therefore it is important, I think, to have a strong public sector and a strong private sector, that together innovations can be created and spread around the world. You have to have these products created in the first place and for the private sector to be able to do that, it is a fact of life that effective intellectual property is necessary. I think it is important for all of us to go out and remind governments that they need to put resources in so that there is strong public support for innovation and particularly to develop products and technologies in areas of the world that the private sector cannot reach.

Mr. Peter LANGE, Chairman of the Intellectual Property Committee of European Seed Association (ESA)

I would like to comment on something what Mr. Stephen Smith has said. I can of course support two of his statements which I think were very well addressed: first of all, that intellectual property is an important pre-requesite for supporting trait and germplasm development and the second statement that we should encourage the use of new genetic diversity. However, I must say that some other statements of his speech were in contradiction to this statement. For instance, the statement that the breeder's exemption in UPOV has to be revised because it would undermine research investment and would lead to narrowing the genetic base. I think the opposite is right and of course we will have to discuss this further on in this afternoon's session, but it was interesting also for me to hear during his speech that he was just focussing on biotech trait development and not at all mentioning the breeding work. I think both parts are important for the development of germplasm and traits and we have to look for the appropriate intellectual property right for both. Technically speaking, not legally speaking which will be addressed later in the afternoon, we have to consider that first of all there is plant breeding needed and there maybe some traits incorporated in plant material, but still you need plant breeding and you need the germplasm in its totality, adequate protection, and therefore we, from ESA, I am representing today, fully support the breeders exemption. I would like to come back to this important issue this afternoon and will give you some more information about ESA´s opposition against any revision of the breeder's exemption.

Mr. Stephen SMITH, Germplasm Security Coordinator, Pioneer Hi-Bred International Inc., Johnston, United States of America (Speaker)

If I may, I welcome the discussion. I was at pains, I think, to state that both germplasm and traits are critical. The increases in yield that I showed in US Maize were not due to biotechnology, they were due to classical plant breeding. The only traditional thing about plant breeding and agriculture is that it keeps changing and it begins to incorporate new biotechnological approaches and biotechnology, as I mentioned, is far more than just transgenes, it's an increasing ability to understand how to more effectively utilize the basic genetics.

* * * *

SECTION III

INTELLECTUAL PROPERTY IN PLANT BIOTECHNOLOGY: NATIONAL/REGIONAL EXPERIENCES

The Interface Between Patents And Plant Variety Rights In Europe

MR. RAINER MOUFANG
Legal Member of the Boards of Appeal, European Patent Office (EPO), Munich, Germany

I. Introduction

Issues of interface between different systems of protection are one of the most interesting and complex aspects of modern IP law. Although not a completely new phenomenon, such interfaces seem to have proliferated recently. The main reasons for this development are, on the one hand, the creation of new IP systems and, on the other, the fact that the traditional IP systems (patents, copyright and trademarks) have gradually expanded their scope of application, either as a result of explicit decisions by the legislator or, more frequently, by the development of case law.

Consequently, IP practitioners are increasingly confronted with situations where the same subject-matter may, at least theoretically, fall under more than one system of protection. The most prominent example is software related innovations for which, in several national legal systems, both copyright and patent protection are available. Further examples include the specific shape of a razor head or a car grille which might be protected as a technical innovation in patent or utility model systems, as an aesthetic creation in industrial design or copyright systems, or even as a three-dimensional mark under trademark law.

In such a situation, typically the following key question arises: Should the legal framework let the relevant systems of protection work independently of each other or should it contain specific provisions for the area of possible overlap? This question comprises two main aspects:

- The first relates to the availability of protection: Should subject-matter capable of being protected under system A be precluded from protection under system B (exclusive availability) or should the innovator be able to choose one of the systems (alternative availability) or even both systems (cumulative availability)?

- The second aspect relates to the scope and exercise of the rights concerned: Should the exercise of rights under system B be autonomous from that of rights under system A, or should there be a convergence of the two systems insofar as the interface area is concerned? In particular, do the limits and exemptions foreseen in system A have a limiting impact on the rights under system B?

This key question and its different aspects are also at the centre of the discussions on the interface between patents and plant variety rights (PVRs). They play an important role in legislation and case law, both at the international level and at the national or regional level. In this context, attention is

drawn to the abolition of the double protection prohibition during the UPOV revision of 1991[1], to the options provided for in Art. 27(3)(b) of the TRIPS Agreement[2], but also to the Novartis decision of the Enlarged Board of Appeal of the European Patent Office (EPO)[3] and to the Pioneer Hi-Bred decision of the US Supreme Court[4].

These issues will be dealt with below from the perspective of European law. In this context, one has to be aware that, due to the coexistence of national and regional law, the legal framework within Europe is complex. In addition, the regional law consists of different layers (Community law and non-Community law) and is, to some extent, still work in progress[5]. Notwithstanding these peculiarities which make a comparative assessment rather difficult, European law is of particular interest for the interface problems at issue, for it contains a modern piece of legislation, i.e. the EU Directive on the protection of biotechnological inventions[6], which was enacted, ***inter alia,*** with the explicit goal of promoting the fruitful coexistence of the patent and PVR systems and which directly addresses relevant interface issues in several of its provisions. It may thus give valuable guidance on possible solutions and serve as a legislative model.

II. Availability of protection

International law as set out in the TRIPS Agreement and the UPOV Convention clearly requires IP protection for plant-related innovations. Nevertheless, there is some discretion for national and regional legislators as to the form in which this protection is made available and in particular as to whether the availability of patents or PVRs should be made exclusive, alternative or cumulative[7]. European law appears to give priority to the PVR system: on the one hand, plant varieties may be protected by national PVRs or by a uniform Community-wide PVR[8]. On the other hand, European patents are excluded for plant varieties and for essentially biological processes for the production of plants[9].

Notwithstanding these provisions, the European legal framework does not really reduce the area of possible overlap between the two systems, since the patent system remains capable of covering plant-related innovations. The reason for this is a very characteristic feature of IP rights in general and of patent law in particular, namely the distinction between subject-matter eligible for protection as such and subject-matter falling under the scope of protection. For example, a product per se may not be claimed in a patent if it does not fulfil the requirement of novelty. However, a new and inventive

---

1 Prior to the revision of 1991, Art. 2(1) of the UPOV Convention read as follows: "Each member State of the Union may recognise the right of the breeder provided for in this Convention by the grant either of a special title of protection or of a patent. Nevertheless, a member State of the Union whose national law admits of protection under both these forms may provide only one of them for one and the same botanical genus or species."

2 TRIPS Members may exclude from patentability plants and essentially biological processes for the production of plants. However, Members must provide for the protection of plant varieties either by patents or by an effective ***sui generis*** system or by any combination thereof.

3 G 1/98, ***Transgenic plant/NOVARTIS II,*** OJ EPO 2000, 111.

4 ***J.E.M. Ag Supply Inc. v. Pioneer Hi-Bred International Inc.***, 10 December 2001, 60 USPQ2d 1865.

5 The most prominent examples are the Proposal for a Council Regulation on the Community patent and the draft optional Protocol on the settlement of litigation concerning European patents.

6 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (EU Biotech Directive), OJ EPO 1999, 101.

7 Supra, notes 1 and 2.

8 On the basis of the EC Council Regulation No. 2100/94 on Community plant variety rights (CPVR Regulation). If a Community plant variety right is granted, Art. 92(1) CPVR Regulation prohibits the grant of national PVRs or patents for the same plant variety by EU member States.

9 Art. 53(b) European Patent Convention (EPC); Art. 4(1)(a) and (b) EU Biotech Directive. Since it also follows from Art. 53(b) EPC that microbiological processes and their products are patentable, it has been argued that plant varieties may be patented if they are the products of a microbiological process. However, this argument was rejected by the Enlarged Board of Appeal in the Novartis decision (supra, note 3).

process for making the product is patentable, and the protection conferred by this process patent will extend to the product when directly obtained by the patented process.

The analysis as to where possible overlaps between the two systems exist therefore needs to be broadened in order to take into account the above-mentioned characteristic of IP law. In particular, attention has to be paid to the following constellations:

- If a patent claims a non-essentially biological process for the production of plants, the protection conferred by this patent will extend to all plants which are directly obtained by the claimed process[10]. According to Art. 8(2) EU Biotech Directive, this extension not only comprises the first generation plants, but also the following generations (as long as they possess the same characteristics as the first generation plants). The production or use of a plant variety may therefore fall under such a process patent[11].

- If a patent claims a DNA sequence, for example a gene or a vector, the protection conferred extends to any material into which the patented DNA sequence has been introduced and in which it functions[12]. Such material may well be a plant variety.

- Furthermore, European patent law also permits patent claims on plants in general, i.e. claims which are not restricted to one or more specific plant varieties. If, e.g., a claim is directed to transgenic plants characterised by the insertion of a specific DNA sequence, it is considered not to be directed to plant varieties per se (and thus not hit by the patent exclusion of plant varieties) since plant varieties are defined by their whole genome and, hence, are characterised by a multiplicity of genetic traits. Nevertheless, the scope of protection of such claims may also encompass plant varieties, namely when those varieties contain the specific DNA sequence[13].

This analysis demonstrates that, notwithstanding the exclusivity of protection of plant varieties under the PVR system, the European legal framework is far from drawing a clear demarcation line between the two systems of protection. Instead, the overlap area remains rather broad so that, on the issue of availability of protection, European law is, in its practical consequences, not so different from national systems such as the US or Australian systems which accept the patentability of plant varieties.

III. Independence versus convergence of the prerogatives of right holders

a) Overview

Since each IP system tailors the prerogatives of the right holder in a specific manner, it does not come as a surprise that the prerogatives of a patentee differ from those of a PVR holder to some

---

10 See Art. 64(2) EPC.

11 In the Novartis decision (above, note 3), the Enlarged Board of Appeal declined to infer from the patentability exclusion of plant varieties that a process claim the protection of which might extend to a plant variety has to be refused. See headnote II: "When a claim to a process for the production of a plant variety is examined, Art. 64(2) EPC is not to be taken into consideration."

12 See Art. 9 EU Biotech Directive: "The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function."

13 In view of this consequence, claims on transgenic plants were, for a considerable amount of time, very controversial in Europe. It was strongly advocated that the exclusion of plant varieties should be given a broader reading, i.e. by making unlawful those claims which merely encompass plant varieties. In the EPO appeal case law, this view was expressed in the well-known decision ***Plant cells/PLANT GENETIC SYSTEMS*** (T 356/93, OJ EPO 1995, 545). The issue has now been resolved by the Novartis decision of the Enlarged Board of Appeal (above, note 3) and by the European legislator. According to this legislative-judicial consensus, plants can be patented as long as plant varieties are not individually claimed. Thus inventions which concern plants are patentable if the technical feasibility of the invention is not confined to a particular plant variety (see Art. 4(2) EU Biotech Directive; Rule 23c(b) EPC).

extent. According to the traditional philosophy of IP law, exemptions and limits foreseen under a specific protection scheme cannot be invoked against the owner of a different IP right. The beneficiaries of an exemption are generally not considered to possess a positive right which would exist independently from the statutory scheme of the IP right in the context of which the exemption is foreseen. Courts have been very reluctant to recognise such exemptions as rights per se which would also prevail against other IP rights. A pertinent example with respect to the interface at issue is the recent Monsanto decision of the US Court of Appeal for the Federal Circuit[14]. It therefore appears to be a matter for the legislator rather than for the courts to take over a right limitation from a specific protection scheme to another or to create specific exemptions in the overlap area. The EU Biotech Directive uses both mechanisms, as will be demonstrated below.

b) Breeder's privilege and compulsory dependency licences

It is an important principle of the international PVR system that the right holders cannot prevent other breeders from using the protected plant varieties in research and development ("breeder's privilege"). Furthermore, any newly developed variety may be freely marketed if it is clearly distinguishable and not essentially derived from the protected variety and if its production does not require the repeated use of that variety[15]. Since general patent law does not contain a similar broad exemption, the EU legislator perceived the risk that patents on plant-related inventions might be detrimental to innovation activities in the plant breeding industry. The EU Directive therefore foresees the possibility of compulsory licences in cases where a plant variety right cannot be exploited without infringing a prior patent, and vice versa. A requirement for such a dependency licence is that the plant variety or the invention constitutes significant technical progress of considerable economic interest[16].

However, compulsory licenses against dominant patents do not solve the issue completely since they presuppose the very existence of a new plant variety. The question as to whether the plant breeder is allowed to use patented material in his breeding activities thus remains a matter of the research exemption under general patent law. While the scope of this exemption, which is governed in Europe by national law, is not clear-cut, it is mostly believed to allow research which aims at improving the invention. This does not mean that automatically all plant breeding activities will be exempted from patent infringement. Nevertheless, when balancing the interests of patentees, on the one hand, and competing innovators, on the other, European patent law seems to give some comfort to the competitor, at least when compared with the situation, e.g., under US patent law.

c) Scope of right vis-à-vis farmers (exhaustion doctrine, farmer's privilege)

Following the exhaustion principles contained in Art. 16(1) UPOV 1991[17] and Art. 16(1) CPVR Regulation, a farmer is allowed to use protected plant material in order to produce his harvest. In order to achieve a similar result when the plant material is covered by patents, the EU Biotech

---

14 ***Monsanto Co. v. McFarling,*** 23 August 2002, 64 USPQ2d 1161, 1166 ("It is thus established that the right to save seed of plants registered under the PVPA does not impart the right to save seed of plants patented under the Patents Act"); for a summary see the case comment by ***J.C. Orlet,*** Patent World, December 2002/January 2003, p. 8.

15 Art. 15(1)(iii) UPOV 1991; Art. 15(c) and (d) CPVR Regulation.

16 For further details see Art. 12 EU Biotech Directive and, as an example of national implementation of this provision, the UK Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002 (Statutory Instruments 2002 No. 247).

17 "The breeder's right shall not extend to acts concerning any material of the protected variety ... which has been sold or otherwise marketed by the breeder or with his consent in the territory of the Contracting Party concerned ..."

Directive contains an explicit provision which adapts the exhaustion doctrine of general patent law to the specific situation of patents on biological material[18].

However, the exhaustion principle cannot be invoked with respect to acts that involve a subsequent cycle of reproduction[19]. Nevertheless, there is a strong tradition in PVR systems to acknowledge to some extent a so-called farmer's privilege, i.e. an exemption for farmers who use saved seed for a further round of producing the harvest. The UPOV system gives room for such exemptions under certain conditions[20], and its Members have made use of this exception in a rather heterogeneous manner. A high degree of variation has traditionally existed even between the national PVR systems within Europe. However, in 1994 the CPVR Regulation established a common standard for Community plant variety rights which also appears to have had a harmonising influence on the national PVR systems. According to this standard, the farmer's privilege only exists for certain agricultural plant species (fodder plants, cereals, potatoes, oil and fibre plants) and is subject to an equitable remuneration from which only small farmers are exempted[21].

Most interestingly, the EU Biotech Directive has created an identical exception under patent law and, in this respect, directly refers to the scheme of the CPVR regulation. Due to the legislative link, patents and PVRs completely converge in this particular respect. Patent lawyers will therefore have to follow the future legislative development of the European PVR system and its judicial interpretation very closely.

An important issue of the breeder's privilege under European law concerns the enforcement of the obligation of the farmer to pay an equitable remuneration to the right holder. The CPVR Regulation emphasises that monitoring compliance with the provisions is a matter of exclusive responsibility for the holders and that in organising that monitoring they may not provide for assistance from official bodies[22]. In order to permit such monitoring, however, the Regulation foresees that relevant information must be provided to the right holders at their request, by farmers and by suppliers of processing services[23]. While the implementing rules list the items of information to be provided in some detail[24], there is some ambiguity as to the conditions under which the information right exists.

In particular the question arose whether the right holder may request the relevant information from any farmer or only from those farmers who have made use of the agricultural exemption with respect to the protected variety. Upon referral by a German court, this issue was recently decided by the European Court of Justice in its first judgment on the interpretation of the CPVR Regulation[25].

The Court took the view that an interpretation of Art. 14(3) of the CPVR Regulation as meaning that all farmers, merely by belonging to that profession, must provide the right holders with the

---

18 Art. 10 EU Directive reads: "The protection ... shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication."

19 This is made clear by the proviso contained in Art. 10 EU Biotech Directive (above, note 18). The dicta of the US Court of Appeal for the Federal Court in ***Monsanto Company v. McFarling,*** 64 USPQ2d 1161, 1167 (2002) ("The 'first sale' doctrine of exhaustion of the patent right is not implicated, as the new seed grown from the original batch had never been sold.") appear therefore equally valid under European patent law.

20 See Art. 15(2) UPOV 1991 (optional exception).

21 For details cf. Art. 14 CPVR Regulation and the Implementing Regulation (EC) No. 1768/95 of 24 July 1995, amended by Regulation (EC) No. 2605/98 of 3 December 1998.

22 Art. 14(3), fifth indent, CPVR Regulation.

23 Art. 14(3), sixth indent, CPVR Regulation.

24 See Art. 8 of the Implementing Regulation No. 1768/95

25 Judgment of the Court (Fifth Chamber) of 10 April 2003, C-305/00, Christian Schulin/Saatgut-Treuhandverwaltungsgesellschaft mbH, EuZW 2003, 404. The same issue is also the subject-matter of another referral (C-182/01, Saatgut-Treuhandverwaltungs GmbH/W. Jäger) which is still pending before the ECJ.

requested information would go beyond what is necessary in order to safeguard the legitimate interests of both the breeder and the farmer. However, it also recognised the difficulty the holder has in asserting his right to information since examination of a plant does not reveal whether it was obtained by the use of the product of the harvest or of purchased seed. The holder must therefore have the right to request information from a farmer where he has some indication that the latter has relied or will rely on the agricultural exemption. In particular, the acquisition of propagating material of a protected variety should be considered to be such an indication. The Court considered that it should be possible for the right holder to make arrangements to know the name and address of the farmers who buy propagating material of one of his protected varieties, however long the distribution chain between the holder and the farmer.

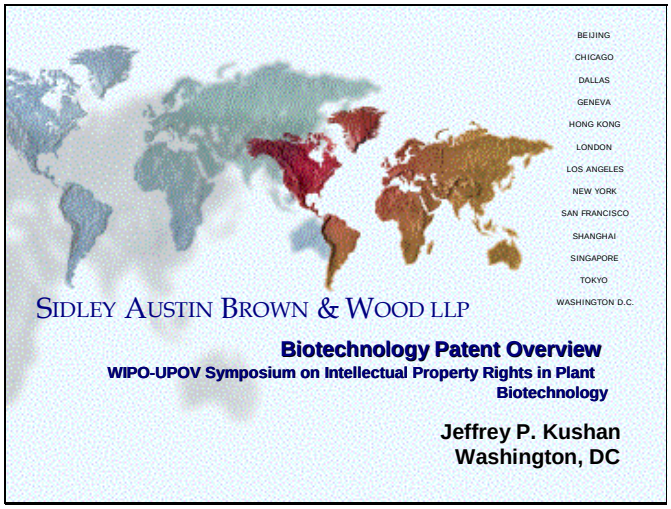
This decision of the European Court of Justice, which also has a direct impact on the enforcement of plant-related patent rights, appears to be in line with a previous decision of the German Federal Supreme Court on national plant variety rights[26]. Nevertheless, it will certainly not simplify the enforcement of intellectual property rights in plant biotechnology against European farmers.

[26] Decision of the Bundesgerichtshof of 13 November 2001, X ZR 134/00, GRUR 2002, 238.

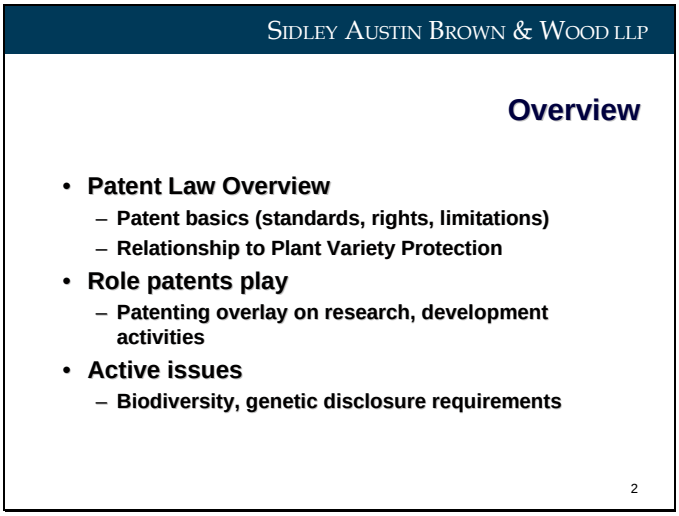
Plant Biotechnology Overview

MR. JEFF KUSHAN
Attorney, Sidley, Austin, Brown & Wood, Washington, D.C., United States of America

Slide 1



Slide 2



Slide 3

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Patent Requirements – Written Description

- **Disclosure Requirements (cont'd)**
  - ***Written description* requirement subject of extensive PTO and judicial developments**
    - **What must be established to support genus claim**
      - Claim to genus of functionally related compounds can be supported by identification of either representative number of species, or identification of structure-function relationship
      - Must consider predictability in the the field of the genus
    - **EST claims not usually sufficient to establish written description for the full length gene**
      - Critical inquiry is knowledge of the function of the gene, particularly where there is a substantial degree of variability for members of a family of related genes with conserved domains

9

Slide 4

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Patent Requirements – Inventive Step

- **Invention must be nonobvious / involve an inventive step**
  - **Obviousness measures the difference between what is in the prior art and what is claimed**
    - The prior art must not suggest what is claimed as the invention
  - **Critical inquiry is the claimed invention relative to the prior art**
    - Knowledge that some unidentified substance exists in a plant extract does not mean that an isolated, purified and characterized chemical compound is "obvious"

4

Slide 5

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Patent Requirements - Utility

- **Invention must be "useful" / industrially applicable**
  - **U.S. uses a more general standard**
    - Invention must have "practical utility" (real world use) or application in any field or industry, including agriculture
  - **EPC**
    - Articulates broad eligibility but then identifies certain types of inventions that do not have an industrial application
  - **Both standards differentiate abstract ideas, laws of nature, unapplied concepts from patentable inventions**

5

Slide 6

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Eligibility –Utility Requirements

- **U.S. utility requirement articulated in USPTO utility examination guidelines -- invention must has specific, substantial and credible utility**
  - **Specific** = the utility of the invention must relate to the specific compound claimed, not the class of compounds to which the compound belongs
  - **Substantial** = the utility claimed for the invention must not be inconsequential to the claimed invention (e.g., use of sophisticated bioactive protein as an amino acid source)
  - **Credible** = the utility of the invention has a well-founded scientific basis
- **These standards are reflected in EPC decision of *Icos v. SmithKline* (OJ EPO 2002, 263)**

6

Slide 7

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Patent Requirements - Disclosure

- **Disclosure requirements**
  - **The "quid pro quo" of the patent system – early disclosure of technical information for exclusive rights**
  - **Purpose of disclosure requirements is to put the public in possession of the invention once patent expires**

7

Slide 8

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Patent Requirements - Disclosure

- **Main U.S. requirements**
  - **Enablement –** requires that the disclosure enable a person of ordinary skill to reproduce and make the invention
  - **Written description –** the patent application viewed as evidence of what the inventor "invented" as of the filing date
  - **Best mode –** what did the applicant believe to be the best mode of practicing if the invention – if any – at the time the application was filed
  - **Subjective best mode –** best mode is not objective, but subjective - what the patent applicant actually believed at the time the application was filed

8

Slide 9

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Patent Requirements – Written Description

- **Disclosure Requirements (cont'd)**
  - ***Written description* requirement subject of extensive PTO and judicial developments**
    - **What must be established to support genus claim**
      - Claim to genus of functionally related compounds can be supported by identification of either representative number of species, or identification of structure-function relationship
      - Must consider predictability in the the field of the genus
    - **EST claims not usually sufficient to establish written description for the full length gene**
      - Critical inquiry is knowledge of the function of the gene, particularly where there is a substantial degree of variability for members of a family of related genes with conserved domains

9

Slide 10

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Patent Requirements - Enablement

- **Disclosure requirements (cont'd)**
  - **Enablement law relatively settled in US**
    - **Patent specification must enable person of skill to practice the patented invention**
      - Wands factors (i.e., *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988)) include (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the level of one of ordinary skill, (5) the level of predictability in the art, (6) the amount of direction provided by the inventor, (7) the existence of working examples, and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.
    - **Deposits played significant role at dawn of biotech industry, now less critical for enablement, but now used to support written description**

10

Slide 11

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Patent Requirements – TRIPS Disclosure

- **Disclosure requirements (cont'd)**
  - **TRIPS Article 29 - Members can require disclosure of invention only to the degree necessary to "permit the invention to be carried out by a person skilled in the art"**
    - Members *optionally* can require disclosure of "best mode" if one is known to the applicant at time of filing of application
  - **Purpose to ensure that standards are consistently applied in all WTO Members**
    - Members cannot impose additional special disclosure requirements

11

Slide 12

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Eligibility in the US

- **U.S. standard most "inclusive" as to eligibility**
  - **Any invention "made by the hand of man" is eligible to be patented**
    - Eligible does not mean it will be granted a patent – invention must be new, useful, nonobvious, adequately disclosed and described
  - ***Diamond v. Chakrabarty*, 100 S.Ct. 2204 (1980)**
    - "A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability and the inventions most benefiting mankind are those that "push back the frontiers of chemistry, physics, and the like."
    - "Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable."

12

Slide 13

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Eligibility - TRIPS

- **TRIPS Article 27.1 mandates eligibility for all inventions that are novel, involve inventive step, and are industrially applicable**
- **Articles 27.2, 27.3 then define permissible optional exceptions Members may make to the general rule**
  - Critical perspective for interpretation – everything is to be eligible to be patented unless there is a specifically defined exception authorized by the Agreement

13

Slide 14

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Eligibility – 27.2 Exclusions

- **Article 27.2 exclusion:**
  - **Permits Members to exclude patents on inventions that may not be used in their territory because the invention presents serious threats to "*ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment"**
    - Members cannot deny patents under Article 27.2 but allow parties to use the technology in their territory

14

Slide 15

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Eligibility – 27.3(a) Exclusions

- **Article 27.3(a) exclusion**
  - **Permits Members to exclude patents on process inventions (i.e., therapeutic, surgical or diagnostic methods performed on the human or animal body)**
    - Based on EPC Article 53(c)
  - **Does not allow Members to limit eligibility for product claims (e.g., compounds or compositions to be used in therapy, diagnosis or surgical methods)**

15

Slide 16

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Eligibility – 27.3(b) Exclusion

- **Article 27.3(b)**
  - **Permits members to exclude plant and animal inventions (i.e., products) or essentially biological processes**
  - **Patents must be made available for**
    - **Microorganisms**
      - Bacteria, yeast, fungi
      - Cell lines (e.g., hybridomas, transformed cell lines)
    - **Processes that are not essentially biological (e.g., manipulation of particular cellular function to produce desired result)**
    - **Definition of "essentially biological"**

16

Slide 17

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Eligibility – 27.3(b) Plant Variety Protection

- **Article 27.3(b) (cont'd)**
  - **Also imposes conditional requirement – if patents not granted on plant inventions, Member must make available effective *sui generis* protection for plant varieties**
  - **Effective must be construed in light of purpose of protection**
    - Gives exclusive rights in the plant variety
    - Look to UPOV as standard recognized as establishing effective standards for protection

17

Slide 18

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Eligibility – Gene Patents

- **Patents on "genes"**
  - **Gene is a sequence of nucleotides that encodes a polypeptide**
    - "Naturally" occurring gene is found as a non-contiguous sequence of nucleotides in a chromosome
    - Research identifies the parts of the sequence that encode the polypeptide
- **Patent gives rights in a chemical compound made using this information**
  - **A new, non-naturally occurring nucleotide sequence that excludes non-coding nucleotides found in the naturally-occurring sequence**

18

Slide 19

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Eligibility – US/EPC Developments

- **US/EPC law requires identification of the complete coding sequence and the function/role played by the gene or its expression product**
  - Patents not granted on sequences lacking a characterized function
  - EU Biotech Directive Recital 23 ("Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention")

19

Slide 20

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Eligibility – Natural v. Non-Natural

- **Naturally occurring materials**
  - Patent law draws line between "naturally occurring" materials and inventions made through human intervention
  - Patent rights cannot give exclusive rights in living organism in the form it is found in nature (i.e., unchanged by human intervention)
- **Non-naturally occurring inventions**
  - Genetically transformed plant or animal
    - Made by "genetic engineering" or through other techniques
  - Chemical compounds or compositions isolated from plant, animal or microorganism
  - Composition of purified, cultured, stable microorganism

20

Slide 21

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Rights Conferred

- **Patents confer exclusive rights**
  - **Right to prevent others from making, using, selling, offering for sale or importing invention without authorization**
  - **Patents convey much information, but give rights only as defined in the claims.**
    - Claims define the "invention" that is found to be patentable

21

Slide 22

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Limitations on Patent Rights

- **Most countries limit ability of patent owner to enforce rights in certain circumstances**
  - **Experimental use of the invention –** to investigate and evaluate the invention to determine how it works
  - **U.S. unusual** – no statutory research exception, some freedom left to conduct purely non-commercial research using patented invention

22

Slide 23

SIDLEY AUSTIN BROWN & WOOD LLP

Patent Basics
Limitations on Patent Rights

- **Practical limitations**
  - **Not efficient, practical or conducive to product development efforts for patent owners to aggressively enforce patents whenever possible**
    - Common to permit use of patented technology by universities and other research-focused organizations to facilitate development of the technology
  - **Real world experience shows that patent litigation rare relative to patent licensing activities**

23

Slide 24

SIDLEY AUSTIN BROWN & WOOD LLP

Patent versus Plant Variety Protection Requirements

Patent	Plant Variety Protection
Novel Useful/Industrially applicable Non-obvious/inventive step Adequately described in the application	Novel Stable Distinct Uniform Application to be filed but not substantive

24

Slide 25

SIDLEY AUSTIN BROWN & WOOD LLP

Patent versus Plant Variety Protection Rights Conferred

Patent	Plant Variety Protection
Prevent unauthorized making, using, selling, offering for sale or importing of patented invention	Prevent production or reproduction (multiplication), conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing, stocking for any of these purposes
Rights exist with respect to what is defined by the claims of the patent	Rights in propagating material, in harvested material and products derived from the harvested material

25

Slide 26

SIDLEY AUSTIN BROWN & WOOD LLP

Patent versus Plant Variety Protection Exceptions

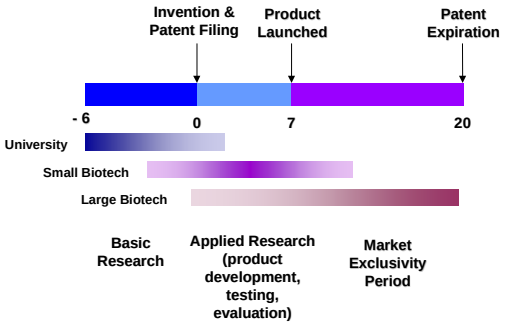
Patent	Plant Variety Protection
TRIPS Article 30 – uses that do not unreasonably conflict with the legitimate rights of the patent owner, taking into account those of third parties *Generally* – experimental use that does not have clear commercial implication	Mandatory exceptions permit use of propagating material for (i) private, non-commercial use, (ii) research on the protected variety, (iii) to produce a new variety. Optional exception to permit farmers to use harvested material from their plantings for future planting on their holdings.

26

Slide 27

SIDLEY AUSTIN BROWN & WOOD LLP

Practical Considerations on Patent Use



27

Slide 28

SIDLEY AUSTIN BROWN & WOOD LLP

Role of Patents in R&D

- **Role of patent exclusivity**
  - **Patents enable members of a research and development team to ensure that the "output" of the effort (e.g., a new product or service) cannot be used without authorization**
    - **Prevents "free riding" on the investments made by the team by preventing unauthorized use of what is patented**
    - **Enables the team to (a) receive a fair return on their investment, and (b) ensure that the patented technology is effectively exploited by delivering new products and services to the market**

28

Slide 29

SIDLEY AUSTIN BROWN & WOOD LLP

Role of Patents in Product Development

- **Patent rights can be licensed in the manner that best promotes commercial exploitation of the invention**
  - **Field-limited exclusive licenses – exclusive licenses within defined fields of use**
    - License conveys exclusive use of patented gene in specific crops for one entity, and to other crops for another entity
  - **Non-exclusive licensing limited by scope of license**
    - Right to incorporate/use gene in specific varieties, and to sell specific varieties on non-exclusive basis

29

Slide 30

SIDLEY AUSTIN BROWN & WOOD LLP

Active Issues
Special Disclosure Requirement (SDR) Proposals

- **Genetic resource disclosure requirements**
  - Proposals to require – in addition to patent-relevant disclosure – special disclosure requirements for determination and disclosure of origin/source of "genetic resources" (anything having DNA)
  - Purposes ostensibly to ensure compliance with benefit sharing obligations of the Convention on Biological Diversity or individual countries
  - All concepts envision penalty of refusal of patent grants, or loss of patent rights

30

Slide 31

SIDLEY AUSTIN BROWN & WOOD LLP

Active Issues
SDR Concerns

- **Scope of proposals is unrelated to the objectives of the CBD**
  - Few patentable inventions arise from screening of undeveloped "genetic resources" (e.g., undeveloped germplasm samples)
  - Every biotech application mentions "genetic resources" but only a tiny fraction might concern genetic resources collected through bioprospecting activities covered by the CBD
  - Immense compliance burden and risks for system that, *by definition*, will not address the vast majority of bioprospecting activities

31

Slide 32

SIDLEY AUSTIN BROWN & WOOD LLP

Active Issues
SDR Concerns

- **Incentives for use of genetic resources are needed – special disclosure requirements being proposed will have the *opposite* effect!**
  - Very few incentives exist now for biotech companies to invest in research and development of undeveloped "genetic resources"
    - Immense cost and effort required with little prospect for commercially successful results
  - Attaching possible risks to patents on inventions made from use genetic resources creates an additional strong *disincentive* to develop products using such materials

32

Slide 33

SIDLEY AUSTIN BROWN & WOOD LLP

Active Issues
SDR Concerns

- **Proposals attempt to impose unfair and inappropriate burdens on all patent applicants**
  - Disclosure of origin would require research and analysis to produce results that are, by definition, unclear
    - Genetic lineage of a sample may reveal multiple "origins"
    - Origin at what date
    - What degree of relationship
  - Time pressures on filing applications are immense – proposed requirements would involve unworkable delays
- **Patent system is not the appropriate means to enforce CBD provisions**
  - If you don't pay taxes, you don't lose patent rights!

33

Slide 34

SIDLEY AUSTIN BROWN & WOOD LLP

Active Issues
SDR Conclusions

- **Regulate bioprospecting directly through laws/practices based on the CBD**
  - Creating uncertainty in validity of patents will eliminate commercial interest in R&D on genetic resources
  - Inappropriate to attempt to regulate this behavior using the patent system – both overbroad and ineffective
  - Presumes innovators are acting outside CBD-based regimes – no basis for this claim
  - Would introduce unworkable provisions into patent standards due to immense uncertainty as to the nature of the requirements for disclosure

34

Slide 35

SIDLEY AUSTIN BROWN & WOOD LLP

Questions?

- **Please send questions to:**

Jeffrey P. Kushan
Sidley Austin Brown and Wood LLP
1501 K Street, N.W.
Washington, D.C. 20005
jkushan@sidley.com
202-736-8914 (ph), 202-736-8711 (fax)

35

IPR Protection in China-A General Review

QIN FANG WANG
Associate Professor, Biotechnology Research Institute,
Chinese Academy of Agricultural Sciences
YINLIANG LIU
Associate Professor, School of Civil and Commercial Law,
China University of Political Science and Law

The modern intellectual property system in China was developed only since the early 1980s as a result of the economic reform and opening-up of China's economy to the rest of the world. In 1980, with the approval of the State Council, the Chinese Patent Office (CPO) was founded to be the sole patent administration at state level. In 1998, the CPO was reconstructed and renamed as the State Intellectual Property Office (SIPO), which is directly under the State Council. At present, the SIPO is mainly in charge of patent affairs and serves also as the coordinating authority for foreign-related intellectual property right (IPR) issues.

On June 3, 1980, China acceded to the ***Convention Establishing the World Intellectual Property Organization***. Additionally, regarding the patent issue alone, China is now a member state of the ***Paris Convention for the Protection of Industrial Property***, the ***Patent Cooperation Treaty*** (PCT), the ***Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure,*** the ***Locarno Agreement Establishing an International Classification of Industrial Designs***, and the ***Strasbourg Agreement Concerning the International Patent Classification***. Since January 1, 1994, after becoming a member state of the PCT, SIPO has been serving as the Receiving Office of International Searching Authority and International Preliminary Examining Authority, and the Chinese language is now one of PCT's working languages.

Under the guidance of SIPO, besides the CPO, there are two main administrations, i.e., the Trademark Office (temporarily being under the State Administration for Industry and Commerce) and the State Copyright Office, who are responsible for administration of trademark and copyright issues, respectively.

Regarding the patent law legislation in China, the Patent Law was first adopted by the National People's Congress on March 12, 1984, entered into force on April 1, 1985, and has been amended twice in 1992 and 2000, respectively. Meanwhile, in accordance with the Patent Law, the Implementation Regulations for the Patent Law have also been issued and amended accordingly.

For the issue of new plant variety protection, upon becoming the 39th member country of UPOV, China has issued its Regulations on the Protection of New Varieties of Plants in 1997 and entered into force on April 23, 1999.

This paper summarizes our survey of the current situations of patent application in the field of genetic engineering. Section I provides the current situation of IPR protection for genetic engineering and plant variety rights protection; the problems and challenges met in IPR management will be discussed in Section II; and Section III provides the Bt cotton case study. The concluding remarks are provided in the final Section.

SECTION I: CURRENT BIOTECHNOLOGY IPRS IN CHINA

1.1 Patents on Genetic Engineering

With the fast increment of patent applications in the field of biotechnology in China, a Division for Biotechnological Inventions Examination within the CPO was specifically set up to meet the needs of increasing patent application on biotechnology. This Division mainly deals with the applications and examinations of genetic engineering patents. In addition, an IPR Affair Center under the Ministry of Science and Technology was set up in 1995 as a governmental consulting agency for IPR issues in China (SIPO, 1999).

The data presented by the SIPO show that, from April 1, 1985 to the end of 2000, about 1265,974 patent applications have been filed in the CPO, with 687,541 patents granted during that time. It is shown that, in the 1990s, the number of patents on genetic engineering is ranked among the top 20 groups, with however as low as about one percent of the total patents granted (SIPO, 2000). But on the other side, as our figure and data indicate, the number of patent applications on genetic engineering has been increasing overtime, particularly after 1998.

Further analysis shows that multinational companies filed the most applications in genetic engineering in 1985-1998. An average of 90% applications were from foreign companies in this period. Among the patent applications filed in the CPO on genetic engineering, about 75% of them were filed by foreign entities (companies or institutes. Comparatively, applications submitted by Chinese scientists accounted for 25% only. Compared with foreign companies, the percentage of domestic application on genetic engineering is less than 10% in the first five years since the Patent Law was enforced (1985 to 1989). However, domestic applications have increased dramatically since 1998, and surpassed the foreign applications to account for 55% of the total applications in 1999 and more than 90% thereafter. The major reason lies in the huge amount of application by the United Gene Holdings LTD (United Gene for short), a pharmaceutical company established in 1997 by two professors from FuDan University, Shanghai. United Gene filed 240,2940 and 188 applications for gene invention in 1999, 2000 and 2001, which accounted for 25.6%, 85.3% and 34.3% of the total annual applications, in this subject area. All of these applications were in the field of pharmaceutically related genes, technology or products. In the year of 2000 alone, the patent application reached up to 3447 cases, which accounted for 51.3% of the total applications in the period of 1985 to 2001. This result may link with the enforcement of the new amended Patent Law.

The top ten countries accounted for about 92% of the total foreign applications filed in the CPO in 1985-2001, which includes the USA, Japan, Germany, UK, Switzerland, Denmark, France, the Netherlands, Canada, and Australia. Depending on its advancement of biotechnology industry, USA becomes the top country in applying gene patents in China, accounting for 39.7% of the total foreign applications in the period of 1985 to 2001.

It is shown that the majority of patents on genetic engineering are within the field of pharmaceutical and agriculture. The former accounted for 72.7% and the later accounted for 8.9% in 1985-2002. This might reflect the fact that pharmaceutical products, produced in confined factories, are easy to be protected. On the other hand, the benefits returned from pharmaceutical products may be more direct than those on agricultural products.

1.2 Protection of New Varieties of Plants in China

In China, it's the Plant New Variety Protection Office under the Ministry of Agriculture (MOA) and State Forest Agency (SFA) that is responsible for granting Plant New Variety Right. The administrating system for PVP was established in 1999. The MOA is responsible for granting rights for the agricultural crops, such as grain, cotton, oil plants, hemp plants, mulberries, tea, sugar, vegetable, edible fungi, tobacco, fruit trees (juicy), herbaceous medicinal materials, herbaceous ornamental plants, grass, rubber, and green manure; and the SFA is in charge of the forestry plants like forest trees, bamboo, xyloid vine, ornamental woody plants, fruit trees (dry), woody oil-bearing, beverage plants, condiment plants, and woody medicinal materials. (MOA, 2001)

MOA has issued five batches of agricultural plants for Plant New Variety Rights since 1999 (MOA, 2003). Totally, there are 39 genera/species of agricultural plants being listed for the protection by the new plant variety protection policy in China (Table 1). MOA has received 1061 applications for Plant New Variety Rights from April of 1999 to August of 2003. Rice and corn are two major field crops for new variety protection, the applications and granting on these 2 crops account for 77% and 80%, respectively (Table 2). Regarding the planting area in China, 50% of rice and 95% of corn are hybrids (Huang Jikun, 1998). Farmers and small seed dealers can't make hybrid seeds by themselves, so that the plant variety rights can be protected sufficiently in hybrids. In terms of the conventional varieties, the Seed Law and Regulations on the Protection of New Varieties of Plants (1978 version of UPOV) protect the farmer's rights, which means Chinese farmers can save the seeds for their own field or exchange crop seeds with other farmers. So the IPR of conventional crop varieties is difficult to be protected by the current Regulations on the Protection of New Varieties of Plants.

A total number of 412 varieties have been granted with the Plant New Variety Right. There are 317 applications from January to August in 2003, while only 172 applications were made in the same period of 2002. The breeders have recognized the importance of Plant New Variety Right, so the application on the Plant New Variety Right is increasing yearly. However, there is still no transgenic plant variety that has been granted by the PVP rights in China.

At the meantime, to strengthen the management to plant new varieties, MOA has established a Propagation Material Preservation Center for Agricultural Plant New Varieties, which is responsible for the quality & quantity detection and preservation of propagation materials. MOA has also established one Center and 14 branch centers for the DUS test of new agricultural plant varieties.

SECTION II: PROBLEMS AND CHALLENGES IN PLANT BIOTECHNOLOGY IPRS

Great achievements have been made on IPR protection for genetic engineering in general and for plant biotechnology particularly in the past twenty years. However, problems and challenges are emerging with the implementation of IPR policies and regulations. The following are some of the obvious examples.

(1) Public Awareness:

During the past 20 years, although both the government and scholars concerned with IPR management and research have done much work on explaining IPR matters. However, there remains less public awareness compared with that in some developed countries. This phenomenon sometimes exists in public research institutes whose fiscal incomes rely significantly on governmental inputs. Some writers have suggested that this can be traced back to the centrally planned economy period (Huang, Jikun, Ruifa Hu, Scott Rozelle, 2003[a]). The main source of investments in biotechnology research in China is the national government (Huang Jikun et al, 2001). Donor agencies contributed between 1.5 percent in 1986 to 6.9 percent of the total plant biotechnology budget for 22 major plant biotechnology institutes surveyed in 1999. It's believed that this recognition of IPR can be improved through education, training, and information exchange.

(2) Capacity Building on IPR Protection

This aspect may involve several dimensions, such as educational or training programs and fiscal aids. For example, a particular concern of IPAC in MOST is to encourage the scientists to look for more opportunities to protect the technology, processes or products they have developed by patents and other IPRs, if necessary. Policies concerning financial aids or economic benefit have also been adopted.

(3) Implementation on IPR Protection

The legislation on IPR laws has made obvious progresses in the past ten years, especially in the 1990s. But the implementation of the IPR laws is not yet fully completed. This is reflected in both

the IPR administration and judicial practice. Monitoring actual implementation of IPR protection is also a difficult task that may be improved in the future.

(4) Emerging Mechanisms for Technology Transfer

Mechanisms of technology transfer are still developing in China, and particularly in the transfer of high technology, such as plant biotechnology. This may affect China's emerging technology market and venture capital activity (especially in agricultural or plant biotechnology). Additional human resources and capacity building would be helpful. The government is now encouraging private funds to enter this field. The cost-benefit analysis is being applied more frequently to evaluate different models of technology transfer.

(5) Enforcement of Laws and Regulations

Although the IPR legal system has been established in China, the unauthorized use of IPR protected plant biotechnology occurs frequently.
There have been many reported illegal transactions, which may infringe a patent right or a plant breeder's right. This may involve some small seed companies or the farmers themselves. Therefore, how to check the infringement and at the same time balancing farmers' right is a challenge in China as well as in other countries. Regional concerns may in some instances affect the settlement of legal disputes because local government may put the conduct accused of infringement under their protection.

SECTION III: THE BT COTTON CASE STUDY

Under the support of the National High-Tech Program, the so-called "863 Plan", a great breakthrough has been made in the research and development of transgenic cotton resistant to cotton bollworm. ***Bacillus thuringiensis*** (Bt) and Cowpea Trypsin Inhibitor gene (CpTI) have been modified, synthesized and transferred into a few dozens of cotton cultivars, which have been approved by the Biosafety Committee at the Ministry of Agriculture for commercialization in China since 1997. The key technology of insecticidal gene's synthesization, vector construction and pollen tube pathway transformation method was patented in China in 1998, and it was granted as the "Golden Award for Patent" by the WIPO and SIPO in 2001. Upon this patent, China becomes the second country in the world to successfully develop Bt cotton with its own IPRs.

Bt cotton is the transgenic crop with the largest commercial area in China. Thirteen transgenic cotton varieties and 5 transgenic cotton hybrids have been registered and commercialized in 12 cotton production provinces. The accumulative total area of Chinese transgenic cotton (exclude Bt cotton area from Monsanto) by 2003 was 3.4 million ha.

Bt cotton not only increases the yield, but also reduces the spry of pesticide and labor input, therefore Bt cotton has dramatic economic and social impact. According to Jikun Huang's field survey (Jikun Huang et al, 2003[b]), in the provinces that still grew some non-Bt cotton in 2001, the mean yield of the Bt cotton varieties is 17% higher than that of non-Bt varieties in 2000 and 6 to 7 percent in 2001. Chinese Bt cotton farmers reduced pesticide use by an average of 13 sprayings (49.9 kg) per hectare per season (Jikun Huang et al, 2002). This reduced $762 of cost per hectare per season. Farmers also significantly reduced labor for pest control. According to Jikun Huang's estimate the total benefit from the adoption of BRI (Biotechnology Research Institute, Chinese Academy of Agricultural Sciences) Bt cotton in 1999 alone was $197 million (Jikun Huang et al, 2002). More than 5 million farmers have adopted Bt cotton in China.

Concluding Remarks

This paper gives a review for the IPR in general and that of the plant biotechnology in particular, together with a description of the Bt Cotton Case. The legal system for IPR protection in China has been established. Patent applications on genetic engineering are increasing year by year. During the period of 1985 to 1998, multinational companies filed the majority of patent applications in China,

but with the establishment of United Gene, the domestic application increased dramatically from 1999. Although there is no transgenic plant granted by PVP, great progress has been made in non-transgenic plants for PVP, particularly for hybrid rice and corn in China. Through patents and PVP, plant biotechnology can be protected in China now, but the situation is far from being satisfactory. Various problems and challenges concerning IPR protection in China still exist with the rapid development of biotechnology. To solve or minimize the current problems, the capacity building, legal system and enforcement of Laws and Regulation on IPR protection need to be further improved. Bt cotton is the only transgenic crop with large commercial areas in China, and the commercialization of Bt cotton has achieved great positive impacts on farmer's income and environmental protection.

Reference:

Huang, Jikun and Scott Rozelle, 1998, China's Grain Economy to the Twenty-First Century, China Agriculture Press.

Huang, Jikun, Qinfang Wang, Yingding Zhang, Jose Falck Zepeta, 2001, Agricultural Biotechnology Research Indicators: China, International Workshop on Plant Biotechnology Policy in China: Initial Findings, Research methods, and Research Priorities, July 18-20, 2001, Beijing

Huang, Jikun, Scott Rozelle, Carl Pray, Qinfang Wang, 2002, Plant Biotechnology in China, ***Science***, Volume 295, pp.674-677

Huang, Jikun, Ruifa Hu, Scott Rozelle, Fangbin Qiao, and Carl Pray. 2002. "Transgenic Varieties and Productivity of Smallholder Cotton Farmers in China," ***Australian Journal of Agricultural and Resource Economics,*** 46:3, (2002): 367-387.

Huang, Jikun, Ruifa Hu, Scott Rozelle, 2003[a], Agricultural Research Investment in China: Challenges and Prospects, China Finance and Economic Press.

Huang, Jikun, Ruifa Hu, Cuihui Fan, Carl E. Pray and Scott Rozelle, 2003[b]. Bt Cotton Benefits, Costs, and Impacts in China, ***AgBioForum***, 5(3) 2003: 1-14.

MOA, 2001, Plant New Variety Protection Policy in China.

Office of Plant New Variety Protection, MOA, 2003, Variety Protection Gazette for Agricultural Plants, Vol 25.

SIPO (The State Intellectual Property Office), 1999. Report on the IPR Protection in China in 1999.

SIPO (The State Intellectual Property Office), 2000. Annual Report of 1999.

Table 1. Protected botanical genera and species of plants by the MOA

Issue date	Plant species
June 16, 1999	Rice, maize, Chinese cabbage, potato, spring orchids, chrysanthemum, Chinese Pink, clover, grass
March 3, 2000	Wheat, soybean, oil rape seeds, peanut, tomato, cucumber, chili, pear, dock
Feb. 26, 2001	Orchids, lily, bird of paradise, sea lavender
Jan. 4, 2002	Sweet potato, millet, peach, Litchi, water melon, cabbage, radish
July 14, 2003	Broomcorn, barley, ramie, apple, citrus, banana, kiwi fruit, grape, plum, eggplant

Table 2 Summary of applications and granting for Plant New Variety Rights on agricultural plants

Plant species		1999.4 – 2003.8		Application	
		Application	Granted	2002	2003
Field crops	Rice	318	82	38	141
	Corn	499	248	68	95
	Soy bean	29	19	2	6
	Wheat	69	22	23	28
	Brassica	36	11	8	17
	Peanut	10	5	1	3
	Sweet potato	2	0	0	2
Vegetables		60	14	20	16
Flowers		11	0	2	3
Fruit trees		26	11	10	6
Pasture		1	0	0	0
Total		1061	412	172	317

* Data provided by Plant New Variety Protection Office, MOA, 2003

Experiences in Plant Variety Protection under the UPOV Convention

MR. EVANS SIKINYI
Manager, Plant Variety Rights Office, Kenya Plant Health Inspectorate Service (KEPHIS), Kenya

I. Introduction

1. The Consultative Committee of UPOV, at its sixty-second session in October 2001, decided to establish an Ad hoc Working Group (the "Working Group") with the participation of selected new members from developing countries and countries in transition to a market economy to conduct a study on the impact of plant breeders' rights on the basis of empirical data collected.

2. In my presentation I will introduce briefly the project of the UPOV study on the impact of plant breeders' rights (see Part II), followed by some experiences in plant breeders' rights in Kenya (see Part III), one of the countries participating in the UPOV study.

II. *Ad hoc* Working Group to Study the Impact of Plant Breeders' Rights

3. The purpose of the study is to conduct an empirical analysis of the impact of the introduction of a plant variety protection system on the basis of data collected in selected UPOV member States: Argentina, China, Kenya, Poland and the Republic of Korea. Profiles of these countries are summarized in Table 1 of the Annex.

4. The study should concentrate on the analysis of the impact of plant variety protection on developments in plant breeding. The Working Group agreed to collect data concerning the following parameters on the input side and output sides:

Paragraph (a) Measurable factors to indicate the inputs in the national breeding program:

- Parameter 1: Number of breeding entities (individuals, companies, governmental institutions, etc.);
- Parameter 2: Investment for plant breeding (for breeding facilities and/or for technical innovation).

Paragraph (b) Measurable factors to quantify the development of new varieties (out-puts of the national breeding activities):

- Parameter 3 Number of released varieties;
- Parameter 4 Improvement of released varieties (in terms of increased yield, agronomic performance, quality, market chance of recently-released varieties, etc.).

III. Experiences in Kenya in Plant Breeders' Rights

5. The Office to administer plant variety protection (PVP) in Kenya was founded in 1997 and has functioned under the Kenya Plant Health Inspection Service (KEPHIS) since 1998. Kenya acceded to the 1978 Act of the UPOV Convention on May 13, 1999, and KEPHIS has put in place the necessary structure for plant variety protection. The development in the number of applications for protection is given as follows:

Years	Kenyan Applications	Foreign Applications	Notes
1998	42	33	PVP System in operation
1999	16	45	Accession to UPOV
2000	24	45	
2001	164	33	
2002	11	27	

6. The principal aims of the establishment of PVP services were to:
- Provide incentives to breeders and thus encourage investment and efforts into plant breeding in Kenya;
- Allow Kenyans access to foreign varieties;
- Increase number and range of improved varieties available to farmers.

7. With these objectives in mind, a study was conducted to review the impact of the establishment of plant variety protection services in Kenya. Data was collected through interviews with breeders in public and private institutions and a questionnaire was developed to guide the discussions. Secondary data was also collected from records of Plant Breeders' Rights (PBR) applications submitted to the PVP Office. A total of fourteen (14) breeding institutions were visited (see the Table below).

Profile of Institutions Covered

Institution	Number Visited
Public Universities	2
Public Research Centres	5
Private Breeding Firms	4
Ornamental Firms	3
Total	14

Changes in Investment

8. The results revealed a general increase in investment in breeding activities since the establishment of PVP services amongst the visited institutions. Investment was greatest and more diverse in physical facilities and in technology (see Table 2 of the Annex). Most of these investments occurred in private institutions. Seven (7) institutions had invested on various forms of physical facilities. All the public institutions covered had experienced decreases in land acreage and financial allocations. In contrast, financial investment had increased in all private institutions within the same period. All the private institutions interviewed had acquired more land for research and seed multiplication.

9. A significant impact of the establishment of PVP services on both public and private breeders was seen in increased collaboration amongst local and foreign institutions. This involved capacity building, donor funding, germplasm exchange and commercialisation of foreign varieties in the country. This is because foreign breeders felt safe to introduce their materials and to invest in Kenya after the implementation of the plant variety protection system. Breeders have also extended partnerships with local farmers for on-farm testing of new varieties.

10. Institutions collaborating with local breeders are as follows:

(1) Donor organizations
- World Bank
- Rockefeller Foundation

- McKnights Foundation
- African Academy of Sciences
- Agricultural Research Fund

(2) International Research Institutions
- International Crops Research Institute for the Semi-Arid Tropics (ICRISAT)
- International Institute of Tropical Agriculture (IITA)
- International Center for Tropical Agriculure (CIAT)
- International Center for Agricultural Research in the Dry Areas (ICARDA)
- International Maize and Wheat Improvement Center (CIMMYT)

(3) International Finance Cooperation
- AFRONET
- SIDA
- USAID

(4) Local Institutions
- Kenya Agricultural Research Institute
- Drought Monitoring Centre
- Kenya National Cleaner Production Centre

Variety Introduction and Commercialization

11. Of the 14 institutions visited, 10 had introduced new plant varieties into the market over the last five years, an achievement that they all reported to be higher than during preceding periods. In total 81 new varieties had been introduced by the institutions visited, most of which were still under NPT and distinctness, uniformity and stability (DUS) examinations (see the Table below).

Varieties released by the 10 breeders Within the Last Five Years

Plant	Number of Varieties Introduced
Maize	29
Wheat	6
Sugarcane	9
Tomato	2
Rose	21
Limonium	14
Total	81

12. Of these, 56 were bred locally, 17 were bred abroad while 8 were bred both locally and abroad through collaborations. Maize had the largest number of new varieties as well as diversity in quality improvement (see Table below). Maize is a staple food crop for 80% of Kenyans.

Improved Factors in New Maize Varieties	
Parameter	***Number of Breeders***
1. Yield	***8***
2. Pest and diseases	
Maize streak virus (MSV)	3
Smut	2
Grey leaf spot (GLS)	1
Mildew	1
Maize stalk borer	1
Blight	1
Striga tolerance	2
3. Nutritional qualities	
High protein content	3
Better cooking quality	2
4. Abiotic stresses	
Drought tolerance in maize	6
Frost tolerance in maize	3
Tolerance to low soil N fertility	2
Tolerance to soil acidity	2
Lodging resistance	1
5. Early maturity	***5***
6. Bare tips	***1***

13. Besides the factors listed in the Table above, one maize breeder focuses on developing varieties that can do well in both low and high potential ecozones. The same breeder targets low input farming and emphasizes on the exploitable potential (as opposed to maximum potential) of a variety that suits small-scale farmers' input conditions. Another maize breeder is preparing to introduce an early maturing variety Open Pollinated Varieties (OPV) for the high altitudes that can be cultivated twice in a year. Improved parameters in the new sugarcane varieties included tolerance to heavy clays, high sucrose content and low fiber content. For wheat, the new varieties had improved resistance to yellow rust and stem rust. Longer shelf life was more important for the new tomato and flower varieties. The performance of the new varieties in the domestic market was reported to be better than previous varieties by eight breeders, whereas two had not explored this market. In contrast, only two breeders offered their new varieties in foreign markets and in which they reported better performance.

Applications for Plant Breeders' Rights

14. In the five years of existence of PVP Service in Kenya, a total of 578 PBR applications have been received. Local (Kenyan) breeders submitted 268 (46.4%) of the total PBR applications while 310 (53.6%) were of foreign origin (Table below). Public institutions presented 137 (51.1%) of the local applications whereas 67 (25%) were from private institutions. Private and public breeders jointly submitted 64 (23.9%) applications. No title of protection has, however, been granted and the applications are still being processed. The following steps are currently being undertaken in processing the applications:

- Issuing official gazette notices of the applications
- Receiving representations of objections on gazetted applications
- Testing for the DUS of the candidate varieties.
- Acquisition of test reports from authorities in other UPOV member states on varieties for which testing has been found not necessary in Kenya.

Distribution of Plant Breeder's Rights Applications by Country	
Country	***Number of applications***
Belgium	1
Ecuador	2
France	59
Germany	89
India	1
Israel	4
Italy	7
Japan	5
Kenya	268
Netherlands	129
New Zealand	2
South Africa	3
Spain	1
United States	7

Influence of Plant Variety Protection on Breeding, Release and Commercialization of Varieties

15. Of the 14 institutions visited, 2 claimed that the establishment of the PVP in Kenya has not influenced their activities in any way. The others, however, stated the following influences:

1) The breeding industry is now harmonized through enhanced description of varieties and, therefore, proper identification that has in turn promoted security in ownership and encouraged breeders;
2) Breeders now take deliberate steps to register and protect their varieties and there is generally increased interest in commercialized breeding;
3) There is enhanced introduction of and access to foreign varieties because of security in ownership created by the implementation of PVP. This has led to an increase in number of foreign varieties introduced into Kenya and enhanced collaboration amongst local and foreign breeders;
4) There is increased competition in the market from both local and foreign varieties, resulting in a strong focus on quality aspects of new materials;
5) Farmers are now growing new crops i.e. increased range of crops available to the farmers.

Summary

16. The evidence assembled from the review suggests that the implementation of plant variety protection in Kenya has stimulated interest in commercial breeding especially in the private sector. The

greatest beneficiary has been the horticulture industry. This has been accompanied by a large increase in the number of foreign ornamental varieties introduced into Kenya for commercialization. The study also highlights an increased emphasis on investment in facilities and acquisition of modern technology for the purposes of breeding high quality varieties to compete in the markets. It is, therefore, evident that local farmers have access to a wider diversity of crop varieties. The impact of plant variety protection on farmers did not, however, form part of this review. Most local breeders are interested in agricultural crops, with maize being the main attraction. Activities in public breeding institutions are decidedly on the decline and the implications of this trend may require investigation. It is indicative that plant variety protection significantly influenced international collaboration and partnership. This is observed mainly in research and commercialization of foreign-bred varieties in Kenya.

Acknowledgement

The report on the Kenyan experiences is based mostly on "Assessment of Impact of Plant Breeders' Rights Service in Kenya" prepared by Mr. M. Gunga, and the staff of the Plant Variety Protection Office of Kenya.

[Annex follows]

Table 1: Profiles of the participating countries

Country	Argentina	China	Kenya	Rep. of Korea	Poland
Region	South America	Asia	Africa	Asia	Europe
Surface (thousand sq. km, 2001)	2,780	9,598	580	99	323
Population (millions, 2001)	37	1,272	31	47	39
Population density (per sq. km, 2001)	14	136	54	480	127
GNI (billion US$, 2001)	260.3	1,131.2	10.7	447.6	163.6
GNI per capita (US$, 2001)	6,940	890	350	9,400	4,230
Rural Population (% of total, 2001)	12	63	66	18	37
Agriculture % of GDP (2001)	4.8%	15.2%	19.0%	4.4%	3.6%
Agriculture annual growth (2001)	1.0%	2.8 %	1.2%	1.4%	1.5%
Land area (thousand sq. km, 2000)	2,737	9,327	569	99	304
Land use (% of land area, 2000)					
--Arable land	9.1	13.3	7.0	17.4	46.0
--Permanent cropland	0.8	1.2	0.9	2.0	1.1
--other	90.1	85.5	92.1	80.6	52.9
Establishment of PVP	1991	1997	1998	1997	1987
UPOV membership (since)	December 25, 1994 (1978 Act)	April 23, 1999 (1978Act)	May 13, 1999 (1978 Act)	January 7, 2002 (1991 Act)	August 15, 2003 (1991 Act)
Number of genera and species eligible for protection	All genera and species	30 genera and species		113 genera and species	All genera and species

Table 2: Investment in Plant Breeding and Variety Introduction and Commercialization in the Last Five Years in Kenya

Investment	No. of Institutions	Investment	No. of Institutions
1. Physical facilities		4. Land	
Laboratory	6	Increased by:	
Seed processing equipments	3	0-5 ha	1
Irrigation facility	3	5-10 ha	2
Stores	3	10-20 ha	1
Photoperiod house	1	20-50 ha	1
Power supply	1	Over 50 ha	2
Grafting facility	1	Decreased	5
Glass house	1	No change	2
None	1	5. Personnel	
2. Technology		Increased:	
Information technology	4	Professional	8
Molecular/DNA mapping, electrophoresis	4	Technical	8
Biotechnology	4	Decreased	3
Photoperiodism	1	No change	3
Automation/computerisation	1	6. Collaboration	
3. Finance		With:	
Increased by:		Foreign institutions	4
Below 25%	1	International research institutions	4
25-50%	1	Farmers (outreach)	3
50-75%	3	Local institutions	3
75-100%	2	Donor institutions	6
Over 100%	2	7. Capacity Building	7
Decreased	5		

Implementation of Plant Variety Protection

MR. ARNOLD VAN WIJK
Head, Plant Variety Research, Centre for Genetic Resources, Wageningen, Netherlands

1. Introduction

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) was signed by 125 countries in 1994 as part of the new General Agreement on Tariffs and Trade (GATT) and established minimum standards for intellectual property rights (IPR). The TRIPS Agreement requires in Article 27(3)b that the members of the World Trade Organization (WTO) - the succeeding organisation of GATT - to provide protection for plant varieties by "patent or an effective ***sui generis*** (= of its own class) system, or a combination thereof ".

All WTO members (146 as of April 2003) are obliged to implement the provisions of the TRIPs Agreement. The least developed countries (LDC's) have until January 1, 2006, to comply, with the possibility of an extension. As a consequence, many countries have ventured into the development of a legal basis for the protection of plant varieties, linking up with other international agreements regulating access to genetic resources and the sharing of benefits.

However, most international discussions on these topics concentrate on the legal issues and not so much on taking into consideration that the introduction of a sound Plant Variety Protection (PVP) system has consequences of an institutional, technical, financial and commercial nature. In the present paper some of these issues are discussed, the coherence of plant variety protection with the other steps in the so - called "Plant Variety Chain" is elaborated and the effect of PVP on the seed industry is presented. The PVP system referred to in this presentation is the UPOV (International Union for the Protection of New Varieties of Plants) ***sui generis*** PVP system.

2. The development of the "Plant Variety Chain"

Many developing countries have an agricultural economy that is mainly geared to domestic markets and that depends largely on farmer-produced seed[1] of both "traditional" and "improved" varieties that are maintained and further adapted to the local conditions by small-scale farmers. These so - called farmer seed systems broadly refer to the processes which farmers use to produce, obtain, maintain, develop and distribute seed resources from one growing season to the next and from one farmer to the other. Every year, plants with high yields, good quality and high adaptability are selected consciously or unintentionally resulting in a gradual and slow improvement of variety performance over time. Many countries have promoted this farmer-to-farmer exchange of new varieties through what became known as 'lateral spread' in order to rapidly disseminate new varieties.

2.1 From a farmer seed system to a formal seed system

With the introduction of a PVP system, the farmer seed system will transform into a formal seed system. Even more so since the 1991 Act of the UPOV Convention restricts the rights of farmers to save and exchange seed of protected varieties between each other and gives breeders greater control over the use of their varieties. However, under the UPOV Convention, countries may allow in their legislation certain categories of farmers to produce seed for certain crops for their own use, as long as the legitimate interests of the breeder are taken into account. The evolution from a farmer seed system to a formal seed system could follow the subsequent steps as shown below.

[1] In the context of this paper "seed" refers to both generatively and vegetatively plant material.

Stage 1 – Public and farmer breeding, small scale seed distribution
At this stage, plant breeding is often undertaken and financed by government agencies (public breeding) as part of their policy to secure an adequate supply of food, feed and industrial needs. Seed of the resulting varieties will then be made available to a few (selected) farmers and seeds may be redistributed to neighbouring farmers. Farmers may also undertake breeding and distribute seed on a small scale.

Stage 2 – Seed production
If a breeding program delivers high performing varieties, an increasing demand for seed of these varieties will soon develop and an ample supply of seed has to be secured. Large scale seed multiplications by selected seed growers have to be set up and seed technology has to be developed (growing and harvesting techniques, seed processing, seed storage, packaging etc).

Stage 3 - Quality control of seed produced
Once large scale seed production has been materialised, the need arises to have a good quality control system on the seed produced to guarantee that the seed the farmer buys is of high quality (germination, purity, free of weeds). Seed certification and marketing will develop.

Stage 4 - Variety consciousness and market regulation
The demand for better varieties will develop and farmers will become aware of the genetic quality of a variety. Variety research is then required to asses the identity of the variety for certification according to the principles of D (distinctness), U (uniformity) and S (stability) and to asses the performance of the variety for marketing purposes (VCU test – Value for Cultivation or Use). These measures will lead to a regulation of the marketing of the developed varieties.

Stage 5 - Legal framework for plant breeders' rights and development of private breeding
Plant breeding is a long - term investment of 10 - 15 years. In order to recapture these costs, a legal framework for intellectual property rights on plant varieties has to be built up to provide the breeder of a new variety the exclusive rights to exploit that variety. Through an effective plant variety protection system the breeder will be able to recover his investments.

Once the preceding stages have been fully implemented, the "Plant Variety Chain" (see Figure 1) then comes into full operation.

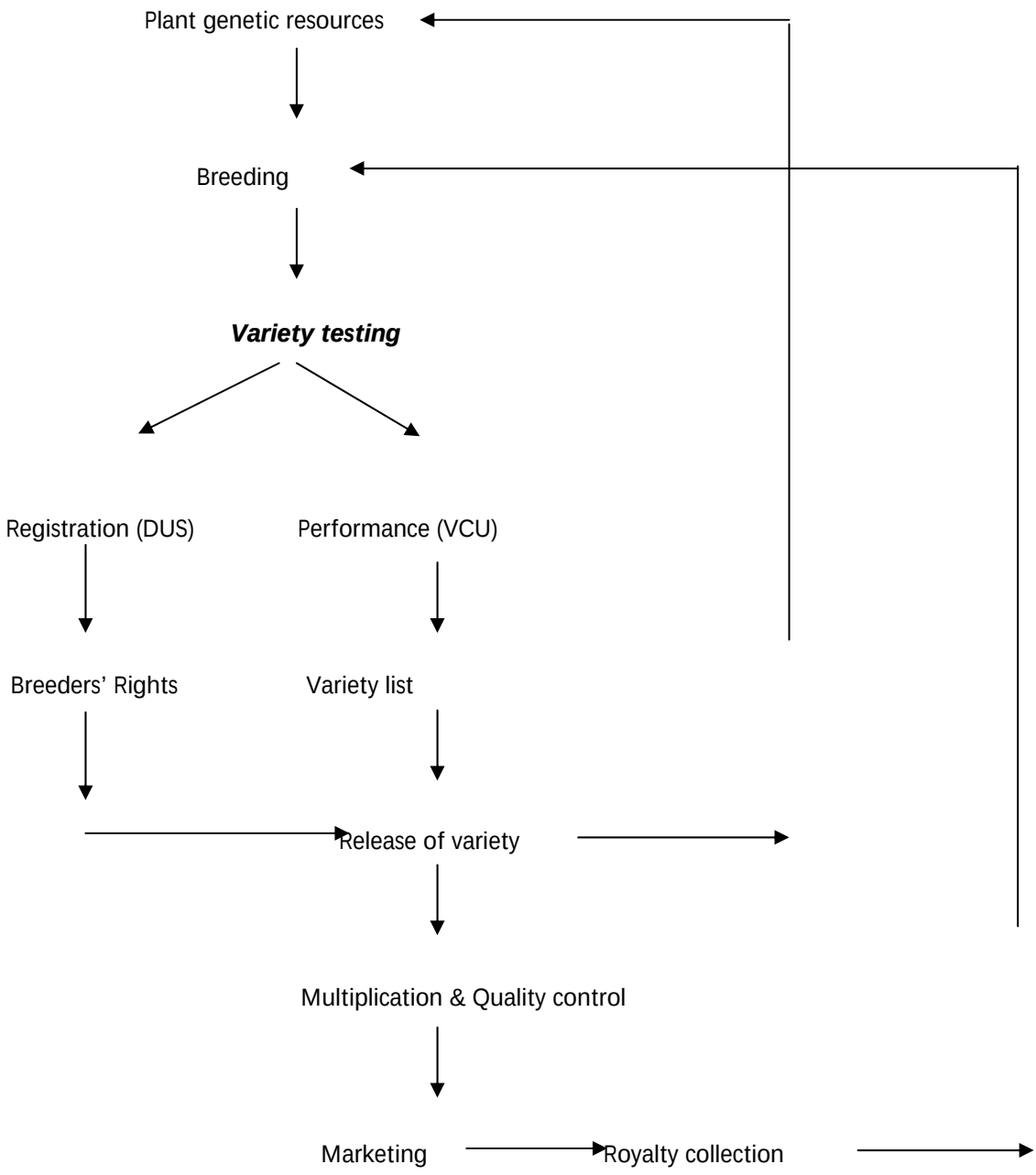
2.2 "Plant Variety Chain"

The "Plant Variety Chain" covers all the steps from plant genetic resources to the end product. Beginning with promising genetic resources, the breeder develops the new variety by either using this germplasm directly or by incorporating it into existing varieties. The varieties developed have to be tested for DUS, whereby the breeder can request Plant Variety Protection. For agricultural and vegetable crops performance may be tested by the breeder or by breeder plus authorities to assess if the new variety is an improvement in relation to existing varieties (VCU test). If the variety is promising, an adequate seed supply has to be built up under the control of a certification authority, in order to make sure that the end-user will receive good quality seed that is true-to-variety when compared to the originally tested variety. Once the variety is brought on the market, a royalty collection scheme should be in operation to ensure the breeder a return on his investment and to finance further breeding. At the same time the developed variety will enter the genepool for usage world wide (breeders' exemption).

Protecting varieties that do not have a good agricultural value does not make sense. The farmer or the grower has to be certain that purchased seed of the protected variety is of good quality and true-to-variety. Adequate supply of the improved and protected varieties must be available in order to give the farmers the opportunity to purchase these varieties. The breeder must be confident that his Plant Breeders Rights will be respected and that a royalty collection scheme is in operation. And finally the farmers or growers should be convinced that the purchase of certified seed provides enhanced variety performance, resulting in better higher financial returns or possibly some other desired objectives.

Plant variety protection will play an important role in improving agricultural and horticultural output, benefiting the breeder, the farmer and the end-user of the produced product, and national food security.

Figure 1 "Plant Variety Chain"



Two important aspects come to the foreground in the "Plant Variety Chain" of Figure 1:

- The royalties collected are poured back into the breeding program for further financing the development of new varieties;

- The improved varieties are incorporated into the gene pool for further breeding (an essential provision provided under the UPOV Convention, the so called "breeders' exemption" from which new varieties can be "built on".

However, good governance in a particular country is essential for a proper enforcement of all aspects of the Plant Variety Chain.

2.3 Examples of the development of a formal seed system

In the Table 1 the development according to the different stages as outlined in 2.1. is presented for Kenya and the Netherlands.

Table 1 The evolution from a farmer seed system to a formal seed system in Kenya and the Netherlands

#	*Stage*	*Kenya*	*The Netherlands*
1	Public and farmer breeding and small scale seed distribution	1956 - Farmers start Kenya Seed Company: seed production of grasses and legumes (ecotypes identified by government stations), production of sunflower seed (1958)	1900-1943 Governmental and private breeding 1934-1942 Breeders Compensation Fund (levy scheme on certified seed)
2	Seed production	1963 - Seed production of hybrid maize, varieties developed by government station Seed production by selected farmers	1900 Seed certification
3	Quality control of seed produced	1960 – Quality control in cereals and grasses (Scott Agricultural Laboratories) 1970 - Inception of a comprehensive quality control service 1981 - Seed health	1932 – Establishment of General Inspection Service Agricultural Seeds and Seed Potatoes (NAK) 1941 – Establishment of General Netherlands Inspection Service for Vegetable and Flower Seeds (NAKG)
4	Variety consciousness and market regulation	1976 - Variety research : DUS, VCU	Since 1880 – Simple performance testing 1914 – Regulation on variety testing for novelty, uniformity and performance 1924 – First Recommended Variety List of Agricultural Crops
5	Legal framework for plant breeders' rights and development of private breeding	Private breeding develops since 1990 1999 - Accession to UPOV 1978 Act Present: Implementing PVP system	1942 – 1967 Kwekersbesluit (1967 – present Seeds and Plant Materials Act 1968 – Accession to UPOV 1961/1972 Act 1998 - Accession to UPOV 1991 Act PVP scheme in full operation

From the presented table it is clear that, in the Netherlands, the development of a formal seed system as stretched over a long period, while the PVP development in Kenya is of a recent date. Both countries are UPOV members, the Netherlands having completed stage 5 while Kenya recently entered stage 5.

New UPOV member states or future members are in different stages of development towards a formal seed system. The evolution towards a formal seed system as outlined in section 2.1 is a logical one. The introduction of a legal framework for plant variety protection is often an effective stimulus to develop the other stages in this process and to strengthen the various links in the "Plant Variety Chain." And countries being or becoming members of UPOV will be a great help to develop these different steps as will be outlined below.

A special note should be made on ornamental, vegetatively propagated crops, not being a first necessity of life but being an important crop to earn foreign currency in many developing countries. With a sound PVP system in operation, foreign breeders will send their most valuable new varieties to that particular country for flower production for export, making it possible to control illegal reproduction of the protected variety. When the importing country has a protection system for such varieties it may block the product from entering the country when the breeder has not given permission to multiply the crop in the exporting country. Countries where their interests are not secured, tend to loose potential export income when an acceptable level of protection cannot be granted. Such opportunity costs may negatively affect employment and tax-income. For the development of this sector the outlined evolution does not apply and the different steps are bypassed.

3. Institutional arrangements for a plant variety protection system

The strength of the UPOV ***sui generis*** PVP system is that a ready–made system is provided, developed over three decades of experience (primarily in Western States) . The greatest asset of the UPOV system is its harmonisation of a PVP system between 53 members, in particular its technical implication for testing distinctness, uniformity and stability. All member states have the possibility to participate actively in the further development of UPOV on all juridical and technical aspects through the various Technical Working Parties and Committees. In this world forum, new and future members can thus benefit from experiences of older members, especially as many countries cannot afford the time to go through the long time evolution from a farmer to a formal seed system as happened in the Netherlands within the few years that they are given to comply with TRIPs.

Implementing a PVP system requires an institutional organisation that

- deals with all procedural aspects regarding the application for and granting of Plant Variety Protection;

- provides technical information on the applied variety on which the authority can base its decisions.

3.1. National authority on PVP

Similar to most intellectual property rights regimes, an application has to be examined before the protection of a plant variety can be granted. This requires a national authority on PVP that can decide on applications and grants for plant variety protection, proposals for variety denominations, variety descriptions, requests for compulsory licences, requests for annulment of a plant variety protection and claims for the property of a PVP by another party.

Such a PVP authority can consist of two departments: one taking the decisions (the actual board) and one carrying out the administrative work (secretariat). Another option is that one PVP Office runs the administration and makes the decisions.

3.2. Technical examination

The national authority bases its decision on a technical examination that is carried out in the field and/or the greenhouse, whereby the variety has to comply with the requirements for DUS according to the standardised UPOV guidelines. A technical examination on a new plant variety is comparative research: the new variety is compared with already existing varieties from which the new variety has to distinguish itself in one or more characteristics, next to being uniform and stable.

The technical examination can be carried out according to different options (Article 12 of the 1991 UPOV Act) as presented below.

Official examination
In many European countries centralised, official testing systems on behalf of the PVP authorities have been developed. The applicant provides the national authority through a technical questionnaire

information on the variety such as species, origin, method of breeding, technical characteristics and other information helpful for the technical examination and provides a seed sample or plant material of the variety. The national authority carries out (or let it carry out) a DUS test incorporating all filed applications and necessary reference varieties.

Breeder testing

The main alternative strategy for the official DUS-testing is to make the breeders themselves primarily responsible for the information on which a decision can be based. Breeders then have to prepare full DUS-reports (according to the UPOV guidelines) to the PVP Office, based on their own trials.

Various types of breeder-testing for DUS are operational in different countries with various levels of involvement of the official authority.

Collaboration among UPOV members

As mentioned before, through UPOV a very high degree of harmonisation in the technical examination has been achieved, which allows for international co-operation in different forms.

- Bilateral co-operation is the most common form, whereby a national PVP Office may request a DUS-testing facility of another country to carry out the technical examination on a certain variety under a formal agreement between the two States. Reasons for such a request can be that the requesting State has no infrastructure for carrying out the test or that the examining country has wide expertise for that special crop or for reasons of efficiency. The Netherlands, for example, is carrying out the DUS test for a certain grass species for France, Germany and the UK, making the testing more cost - efficient for all parties concerned.

It also can happen that a PVP Office purchases the DUS report from another country when the filed variety has already passed (or is in the process of passing) the technical examination in the latter country. UPOV members have agreed on fixed fees for taking - over DUS reports. For example, Kenya is purchasing on a regular basis DUS reports on ornamental crops, roses in particular, and granting PVP in Kenya on the basis of the Dutch DUS examination.

- Regional co-operation can be found in the European Union. The Community Plant Variety Rights System offers protection in all EU countries through one single application and based on one technical examination. For certain genera and species of ornamental crops DUS – testing has been centralised in one of the EU Member States, while the testing of the same species in different countries occurs as well. Clearly defined protocols, based on the UPOV guidelines, are a requisite for the smooth running of such a system. A quality management system for variety testing further guarantees a strict compliance with the defined protocols and as a consequence, quality of DUS testing.

The various options show a varying degree of official involvement and costs. UPOV members are allowed the flexibility to choose the system that suits them most, depending on general policies dealing with the role of the State and capacities in terms of expertise and infrastructure. It should be highlighted however, that an emerging PVP system can rely heavily on the information and data available from experienced UPOV members: the building up of its own, completely independent system is not necessarily required when introducing PVP in a country. The possibilities of bi-lateral and/or regional collaboration should be explored first.

4. Effect of PVP on the seed industry

In the following paragraphs some effects of PVP on the seed industry are given.

- ***Promotion of breeding***

Increased investments in breeding efforts have generally been seen in countries that have introduced PVP in the last few decades (Lesser, 1997; Eaton, 2002). The US PVP Act of 1970 is associated in a number of studies with higher investments by public and private sector breeders for a number of crops (Butler and Marion, 1985; Perrin et al, 1983; Alston and Venner, 2002). A recent review of the Canadian Plant Breeders' Rights legislation of 1990 indicated increased research and development investments particularly in some oilseeds and pulses (Canadian Food Inspection Agency, 2001).

Similar results have also been found in Spain which introduced its first national plant variety protection in 1975 (Diez, 2002). A study of seed breeding companies in Argentina also found a tendency for research investments to rise with the adoption of plant variety protection (Jaffe and Van Wijk, 1995).
Furthermore, research is indicating that the strength of protection offered under PVP may be a key factor in determining its effectiveness as an investment stimulus. This provides further evidence of the potential incentive for R&D that PVP creates. Data for 13 OECD (Organisation for Economic Co-operation and Development) countries covering agricultural R & D expenditures in the 1990s shows a significant link between these expenditures and both the extent of IPR protection available and the number of new varieties granted protection (Srinivasan et al, 2002). The investment patterns observed across crops with different degrees of biological "protection" also support the view that protection possibilities, including IPR, stimulate investment in breeding of improved crop varieties.

In most cases, it is also possible to attribute these favourable investment trends to a variety of economic developments, such as market liberalisation, increasing demand for specific crops or improved access to foreign markets. This makes it difficult to demonstrate the specific effect due to plant variety protection, particularly given the long timeframes involved. It seems likely that some form of intellectual property rights on plant varieties is necessary to ensure that incentive exists for breeders to invest in developing new varieties. But it should probably not be expected that this alone would boost private sector breeding investments; other economic factors play an equally important role.

The Netherlands has a long history in breeding and variety protection as shown in Table 1. The legal and technical conditions for breeding have already been created at the beginning of the last century, stimulating the development of an active breeding industry, resulting in many varieties of agricultural and horticultural crops. This is not only apparent from the large number of protected varieties in the Netherlands, but also comes to the foreground in the number of applications for European Plant Breeders' Rights in comparison with other Member States of the European Union (EU) (see Table 2).

Table 2 Number of applications received by the Community Plant Variety Office for Community Plant Variety Rights (April 1995 – July 2003)

Applications received from	***Number***	***Percentage of total applications***
Netherlands	6322	35.9
Germany	2753	15.6
France	2455	14.0
Denmark	1016	5.8
United Kingdom	947	5.4
Other EU countries (10)	1317	7.5
Total EU countries	14810	84.2
Non – EU countries (12)	2780	15.8
Total	17590	

- ***Introducing foreign varieties***

Where an intellectual property rights system may stimulate breeding, the absence of such a system in a country is likely to deter foreign breeders from introducing their varieties in that particular country. Only if an effective plant variety protection system is in operation, breeders from abroad will be able to protect their long-term investments. The recipient country then benefits through access to varieties with superior characteristics that boost agriculture, benefiting farmers, growers and consumers. The introduced varieties can also be used as good sources of germplasm for local breeders to use in their own breeding programs and therefore to advance local breeding.

References

Alston, J.M. and R.J. Venner, (2002), The effects of the US Plant Protection Act on wheat genetic improvement, Research Policy 31:527-542.

Butler, L.J. and B.W. Marion. (1985), Impacts of patent protection in the US seed industry and public plant breeding. North Central Regional Research Bulletin No. 304, University of Wisconsin, Madison, WI.

Canadian Food Inspection Agency (2001), 10-Year Review of Canada's Plant Breeders' Rights Act, Ottawa, Canada.

Diez, M.C.F. (2002), The Impact of plant varieties rights on research: the case of Spain, Food Policy 27:171-183.

Eaton, D. (2002), TRIPS and Plant Varietal Protection: Economic Analysis and Policy Choices, Report 7.02.01, LEI, The Hague. (available at www.lei.wageningen-ur.nl)

Jaffe, W. and J. van Wijk. (1995). The Impact of Plant Breeders' Rights in Developing Countries. Inter-Am Institute for Co-operation on Agriculture, University of Amsterdam, October 1995.

Lesser, W. (1997), Assessing the implications of intellectual property rights on plant and animal agriculture. American Journal of Agricultural Economics 79 (November 1997): 1584-1591.

Perrin, R.K., K.A. Hunnings and L.A. Ihnen. (1983), Some effects of the US Plant Variety Protection Act of 1970. Economics Research Report No. 46, Dept. of Economics and Business, N.C. State University, Raleigh.

Srinivasan, C.S., B. Shankar and G. Holloway (2002), An Empirical Analysis of the Effects of the Plant Variety Protection Legislation on Innovation and Transferability, Paper presented at the meeting of the European Association of Agricultural Economists, August 2002, Zaragoza, Spain.

SECTION IV

MANAGEMENT OF INTELLECTUAL PROPERTY RIGHTS

The Management of Intellectual Property Rights in Plant Biotechnology

MR. BERNARD LE BUANEC
Secretary General, International Seed Federation (ISF), Nyon, Switzerland

The subject proposed by the organizers, "The management of intellectual property rights in plant biotechnology," is extremely broad. It is certainly difficult to give it exhaustive and detailed coverage in the course of a 15-minute presentation. In particular, it may be asked where the management of intellectual property rights begins and where it ends. Should the policy of publishing research results and the correct application of procedures for safeguarding the secrecy of know-how be included?

In this presentation, I will restrict myself to:

- an introduction to the different forms of protection which affect plant biotechnology;
- the management of a portfolio of rights;
- the search for licenses and the "freedom of operation."

1. The different forms of protection

Biotechnology inventions in the field of plants and agriculture are not commercial goods marketed as such for a final user. They are marketed through plant varieties which incorporate them or products obtained, be it directly or indirectly, from the varieties in question. Their protection, either direct or indirect, therefore depends on different laws according to the country in question.

- for biotechnology inventions themselves, essentially patents, but also secret know-how and material transfer agreements;
- for plant varieties containing these biotechnology inventions, plant variety protection certificates (PVPs), in certain countries patents and other legal mechanisms.

Consequently, the environment of intellectual property rights in plant biotechnology has now become very complex.

2. The management of intellectual property rights

2.1 Management of a portfolio of technologies

As a rights' holder, attention should be paid to:

- protection against the fraudulent use of a patented invention by a competitor in order to develop new products;
- protection against fraudulent use by a final user;

- the management of the patent portfolio by licenses and material transfer agreements.

2.1.1 Protection against the fraudulent use of the patented invention by a competitor in order to develop new products

This is a relatively conventional situation, which is not specific to plant biotechnology. Commercial and bibliographical supervision is required in order to verify the appearance of new products and any possible application for protection in relation thereto. In cases where counterfeiting is suspected, it is necessary to contact the counterfeiting party in order to find an amicable solution, or take the matter to arbitration or to the courts.

The introduction of the concept of an essentially derived variety for the varieties protected by a plant variety protection certificate extends the obligation for technological supervision and actualizes the fraudulent or non-fraudulent nature of the use of the patented invention in the research phase.

2.1.2 Protection against fraudulent use by a final user, in general a farmer

This is a much more difficult situation since the essential property of a biotechnology invention, inserted in a plant variety, is to be self-reproducing. This is quite similar to electronic piracy but the counterfeit product can be made even more general, since it requires no investment other than the original seed. There are therefore millions of potential counterfeiters. The only solution is to inform the user appropriately and to undertake surveys. In certain countries, seed companies have come together to defend their rights and have formed contracts with private and professional surveyors. However, given the large number of possible cases of counterfeiting and the low value of each case, the cost of supervision and of legal action is often not justified, other than to establish a precedent.

The situation is complicated still further as a result of the lawful or unlawful use of farm seeds. This is an extremely sensitive subject at the international level.

In the United States, where the protection given by a PVP certificate is non-existent in this area, farmers usually produce their seeds themselves for autogamous plants and would like to be able to continue to do so, irrespective of the varieties in question. Furthermore, two members of the House of Representatives introduced a Bill on July 8, 2003, designed to authorize the farm seeds of genetically modified varieties.

In Europe, the Directive on the protection of biotechnological inventions provides that the authorization to produce farm seeds for the varieties protected by a PVP, in return for financial compensation for the breeder, should be extended to transgenic varieties.

In conclusion, this aspect of the management of intellectual property rights is complex, costly and politically sensitive.

2.1.3 The management of the patent portfolio by means of licenses and material transfer agreements

The developers of biotechnology inventions, known as biotechnology suppliers, use two principal means to enhance their research work:

- either they commercialize plant varieties including their inventions themselves;

- or they authorize third parties, on the basis of licenses, to use those inventions in their own varieties.

These means are not mutually exclusive and biotechnology suppliers implement a "mix" with more of one or the other, according to the companies.

The licenses may be subject to a fee or are free of charge according to the licensee. Free licenses are more and more the case for public research in developing countries. Numerous examples are known, one of the most widely publicized being the case of Golden Rice.

The recent creation of the "African Agricultural Technology Foundation" is a second example of free licenses used by four companies: Monsanto, DuPont, Syngenta and Dow AgroScience. The aim of this Foundation is to enhance, by means of genetic engineering, the crops of importance to small-scale African farmers.

Another means, used more and more widely in both the public and private sectors, is the material transfer agreement. This is a binding private contract between the technology supplier, irrespective of whether the technology is patented, and the person who receives the technology. The contract allows the receiving party to undertake research work but it often contains very restrictive clauses for that party such as:

- the obligation to provide information on the work undertaken, leading to risks of disclosure of the research strategy;
- exclusivity;
- shared ownership of the results;
- responsibility for any damage or risk stemming from the use of the transferred material.

Furthermore, the commercialization of a product subsequently requires a commercial license.

The research license is a mechanism similar to the material transfer agreement for patented inventions.

2.2 License search and "freedom of operation"

Intellectual property rights are crucial for the development of new plant varieties. During the past 30 years, the growing interest of the private sector in the seed industry and, more particularly, during the past 15 years in plant biotechnologies means that most of the technologies and germplasm are subject to commercial control. Public research also has, on more and more occasions, protected its results. The scope of "public good" has therefore been considerably reduced and freedom of operation has become a major concern for the parties involved.

This requires significant means and different approaches are used:

large companies have their internal scientific and technology monitoring units which allow them to monitor patents at the international level;

small and medium-sized enterprises can group together to establish a collective monitoring unit, as is the case in France with VIGIBIO;

several semi-public or public initiatives have also emerged:

- in July 2001, CAMBIA (acronym for "Center for the Application of Molecular Biology to International Agriculture"), an independent non-profit making organization based in Canberra, made public a database on patents in the field of biotechnologies, known as the CAMBIA Intellectual Property Resource or CIPR;
- more recently, in 2003, a number of public research unit heads in the United States have also launched an initiative of the same type, known as PIPRA, the Public Sector Intellectual Property Resource for Agriculture.

All these initiatives have the same aim: to provide awareness of the prior art and its legal position, avoid using technologies which do not appear to be freely accessible, and to negotiate licenses or cross-licenses.

The members of the ISF are not in favor of compulsory licenses. It should, however, be known that the Agreement on Trade-Related Aspects of Intellectual Property Rights, (TRIPS Agreement) allows the principle of such licenses (Article 31.1) "to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), [if] the following additional conditions shall apply:

- the invention claimed in the second patent shall involve an important technical advance of considerable economic significance, in relation to the invention claimed in the first patent;

- the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent […]."

The spirit of this provision of the TRIPS Agreement is reiterated in full in Article 12 of the European Directive 98/44/EC on the legal protection of biotechnological inventions for cross-licenses between a plant variety protection certificate and a patent.

This point leads me to deal with a particular problem for which no clear solution yet exists in certain countries and which is a subject of significant debate in the breeders' community. I am referring to the use of varieties protected by a PVP and containing patented elements. Until the recent past, the freedom of operation for research was complete for the varieties protected by PVPs, where they had been obtained by lawful means. This possibility is known as the "breeders' exception." Varieties protected by PVPs and containing biological material protected by a patent are now on the market. What is the situation with the "breeders' exception" in this case, since in most countries the protection of biological material granted by a patent is extended to all biological material derived from the protected biological material? Is there still freedom to operate? It seems that in certain countries such as the United States, the response is clear but negative. In Europe, there is great uncertainty and opinions differ. At the 1998 ISF Congress, the rapporteur for the European Directive, Mr. Willy Rothley, said that the Directive and its preamble did not provide the necessary response and that, in order to clarify the matter, decisions forming case law would be necessary.

However, the debate is not only one of legal interpretation. It is also internal to the seed industry in relation to the desirable objectives. At its Congress in Bangalore last June, ISF adopted the following position by a very large majority (86 per cent): the ISF is strongly attached to the breeders' exception stipulated in the UPOV Convention and is concerned with the fact that the extension of the protection of a genetic sequence to the appropriate plant variety may bring an end to this exemption.

Consequently, the ISF considers that a commercially available variety, protected only by a PVP and containing patented elements, should remain freely available for new selection work. If a new plant variety resulting from this new selection work, which is not an essentially derived variety (EDV), is outside the scope of the patent claims, it can be freely exploited by its developer. By contrast, if the newly developed variety is an EDV or it is included within the scope of the patent claims, the consent of the owner of the initial variety or the patent must be obtained.

The debate continues within the ISF and to shed further light on the matter, an international seminar on access to genetic resources will be organized in May 2004 in Berlin.

3. Conclusions

The issue of intellectual property rights in plant biotechnology has, in the past few years, become extremely complex, irrespective of whether it is a matter of a rights' holder who wishes to defend and enhance those rights, or whether it is hoped to define the scope of freedom of operation by moving beyond the limits of the existing rights or negotiating research agreements.

The complexity is increased as a result of the method of enhancing plant biotechnology inventions protected by patents, using plant varieties which in most cases are protected by PVPs. Two rights therefore exist, with a coexistence not always easy to define, especially since these issues, which are technically complex, are politically and socially sensitive.

Finally, it should be noted that, in terms of time for developing doctrines, these problems are relatively new. A further few years are required for users to reach agreement on the desirable objectives and for case law to clarify the debate.

Practical IPR Impact on the US Seed Industry

MR. JOHN GERARD
President, ACCESS Plant Technology, Inc., Plymouth, United States of America

Slide 1

PRACTICAL IPR IMPACT
on the
US SEED INDUSTRY

Presented at
WIPO-UPOV Symposium on Intellectual Property Rights in Plant Biotechnology

Geneva, Switzerland
October 24, 2003
By John Gerard
ACCESS Plant Technology, Inc.

Slide 2

Practical Impact
of the
United States
Plant Variety Protection Act (PVPA)
and
Utility Patent Act (UPA)
in
U.S. Seed Industry Practice

Slide 3

PVP and UPA IMPACT

Question:

- Has the U.S. PVPA and UPA had positive impact on the US seed industry?
- Focused on maize, soybean and wheat.

Slide 4

Until 1960's-Early 70's, majority of US germplasm and variety development was by public institutions for both hybrid and varietial crops:

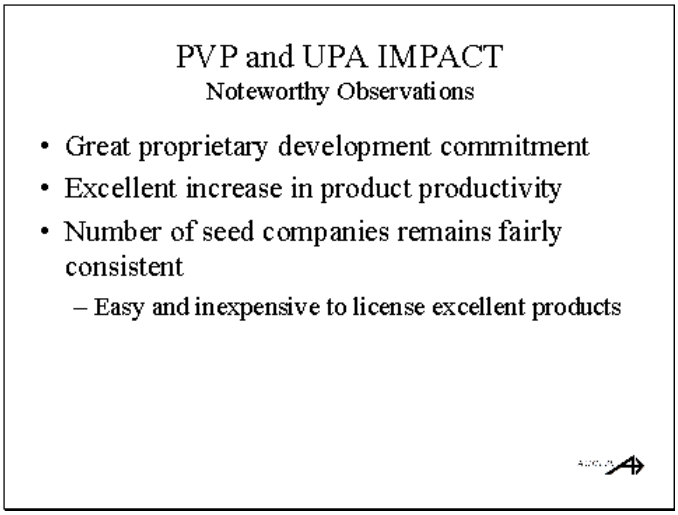
- Free access
- Commodity products
- Low financial return
- Few private companies involved in R&D with relative minor financial investment

Slide 5

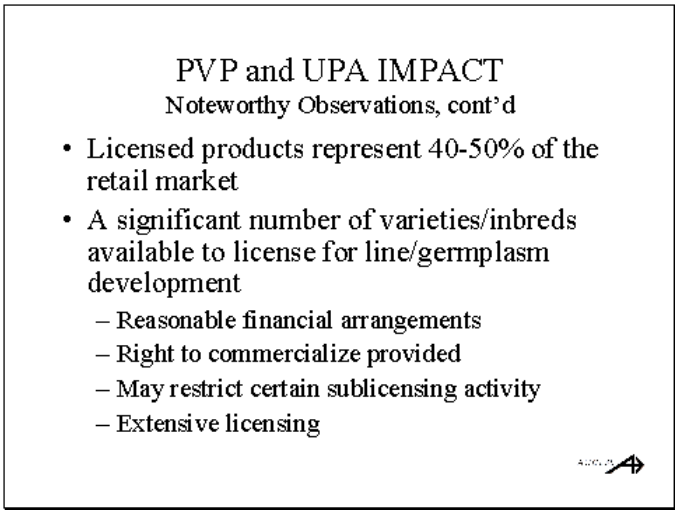
PVP and UPA IMPACT

- Late 1960's public funding began to erode
- Private sector saw an opportunity
- Private sector began effort to develop and get implemented an IPR system: 1970 PVPA became reality
- Private sector then seized the opportunity to get into the R&D business. Large, medium and small companies
- Utility Patent Act became an additional positive for R&D investment

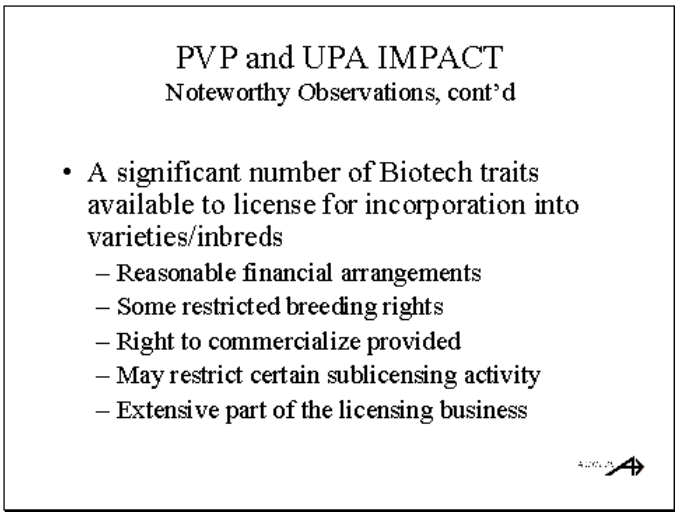
Slide 6



Slide 7



Slide 8



Slide 9

	Maize		Soybean		Wheat	
	1970	2003	1970	2003	1970	2003
Number of Developers	<5	25/30	3	25/30	0	<15
% Proprietary Seed Sales	<10	98+	<10	98+	0	70+
Number of Companies:						
Germplasm/Inbred Development	3/5	10/15	0	10/12	0	3
Variety/Hybrid Development	5/10	20/30	2	25	0	3
Marketing Proprietary inbreds and/or varieties	<5	200+	2	200+	0	150+
% of Products sold that are Licensed Proprietary variety/inbred	0	40+	0	50+	0	70+

Slide 10

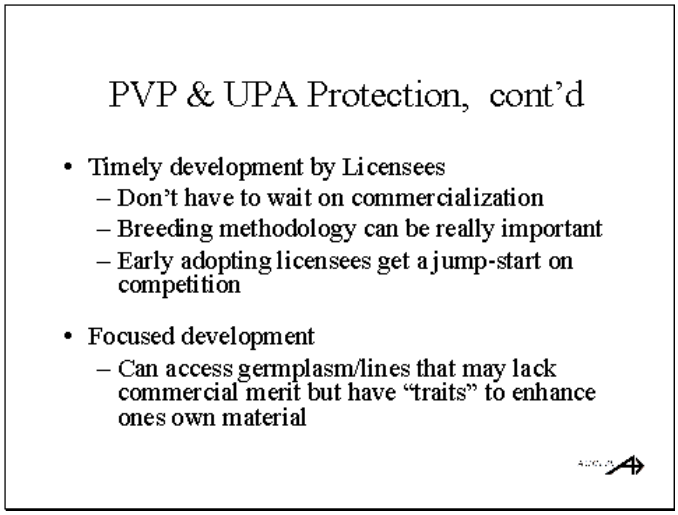
Number of Companies	Maize		Soybean		Wheat	
	1970	2003	1970	2003	1970	2003
Licensing Biotech traits for inbred and/or variety development	0	20+	0	25	0	<5
% of seed companies selling varieties/inbreds that exhibit Biotech traits	0	98+	0	98+	0	0

Slide 11

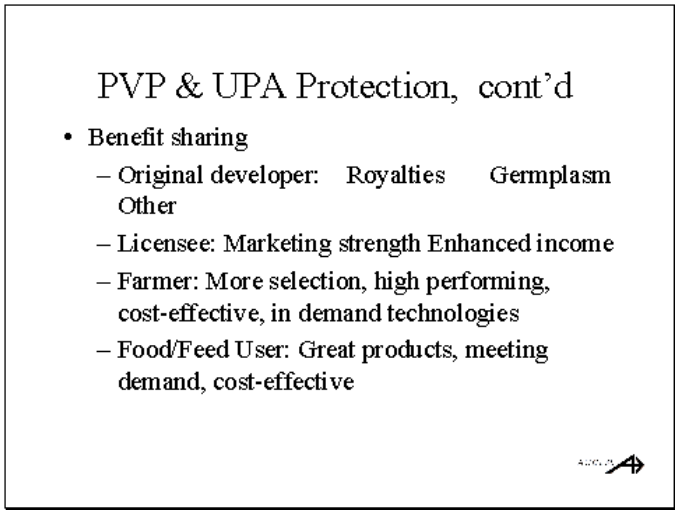
PVP & UPA Protection allows for:

- Broader base of genetic diversity
  - Free germplasm may reduce diversity
  - Breeders tend to focus on only those very few commercialized products
  - Non-commercial products are available to use in product development

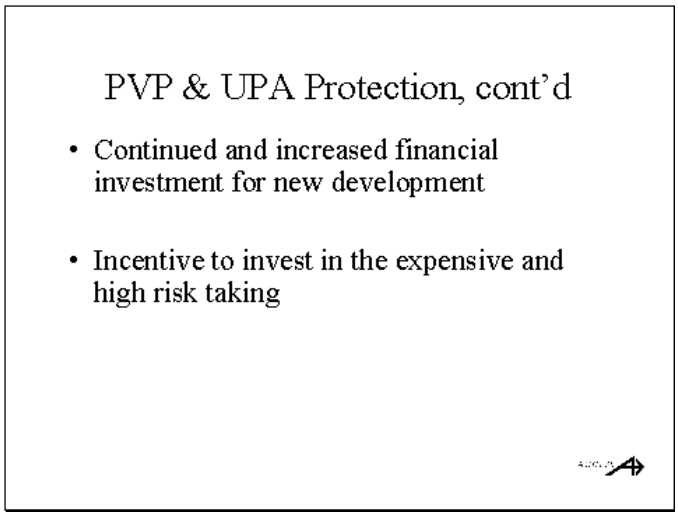
Slide 12



Slide 13



Slide 14



Slide 15

Are there negative issues surrounding PVP and UPA?

- Caused change in the way I do business
- Caused more licensing paperwork
- Caused seed industry more labeling issues
- Caused seed industry more accountability
- Caused seed industry more inventory items to manage

Slide 16

Are there negative issues surrounding PVP and UPA? cont'd

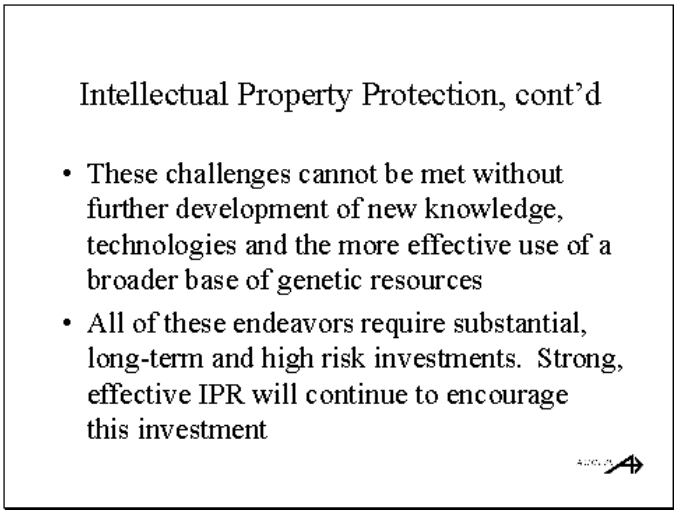
- Caused some restrictions some people aren't comfortable with
- Raised the value that the seed industry brings to the food/feed industry

Slide 17

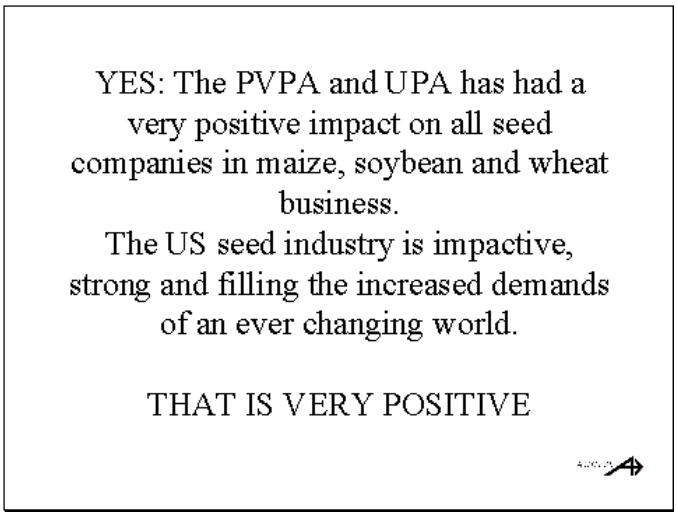
Continuing strong and effective intellectual property protection is:

- necessary to ensure an acceptable return on research investments
- prerequisite to encourage further research efforts
- essential to meet the challenges mankind has to face in the coming years, i.e. feeding an increasing population whilst preserving the planet

Slide 18



Slide 19



Intellectual Property Management in the Development of a Medium-Sized Argentinian Seed Company

MR. OSCAR AGUSTÍN DOMINGO
Director of Relmó, Buenos Aires, Argentina

1. Introduction

This paper will introduce the relations between the licenses and services which RELMO has established with seed companies and research institutes, from the point of view of intellectual property management within the current framework of widely publicized transgenic events.

In order to achieve an understanding of the environment in which RELMO operates, we will describe in brief agriculture in Argentina during the past ten years.

Finally, we will discuss the importance for a medium-sized company of respect for intellectual property, and will highlight advantages and shortcomings in the new context to which the commercial liberation of transgenic events has given rise.

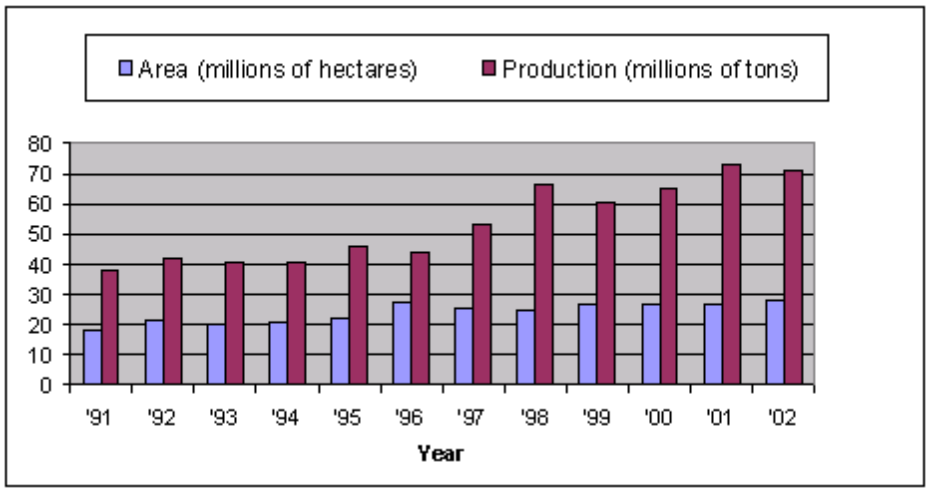
1.1 Agriculture in Argentina

1.1.1 Cash crops and production

Argentina has approximately 28 million hectares under cultivation. In the past decade, grain production (soybean, wheat, maize, sunflowers and other minor crops) has doubled, increasing from 35 to 70 million tons with an increase in the area under seed alone from 19 to 28 million hectares. With an increase of 47 per cent in the area covered, production has doubled. Two factors are relevant, the significant increase in the area and the increase in overall production, with the reasons

being due, as always, to various factors: currency stability and futures market, which have allowed producers to cover themselves against variations in prices, elimination of export taxes and supply of available technology – direct seeding, biotechnology and adapted high-yield varieties which producers rapidly adopted with the consequences that can be seen in Graph 1. The use of technology was spectacular, for example in only six years, the conventional varieties of soybean were replaced by RR (round up ready).

Graph 1 – Production and area per year

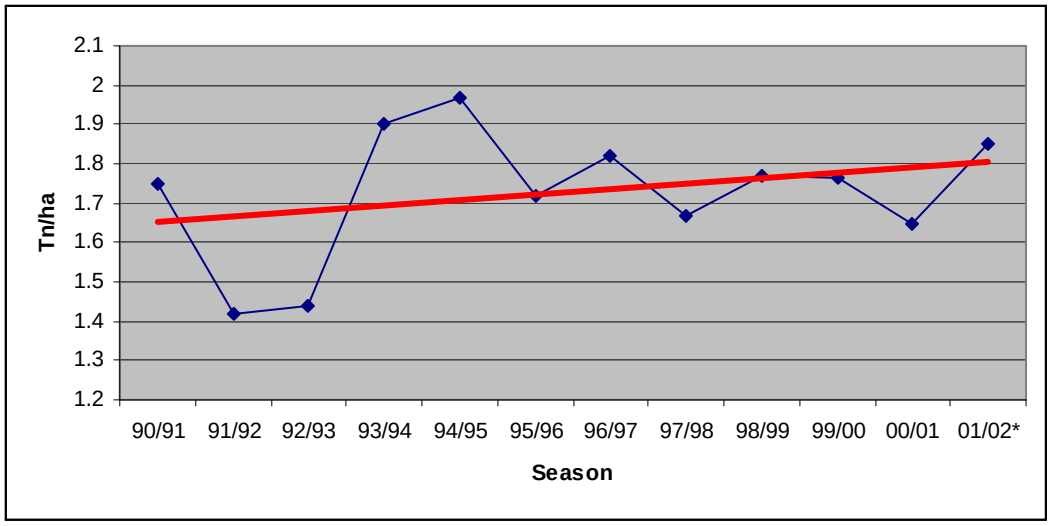


Source: SAGPYA

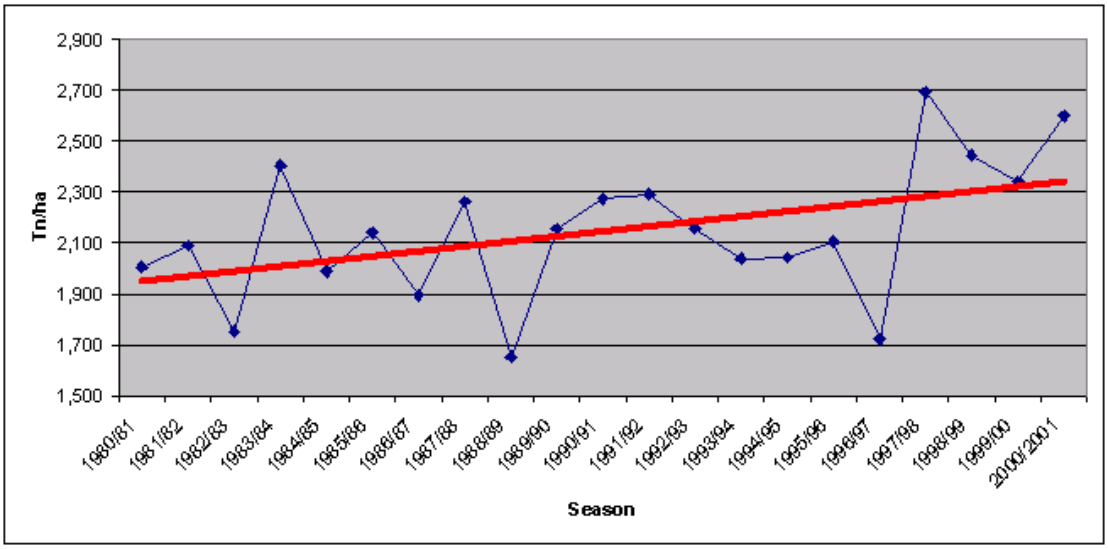
The unit yields of the main crops are shown in Graph 2. The steep increases in the yields are eloquent testimony to the work done and to the value of the seed industry.

Graph 2 –Yields of main crops in Tn./ha. Source: SAGPYA

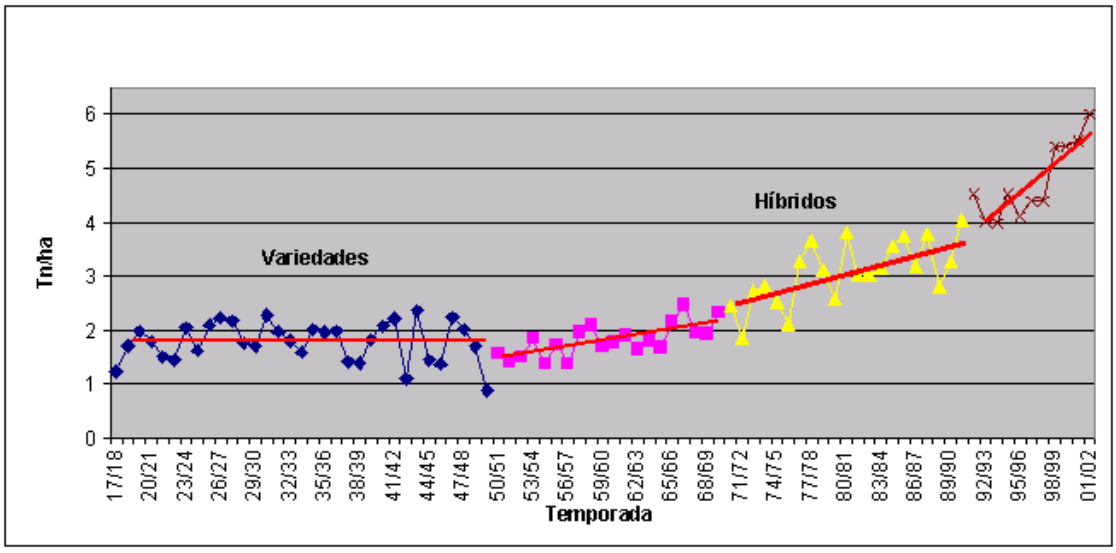
SUNFLOWERS



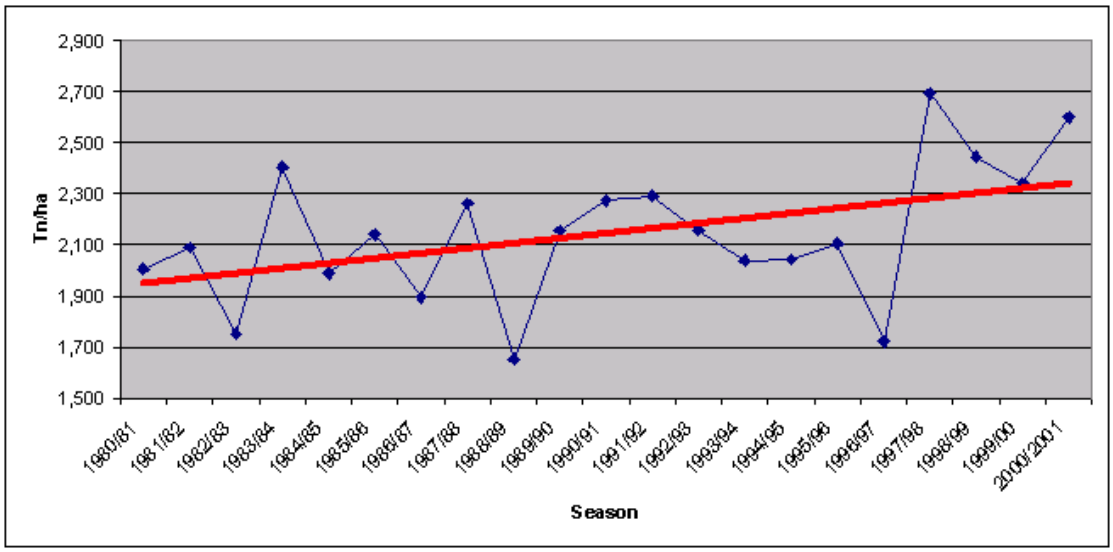
WHEAT



MAIZE



SOYBEAN



1.1.2 Commercially approved transgenic events

There are seven commercially approved transgenic events (Table 1), in three crops, soybean, maize and cotton. The commercially important ones with a strong impact to date have been the event MON 810 in maize, with resistance to lepidoptera and 40-3-2 in soybean, which provides tolerance to glyphosate. Events MON 531 and MON 1445 probably also have a strong impact on the crop, since they provide resistance to insects and to glyphosate for cotton, although the area has been greatly reduced in the past few years, as has been the case in other producer countries, to a certain extent owing to the lack of competitiveness over soybean.

The approval of transgenic events in Argentina takes place in three stages: the first is the study by the National Agricultural Biosafety Commission (CONABIA), which considers each event and provides authorization or otherwise for field tests; the second is food safety and the third is export market analysis, taking into account the country's interests. For example, the event GA21 is judged favorably in the first two areas but not in the last, which is that of market analysis, for which reason it has not been granted free market access.

Table 1 – Commercially-approved transgenic events

Species	***Event***	***Characteristic***
Maize	E-176	Resistant to insects
Maize	MON 810	Resistant to insects
Maize	T 25	Tolerant of ammonium glufosinate herbicide
Maize	Bt11	Resistant to insects
Soybean	40-3- 2	Tolerant of glyphosate herbicide
Cotton	Mon 531	Resistant to insects
Cotton	MON 1445	Tolerant of glyphosate herbicide

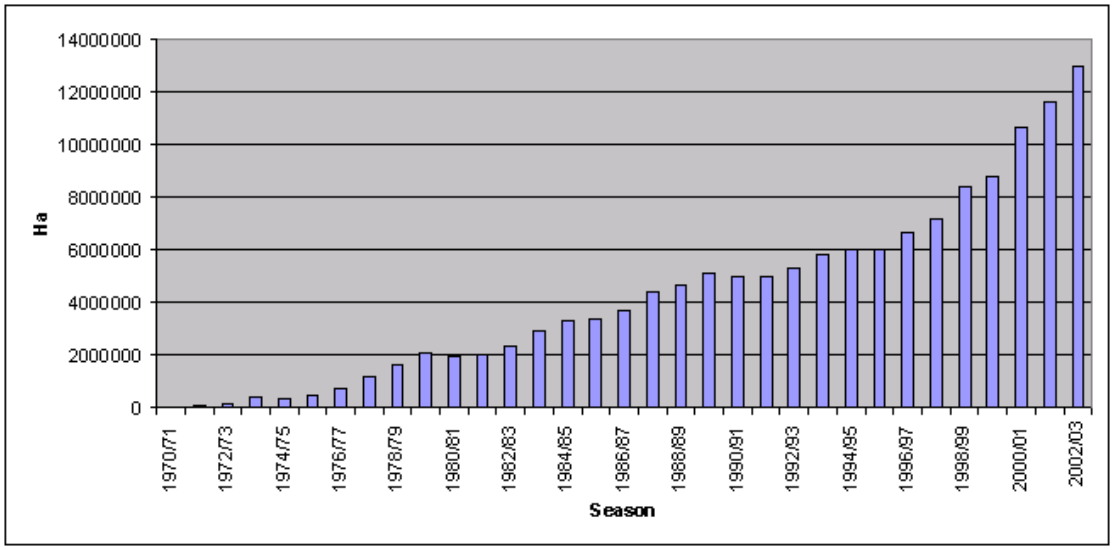
Source: ASA

1.1.3 Soybean cultivated area

In 1973, 170,000 hectares were cultivated and in 2003, 13,000,000 (Graph 3). Argentina is now the major world exporter of oil. With the new technologies – direct seeding and varieties resistant to glyphosate – soybean has become a colonizing crop, with which new areas of cleared ground or pastures are beginning to be cultivated.

Of the total amount under soybean cultivation, 99.5 per cent corresponds to transgenic soybean which has been strongly adopted by producers. And, on the part of seed producers, a rapid and varied supply of varieties has meant that the replacement process has taken place in not more than three years.

Graph 3 – Area cultivated with soybean

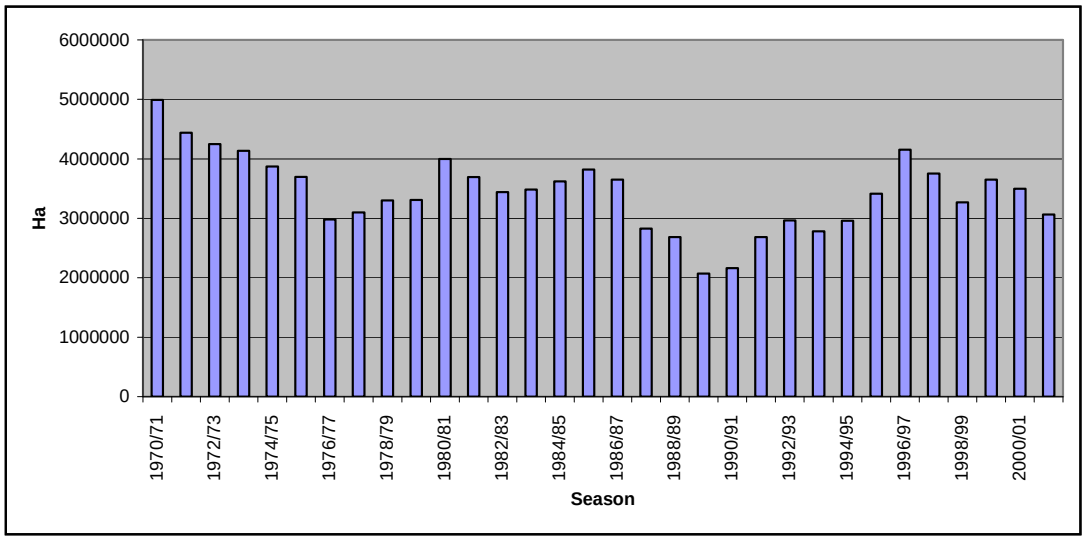


Source: SAGPYA

1.1.4 Corn cultivated area

As may be seen in Graph 4, the area cultivated with corn –maize- has remained relatively stable, despite the fact that soybean is a crop which is simple to handle and which generates better margins for producers.

Graph 4 – Area cultivated with maize

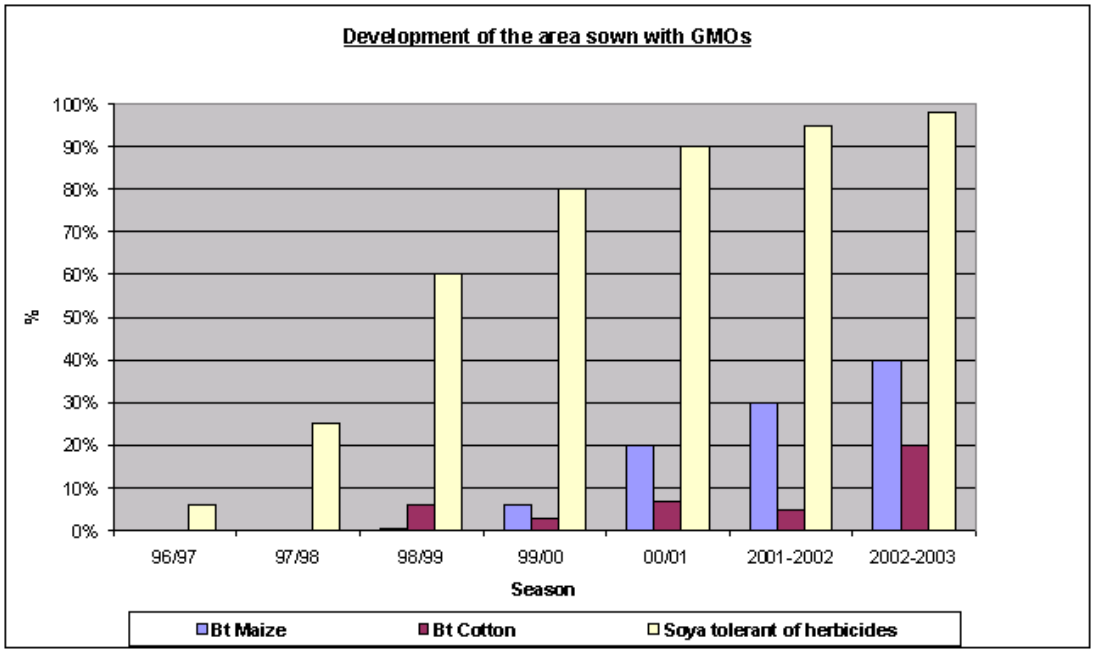


Source: SAGPYA

1.1.5 Impact of transgenes on Argentinian agriculture

The adoption by producers of new technologies has already been mentioned. Graph 5 shows the percentage increase in the share of transgenic crops, and soybean increased from six per cent of the total area under cultivation (37,000 hectares) in 1996 to 99.5 per cent (12,935,000 hectares) in 2002/2003.

Graph 5 – Share of transgenic crops



Source: ASA

Maize increased by only 0.25 per cent (8,000 hectares) to 40 per cent of the total area under cultivation (1.12 million hectares). Cotton increased from 2.7 per cent in 1999 to 20 per cent in 2001/2002.

The registration of new varieties of soybean is now covered almost entirely by RR (round up ready) varieties, as may be seen in Table 2, and that for maize hybrids also shows a strong increase in transgenic varieties (Table 3). This is a clear indication of where genetic improvement is heading in Argentina, based on producers' expectations.

Table 2 – Registered soybean (1995 - 2003)

Year	*Transgenic*	*Non transgenic*
1995	-	8
1996	5	11
1997	12	23
1998	18	18
1999	28	13
2000	19	7
2001	32	3
2002	13	2
2003	9	-

Source: INASE

Table 3 – Quantity of maize hybrids registered by event (1995 – August 2003)

Year	Total	Conventional	IMI (non-GMO)	Transgenic					Total Transg
				LL	*E-176*	*MON 810*	*BT 11*	*MON 810 + IMI*	
1995	34	33	1	0	0	0	0	0	0
1996	33	32	1	0	0	0	0	0	0
1997	47	46	1	0	0	0	0	0	0
1998	42	32	2	2	3	3	0	0	8
1999	58	39	10	0	3	6	0	0	9
2000	49	31	3	1	0	12	0	2	15
2001	82	51	1	0	1	29	0	0	30
2002	55	36	2	0	0	14	3	0	17
2003	39	24	1	0	0	10	2	2	14
Total	***439***	***324***	***22***	***3***	***7***	***74***	***5***	***4***	***93***

Source: INASE

The incorporation of biotechnology in the major crops has led to the broad expansion of the agricultural frontier (six millions hectares in the past ten years) and the movement of soybean cultivation to new areas not previously cultivated has been witnessed; with Bt maize late seedings may be made, known as second seedings, or second cultivation after wheat owing to the resistance to lodging indirectly supplied to it by the transgene, and thereby also increasing the opportunities for cultivation.

Not only the agricultural sector has benefited from the introduction of biotechnology but the whole of society.

Biotechnology has been introduced so as to provide an understanding of the importance of the recognition of intellectual property for the proper management of such technology and also an understanding of the need for a company such as RELMO to have license agreements for the use of genes, by way of example of the commercial prevalence of those enterprises commented on in Table 4, which market maize hybrids with the MON 810 gene, soybean varieties with the RR (Round up

ready) gene, and cottons with Bt gene. A licensing policy may be noted on the part of patent owners, which has allowed numerous national or multinational companies to incorporate those genes in their commercial lines.

Table 4 – Companies participating in the national GMO market, origin and crops on the market

Soybean tolerant of glyphosate:

Company	***Origin***	***Varieties***
Don Mario	***Argentina***	8
Relmó	***Argentina***	8
Nidera	***Multinational Argentina***	28
Seminium	***Argentina***	
Syngenta	***Multinational***	5
Monsanto	***Multinational***	9
Pioneer	***Multinational***	
Santa Rosa	***Argentina***	
Agriseed	***Argentina***	

Bt maize (resistant to insects):

Company	Origin	Hybrid
Don Mario	Argentina	3
Sursem	Argentina	
Dow	Multinational	
Nidera	Multinational Argentina	14
Monsanto	Multinational	16
Pioneer	Multinational	
Syngenta	Multinational	5-2
Seminium	Argentina	
Multisem[1]	Argentina	

Bt cotton (resistant to insects):

Company	***Origin***
Genética Mandiyú**/** Monsanto	Argentina-Multinational

Source: ASA

[1] Introduced into the market in the 2003/2004 campaign.

1.1.6 Argentinian legal framework, Argentine Seed Association (ASA) and Association for the Protection of Plant Breeds (ARPOV)

The Argentinian legal framework, formed by Law No. 20.247 on Seeds and Phytogenetic Creations which establishes the right of ownership of phytogenetic creations, with entry in the Plant Variety Property Register, and by means of which the State guarantees ownership, has been in force since 1978. The National Seeds Board (CONASE), a body set up by the Law on Seeds, comprises the seeds sector (ASA, ARPOV), the State (INASE) and users, and regulates the activities of the seed sector.

ASA, which has been in operation for 54 years and groups together the 67 main seed companies, and ARPOV, set up more recently, are the bodies which deal with sectoral union activity and work for the technological development and protection of phytogenetic creations. ASA, which is member of CONABIA, since it was set up 11 years ago, has played a major role in the discussion of the regulations which Argentina now possesses for the commercial release of a transgenic event.

Three years ago, the Association of Agricultural Technology Chambers (ACTA) was set up and groups together the sectors providing technological material for agricultural production, seeds (ASA), agrochemicals and fertilizers (Chamber of Plant Health and Fertilizers – CASAFE), veterinary products (Chamber of Veterinary Producers – CAPROVE) and agricultural machinery (Association of Tractor Manufacturers – AFAT), which has been acquiring major importance in agro-industrial production activities, and is the most important in Argentina.

As a result of the work of those institutions, Argentina acceded to the 1978 Act of the UPOV Convention and discussions regarding accession to the 1991 Act of the UPOV Convention are very advanced.

2. RELMO in Argentinian agriculture

2.1 What it is

RELMO is a company which continues the activities of the Ferrarotti Countryside Organization (OFPEC) which began working in the 1960s as the first company to devote itself to the genetic improvement of soybean, and the program registering the first Argentinian variety began in 1965. Mr. Julio Rafael Ferrarotti has just been rewarded as a pioneer of the improvement of the cultivation of soybean by PROSOJA, an organization which brings together Argentinian soybean breeders.

RELMO is a typical family company belonging to the Ferrarotti family. Julio Rafael Ferrarotti is the Chairman of the Board of Directors, his eldest son Julio Silvio is the Vice-Chairman and is in charge of the Research and Development Department, and his other son Juan Manuel is in charge of the Marketing Department. I am the only member who does not belong to the family, I joined the company in 1992, and I am currently Director, and deal with new business and international and institutional relations.

This company keeps the traditional initial approach to the seed industry, with the main experimental field operating in the Ferrarotti family farm, located in Maciel, Sante Fe Province, in the Argentinian corn belt.

2.2 What it does

RELMO is exclusively devoted to the business of seeds for the major crops soybean, wheat and maize. Its activities are conducted throughout the whole Argentinian agricultural and livestock industry. Its central offices are in Rosario (Santa Fe), a major grain marketing and soybean grinding center, in addition to being a major seed export port; the most important soybean producing-exporting center in the world is to be found in an area with a radius of 200 km around Rosario.

2.3 Intellectual property as a basis for RELMO's business

RELMO's development in the past few years is based fundamentally on license and service agreements which are supported by intellectual property. For many years, seed companies' activities were governed by the concept of vertical movement, encompassing all the cycles (genetic improvement, seed production and marketing), which could be defined as an isolated autarky. Plant varieties were thus developed, produced and sold. The exchange of experiences was rare and the predominant culture one of isolation.

Development is now horizontal with interaction between companies licensing products, carrying out joint development, providing services and so on. This is possible to a large extent through the practical application of intellectual property rights developed in the past few decades. The advantages are well known and allow technology to be disseminated more rapidly, with a synergy effect that benefits all the sectors involved. The dissemination of transgenic events not only did not hinder this process, but also made it more rapid and the flow of germplasm increased notably.

In the past few years, RELMO has transferred by license to other companies, not only in Argentina, a total of eight varieties and, in turn, has marketed eight varieties with its own trademark also, four of which are part of the current commercial line. This exchange of varieties between companies is possible as part of the legislation guaranteeing ownership of the varieties. What is licensed is commercial use, while the licensing company retains ownership.

2.4. Relations in Argentina

2.4.1 With biotechnology companies

RELMO is a pioneering company in the genetic improvement of soybean in Argentina, and for years its main activity. The commercial liberation of the RR gene; this constituted a major challenge, above all, in terms of its rapid adoption by producers. In this context, it was necessary to prepare for the replacement of all the varieties we had on the market with RR varieties as quickly as possible. This in itself already constituted an extraordinary effort. In the first stage, licenses were obtained for varieties from other companies which had already incorporated the gene in their improvement programs. If it had not done so, RELMO should have waited to incorporate the RR gene in its germplasm, something which takes time, and then at that time market RR varieties, thus losing its market position. This fact is further evidence of the application of intellectual properly law, and some of those licensed varieties were introduced from abroad, thereby confirming what we said before, namely that biotechnology accelerated the exchange of germplasm between companies, which in turn began to explore the possibility of new business deals since they had a commercial relationship for this reason. The fact that foreign companies have transferred their varieties to RELMO for commercial exploitation purposes demonstrates the credibility of the system of ownership of phytogenetic creations, which the State guarantees through the Law on Seeds and the Plant Variety Property Register.

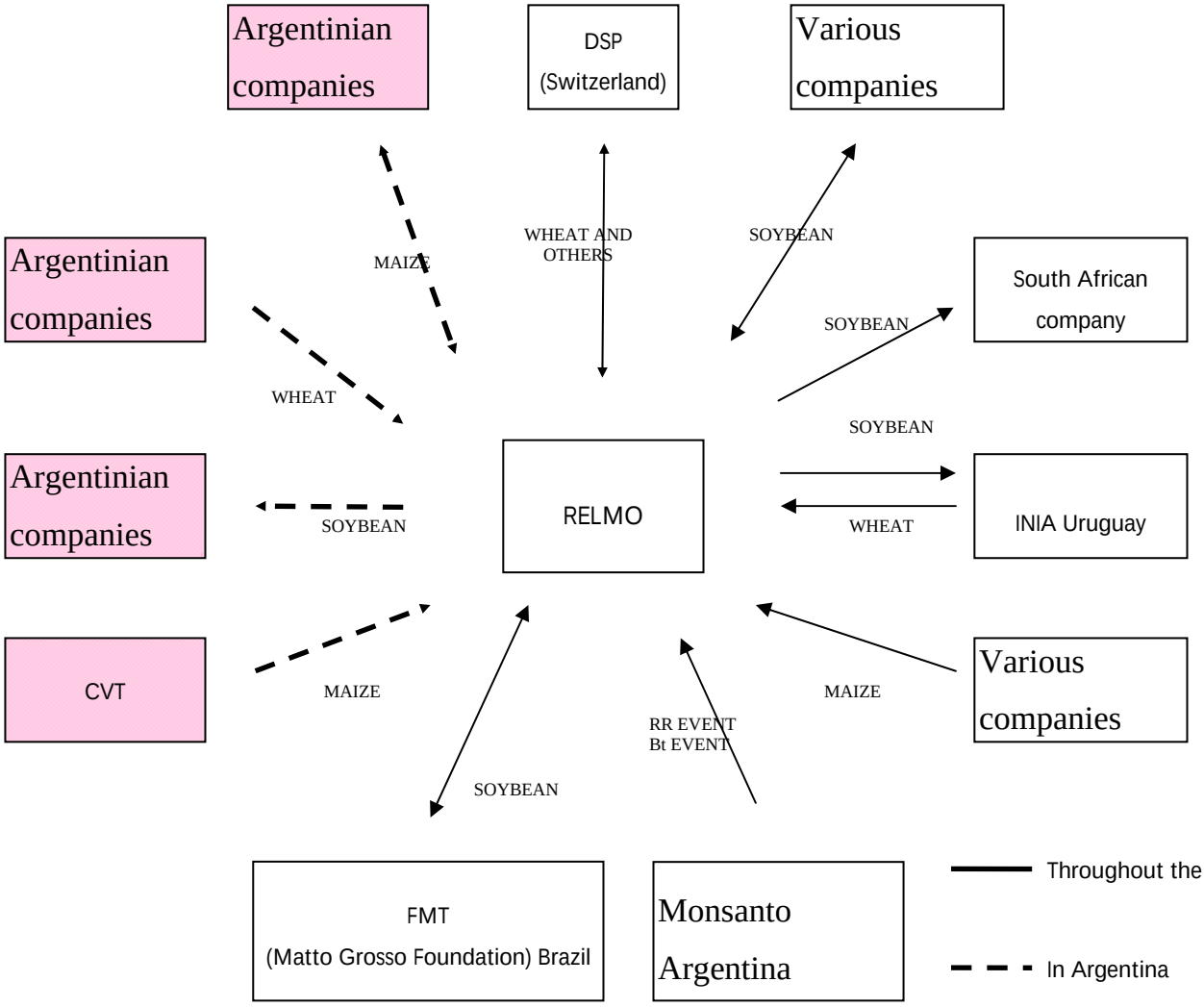
In order to commercialize RR varieties in Argentina, it was necessary to reach an agreement with Monsanto so that we were authorized to use the RR gene. The same was done on the basis of reasonableness which allowed RELMO to compete in the market, although it had to adapt its production and marketing systems to new models. This agreement also allowed us to place our soybean varieties in other countries.

The high degree of adoption of transgenic forms of maize has already been mentioned, for which we have begun working with the Bt gene (MON 810 event), having signed a testing agreement with Monsanto. We have also agreed the commercial license conditions which envisage various alternatives for using the technology. Given the nature of this Symposium, it is interesting to comment on the way in which we are planning our maize business. On the one hand, we take the Bt gene and germplasm which we license from other companies in order to form the hybrids which we will market. The MON 810 gene is protected by the Law on Patents and germplasm (inbred lines) by the Law on Seeds.

2.4.2 With other seed companies

RELMO has licensed soybean varieties to various companies for a number of years. It has taken under license varieties of wheat and licensed maize hybrids to companies operating in the domestic market. Graph 6 shows this flow of licenses.

Graph 6 – Flow of licenses and services



2.4.3 With public institutions

Last year, RELMO concluded an Agreement on Technology Transfer with the National Institute of Agriculture Technology (INTA) of Argentina, with a view to the genetic improvement of subtropical germplasm of maize. This is an interesting example of cooperation between the public and private sectors which thus enhance their capacities. The Agreement operates as follows: INTA provides the germplasm – which it owns -, the installations and the technical staff, and RELMO covers the operating expenditures. The hybrids obtained are marketed exclusively by RELMO which pays INTA a percentage royalty for what is marketed. RELMO thus has access to very good germplasm and a high level of technology, and INTA collects the royalties produced by the sale of hybrid seeds.

The inbred lines used in the production of hybrids are the property of INTA and commercial exploitation is exclusive to RELMO which may license such exploitation to third parties, while

respecting the royalties received by INTA; the flow chart (Graph 6) therefore shows that RELMO takes maize hybrids from the Agreement with INTA, which it licenses in turn to other companies, in addition to producing them with its own trademark.

2.5 Relations throughout the world

2.5.1 With the National Livestock Research Institute (INIA) of Uruguay

The National Agricultural Research Institute (INIA) of Uruguay has one of the oldest wheat breeding programs in South America and is located in an area with a high incidence of fungus and virus-related diseases, which allows it good selection pressure. RELMO obtained licenses of varieties from that program and last year INIA granted RELMO exclusive representation for its wheat in Argentina. In turn, RELMO did the same with soybean, granting INIA exclusive rights over the licenses for its varieties for Uruguay. The varieties of wheat are owned by INIA and RELMO exploits them commercially in Argentina. It is worth explaining that this license agreement allows RELMO to enter the wheat seed market with adapted varieties at a cost probably equivalent to that of developing its own crops, with the advantage of time (the development of a new variety takes six to eight years). Testing and registration costs within the seed certification system are covered by RELMO. The advantage for INIA of Uruguay is the expansion of the potential market and a reduction in cost for each variety obtained. For RELMO, this is a very good commercial opportunity, since the incorporation of seeds of winter crops means that the sales structure has a longer period of occupation and also benefits considerably the cash flow; we reiterate that for years the main business focus for RELMO has been soybean sown in summer.

The scheme of licenses for soybean varieties to INIA, with a view to their marketing in Uruguay, follows the same principles as those commented on for wheat.

2.5.2 With ***Delley Semences et Plantes*** (Seeds and Plants) S.A. (DSP) of Switzerland

We have established a commercial relationship with this company in Switzerland, which includes licenses for varieties of wheat for the whole of South America and technical collaboration, including the training of RELMO staff in Switzerland. As commented on in relation to the Agreement with INIA, the varieties here are also owned by DSP and RELMO is responsible for commercial exploitation. About four years ago varieties from France were introduced into the Argentinian market by one of the important companies with very good marketing skills and which was widely accepted by producers. These French varieties require different technology for cultivation that for the Argentinian varieties, and they constitute a differential share of the wheat seed market; this license agreement has allowed RELMO to participate in the market with varieties of a similar profile to the French varieties.

2.5.3 With the Matto Grosso Foundation (FMT) of Brazil

Brazil and Argentina constitute the major sector for the production of soybean in the world and the genetic improvement of the crop is very developed. The Foundation is an important technical support for the crop in Brazil, where approximately 16 million hectares are cultivated. We have established a program of work which includes the joint launch of varieties of soybean and which is carried out in both countries. Contrary to the previous agreements, this joint project does not involve any licenses but an ambitious joint development of varieties and research on disease resistance, as well as cultivation technology. Brazil and Argentina already represent the major region in the world for soybean production.

2.5.4 With South African companies

First, we have granted licenses for conventional varieties, and more recently for RR in the country, thereby contributing to the development of the crop. As in previous agreements, RELMO is also the owner of the varieties in this area and a South African company exploits them commercially.

2.6 Conclusion

Graph 6 also shows the meaning for RELMO in terms of development of the relationship with other companies, something which is possible only with a legal framework ensuring respect for intellectual property, in our case the ownership of phytogenetic creations (varieties or lines), and provided that a scheme of seed certification exists allowing those tools to be used.

The extremely important role which institutions such as UPOV have played and play is highlighted by their actions which have contributed to countries acceding to its ACTS and adopting the principles allowing the development of companies, as we have shown in the case of RELMO. We attach great importance to these activities as shown through active participation in Argentina by the Association of Argentinian Seed Producers (ASA), which is also a member of the Board of the International Seed Federation (ISF).

We also participate in the Argentinian Association of Protection for Plant Breeds (ARPOV) which deals with the defense of rights and currently plays an important role in the collection of royalties for wheat and soybean. This has recently been implemented and constitutes a significant advantage for a company the size of ours, since it provides the possibility for collecting royalties in that ARPOV has the structure necessary for such monitoring and collection work.

It is interesting to discuss the advantages and opportunities on the one hand, and the disadvantages and shortcomings on the other, of a medium-sized company in the current context characterized by merges which give rise to companies ever greater in size in the biotechnology era.

The main advantage, of no little importance, is that the RELMO executives are its owners, which allows decisions to be taken quickly and direct treatment to be provided in the company's relations both internally and externally. Another advantage, which has nothing to do with the size, is that the company policy is to move forward quickly and very actively in business management.

In relation to events of importance such as that of the RR gene in soybean, the main disadvantage appears to be that of non-access to licenses for its use, which in Argentina would leave us outside the market, a situation which has not occurred so far, not only with this event but also with others more widely disseminated, as we have already commented.

Probably the major problem lies in the difficulty in developing our own transgenic events or those with shared ownership or exclusive commercial exploitation, since the relationship with public institutions or biotechnology companies would allow those developments to be faced jointly, the main problem being the high cost of the deregulation processes required for its commercial release. The companies devoted to biotechnology developments have whole departments dealing solely with this subject. We hope that in future services will be provided by companies specializing in commercial deregulation of transgenic events.

I would like to emphasize by repeating again that without national legislation and an appropriate international framework for intellectual property, the development of a company such as RELMO would be very difficult if not impossible.

IRRI: The Experience of an International Public Research Institute

MS. THANDA WAI
Intellectual Property Rights Specialist, International Rice Research Institute (IRRI), Laguna, Philippines

Introduction

The International Rice Research Institute (IRRI) is one of 16 research centers that constitute the Consultative Group on International Agricultural Research (CGIAR), which was founded in 1971. Although many of IRRI's research programs and collaborators are found in Asia, IRRI's mandate is global in scope. IRRI's mission statement is to "improve the well-being of present and future generations of rice farmers and consumers, particularly those with low incomes."

Research Activities

IRRI engages in a variety of research activities including traditional plant breeding, biotechnology, water and nutrient management, agricultural engineering, and social sciences. Our mission is to produce international public goods (IPGs), which are products and technologies that are made accessible to the public.

- Examples of traditional plant breeding include efforts to increase yield and nutritional qualities of rice (e.g. high iron), incorporating traits for plant disease resistance (e.g. resistance to rice blast, rice tungro virus, among many others), and breeding for resistance to abiotic stress (e.g. drought and salinity tolerance).

- Biotechnology projects include improving the expression and stability of transgenes that express Provitamin A or the Xa21 gene for rice blast resistance to functional genomics and allelic mining.

- The water sciences group works on methods of growing rice using less water and breeding for aerobic rice, i.e. that grows well on dry land. An important contribution of the nutrient management group is the Leaf Color Chart, which is a chart showing different degrees of greenness expressed by rice plant leaves. The farmer matches the color of the rice plant leaves in the field to the color on the chart and makes a decision whether to apply nitrogen and how much. This simple invention saves farmers a great deal of money and materials spent on chemical fertilizers, as well as helping to mitigate the effects of applying chemical fertilizers on the environment.

- Agricultural engineering was a major focus of research at IRRI at one time. This group tested commercially available farm equipment and routinely made improvements. This unit has since been cut back and now concentrates more on solving problems associated with postharvest storage of rice and testing for nutritional quality of the rice grain.

- The Social Sciences Division works on projects from analyzing the economic impact attributed to growing improved varieties of rice to the Geographic Information Systems (GIS) group.

The various types of research partners include Ministries of Agriculture, universities, research institutes, among others.

Access to research materials is obtained in various ways. In terms of having access to germplasm and plant varieties for further breeding, IRRI has over 100,000 accessions in the Gene Bank, as well as an active exchange and contribution program of rice seed, such as INGER (International Network for the

Genetic Evaluation of Rice). More than 80,000 accessions in the IRRI Genebank are Food and Agriculture Organization of the United Nations (FAO)-designated. These accessions fall under the auspices of an agreement between the FAO and IRRI, such that germplasm in this collection will be made available without restriction to researchers around the world and with the understanding that no intellectual property protection is to be taken on these accessions. Materials are also received through research collaborations. Research materials for biotechnological projects come from publicly available sources and from licensing in of third-party tangible and intellectual properties. Licensed technologies are generally "research only" licenses. Few institutions, including academic research institutions and universities, are willing to give technologies royalty-free.

Issues Related to Licensing of Third Party Intellectual Properties

Major issues encountered in the licensing of third-party intellectual properties include exclusivity of licensing, the right to sub-license, and market segmentation.

- In general, the private sector will ask for exclusive licensing of technologies. IRRI cannot give such exclusivity without an exemption to give royalty-free licenses back to resource-poor farmers. This issue was not resolved in license negotiations for the rice genome sequence. Since IRRI was not willing to offer the first right of refusal to a company for any technology that may have been developed through knowledge gained from accessing the rice genome database, a decision was made not to sign the agreement. The International Rice Genome Sequencing Project was completed in December 2002. Therefore, the sequence of the entire rice genome is now publicly available to everyone without any restrictions.

- Another issue related to licensing technologies is whether sub-licenses may be issued. The advantage for IRRI to sub-license technologies is to increase the ease of transferring technologies to the national partners. These partners may not know how to approach the private sector for technologies. However, since they are familiar with IRRI, they are more likely to ask IRRI for technologies that they wish to license. While the ability to sub-license to national partners promotes technology transfer, it is also a serious responsibility, as we have to make sure that the recipient understands the terms of the agreement.

- The issue of market segmentation is a complex one. Market segmentation occurs when technologies are given only to certain territories and/or to a certain class of people (sometimes based on income). The private sector sometimes gives royalty-free licenses based on the country and also income level of the recipient. For example, in the Golden Rice™ sub-license agreement from the co-inventor Ingo Potrykus to IRRI, a royalty-free license to grow the material is given only to farmers in certain countries and to those earning less than 10,000 USD per annum. Unfortunately, the private sector has not been willing to give the same or similar terms in subsequent agreements, as it was felt that the income limit of 10,000 USD per annum was too generous. In other cases of market segmentation, royalty-free licenses are given only for countries for which there are no patent laws that would allow the owner of the technology to pursue intellectual property protection.

Two major technologies licensed in by IRRI are those for Golden Rice™ and the Xa21 gene. Components of the Golden Rice™ technology was licensed by five separate companies to the co-inventor Ingo Potrykus and in turn sub-licensed to IRRI. This technology is sub-sub-licensable to public sector institutions of specified countries. The Xa21 gene was licensed to IRRI by University of California-Davis. This license is also sub-licensable.

IRRI's Policy on the Sharing of Tangible and Intellectual Properties and Issues and Factors Related Its Practice

Factors that affect the decision to protect research results depend on IPR policies and guidelines of donors as well as those of IRRI. Donors generally come in three categories: ones that do not allow intellectual property protection of the results of the research that they fund, ones that encourage IPR protection, and a third group that stays silent on the issue.

Other issues related to the management of intellectual properties at IRRI include defining the meaning of the term "related information" in the Material Transfer Agreement (MTA) for FAO-designated materials and the term "essentially derived," evaluating the effects of reach-through rights associated with licensing-in technologies, and assessing the impact of international treaties such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Convention on Biological Diversity (CBD).

IRRI's IPR policies and guidelines may be summarized as stated below.

- Germplasm and varieties obtained prior to December 29, 1993, the date of entry into force of the Convention on Biological Diversity, and those developed by IRRI are freely shared. Materials obtained after this date are shared as specified by the donor.

- Formal intellectual property protection of biotechnologies will be pursued if it is determined that is the best way to serve our clients, such as defensive patenting of critical base technologies. An example of such a technology would be a new antibiotic resistance-free method of selecting for transgenes.

- IRRI adheres to the policy of free availability of breeding lines, elite germplasm, and parental lines of hybrid rice produced in its conventional breeding program and will not seek intellectual property protection for these materials.

- In the past, when IRRI had an active agricultural engineering group, a number of improvements and new designs were patented in the Philippines with the idea of keeping the designs in the public domain. We no longer actively test and develop large agricultural equipment, nor are we pursuing any further patents on agricultural equipment. We now share engineering designs with our partners by attaching a shrink-wrap MTA, mainly to prevent the recipient from protecting the designs and preventing further sharing.

- IRRI has an active publications unit. Therefore, publications, databases, software, and media assets may be protected by copyright in accordance with normal publishing practice. Educational materials published by the IRRI Training Center may be copyrighted.

- IRRI has obtained trademark protection for the IRRI and IR in the Philippines and has applied for similar protection in India and China, two of the world's largest rice-growing countries.

- Trade Secrets are not used as a method of intellectual property protection, as IRRI's function is to disseminate information and technologies.

Technology transfer is effected in different ways. Licensing of IRRI's IP assets are limited. The use of photos from the IRRI Photogallery is being licensed. We transfer materials (including biological, engineering designs, etc.) with a Material Transfer Agreement. IRRI scientists write numerous publications and give many seminars. Staff members also give scientific advice and conduct field days. Both breeding materials and plant varieties are released. IRRI's research is sometimes publicized in news releases. In the broad sense of the word "commercialization", IRRI does commercialize from the perspective that tangible and intellectual properties and technologies are transferred to national partners and to farmers.

Future Directions

Future developments at IRRI include determining how the terms of rice germplasm exchange will be affected when the International Treaty on Plant Genetic Resources for Food and Agriculture comes into force. There is uncertainty as to how we will exchange germplasm with non-signatory countries.

In summary, IRRI's IPR policy and practice will remain flexible and stay in tune with the ever-changing international laws and practices.

Panel Discussion:

Enhancing the Benefits of Intellectual Property

Mr. Cédric CABANNE, Head of Agricultural Campaign, Friends of the Earth, Montreuil, France

I would like to try and answer a question asked by one of your speakers. This question was "should we wait 70 years for biotechnology applications to be disseminated in developing countries?" For my part, I hope that, yes! Because I think that at least agricultural GMO applications are not socially and environmentally acceptable. In fact, contrary to what another of your speakers said, GMOs are not developed to meet needs such as food security. The truth is that food security is a matter of adequate policies which should maintain diversified agricultural systems and guarantee sustainable revenues to farmers. As we can see in Argentina and China, GMO technologies favor monocultures and favor soil-erosion. Furthermore, in terms of R&D, it is true that the public and private sectors should work together, but we should not forget that the public sector R&D are principally designed to solve agronomic problems of farmers and not commercial problems of industrialists. Finally, I would like to say that, for my association, GMOs represent considerable stakes, and proponents of GMOs are yet to respond to social and environmental problems such as resistance to salinity and drought. I haven't heard anyone talk about the stage they were in research on these subjects. It is true that applications such as resistance to herbicides seem more delicate. Finally, I would like to underline that biotechnology should not serve as a pretext to limit farmer's access to biodiversity through intellectual property rights.

Mr. Alexander OCHEM, Research Assistant, Molecular Biology, International Center for Genetic Engineering and Biotechnology, Trieste, Italy (Speaker)

I would like to point out that biotechnology, genetic engineering, does nothing different from what nature does by itself. What genetic engineering basically does is that is speeds up this natural process. Because when you transfer genes between or among organisms, you do not create genes, you merely transfer, and genetic engineering by definition does this more specifically. Traditional plant breeding takes several years, decades, to generate a new variety. Genetic engineering accomplishes it in a much shorter time and the selection is much more specific. There has been a lot of argument about creating allergies, but it has no scientific background. You do not create them because you do not create the genes. Due to its specificity and accuracy, genetic engineering may actually be employed to remove known allergens rather than create new ones. You can talk about interactions between genes which you cannot foresee, but also you cannot foresee the cross pollination that is effected already by nature itself. If we think that the population of the world is increasing astronomically and then if you think that there are people who really live in Africa with less than 1%, (less than 1 USD per day) taking account of the definition here that USD10,000 is the limit for poverty, then what about those people who live with less than USD1,000. It becomes dramatic. I really do not see the point you are raising.

Mrs. Qinfang WANG, Deputy Director, Research Management Division, Biotechnology Research Institute, Chinese Academy of Agricultural Sciences, Beijing (Speaker)

Concerning the question Mr. Cabanne has raised, maybe I can answer to a certain stage. For the GM cotton crops in China we do not create only one variety, we transfer our gene into all the major varieties in different major cotton production provinces. So it is not a monoculture at all. In terms of the environmental issues, the second generation of GM crops we are emphasizing more on stress tolerance such as salinity, cold and drought tolerance, but compared with the first generation of GM crop, the so-called input traits GM crop, it is not ready to commercialize yet, but we are working on this stress tolerant GM and putting more investment as compared to the first generation of GM crops. In terms of the biosafety issue he raised, compared with conventional varieties, I think that

GM crop varieties are much safer because the GM crop varieties have to pass through the Biosafety Assessment, which includes environment safety and food safety. We have national guidelines for the biosafety assessment of agricultural genetically modified organisms, also a National Biosafety Committee and the Committee members are from all related research areas, such as biotechnology, environment issues and also public health.

Mr. Bernard LE BUANEC, Secretary General, International Seed Federation (ISF), Nyon, Switzerland (Speaker)

I would like to make two comments. The first one on an inaccuracy said by Mr. Cabanne saying that transgenic crops are increasing erosion. All the studies I have seen show the contrary, in particular as regards herbicide resistance allowing the no-till agriculture and decreasing drastically erosion in several parts of the world. So in fact that is simply inaccurate. The second comment I would like to make is that I feel there is a slight inconsistency saying he is hoping that it will take more than 70 years to have GM crops in developing countries and then asking the question as to what are the traits you are working on that could be useful for developing countries. It should be said that you have within IRRI, drought-resistant varieties that are coming very soon. In India, you have salt-tolerant rice varieties in the Swaminathan Foundation very soon also to come and I hope that those very useful varieties will be used before 70 years in those countries.

Mr. Mark CANTLEY, Advisor, Directorate for Biotechnology, Agriculture and Food, European Commission, Brussels

I would like to put a question to Ms. Wai from IRRI. With the germplasm collections, you signed an agreement with the Food and Agriculture Organization of the United Nations (FAO) in 1994, in which you pointed out that the germplasm in your collections was public domain and there could be no intellectual property taken on the accessions or on information derived therefrom. Does that mean that if a company takes one of your accessions, characterizes and develops a useful invention based on some identified genes, you would object to them taking out a patent of such an invention and what would you do about it?

Ms. Thanda WAI, Intellectual Property Specialist, International Rice Research Institute (IRRI), Laguna, Philippines (Speaker)

If it is FAO designated, then I think the terms are clear, you cannot patent it. But if it is an IRRI-developed material, we are not controlling derivatives.

Mrs. Carmen Amelia M. GIANNI, Director of Legal Affairs, National Secretariat of Agriculture, Livestock, Fisheries and Food, Ministry of Production, Buenos Aires

I would like, Chairman, to hear a reply to the question I raised this morning, because it might be motive for discussion. I would like to know whether a benefit-distribution system and transfer of technology system, of course while protecting intellectual property rights under both systems, that is the patent system or the UPOV system with its two exceptions, either the exception for the breeder or the exception for the farmer, which is more equitable a system to achieve those objectives - benefit-distribution, national development and improved food supply. I have no question that the UPOV system, through its benefits, as our speaker Mr. Domingo has said, in the case of Argentina to have recourse to intellectual property systems implemented by UPOV, has been an important element for the development of agriculture and of farmers. I would like to hear the opinion of the Chair as to which is more effective?

Mr. Stephen SMITH, Germplasm Security Coordinator, Pioneer Hi-Bred International Inc., Johnston, United States of America (Speaker)

I would like some clarification. Are you asking which system is more effective or which system is more equitable?

Mrs. Carmen Amelia M. GIANNI, Director of Legal Affairs, National Secretariat of Agriculture, Livestock, Fisheries and Food, Ministry of Production, Buenos Aires

Both of those questions. Which of the two systems is more effective, but taking account not only of the right holders of intellectual property rights, but also the users of technology and phytosanitary users, both agricultural producers or society as a whole, because the objective of intellectual property rights, even in TRIPS, is the transfer of technologies and development of agriculture in favor of the world population.

Mr. Stephen SMITH, Germplasm Security Coordinator, Pioneer Hi-Bred International Inc., Johnston, United States of America (Speaker)

Well, I will define effective in terms of the system that encourages sufficient investments in innovation and risk-taking to be able to create new improved products that meet the needs of farmers. I was talking about a problem that I saw with the current system of UPOV, given the fact there have been rapid advances in technologies that allow much quicker access to existing varieties. There is a balance in UPOV that was desired to be struck between access to germplasm and encourages to take those risks and invest money, financial resources and peoples' time in working with those resources. In my mind, that balance has changed because of the technology advances uses proteomics, genomics, dyhafloids, that are available particularly to larger companies, but not so much at the moment to smaller medium-sized companies, that allow very rapid access and generation of new varieties from existing varieties. Therefore, in my mind, that means there is now a problem with free and immediate access to a commercial variety for further breeding. So when I am talking about a change in the breeder's exemption, I am thinking of a suspension for an initial period of that free access that would reestablish that balance and allow more incentives to make those investments in risk-taking. At the end of the protection period, that variety is in the public domain. So that it is a variety that has been created because of the research investments, and then it is in the public domain. In addition, when there are restrictions on immediate use of a newly created variety under the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty), if materials have been used from the International Treaty to help develop those materials, then royalty flows go back into the system, so that is helping to provide benefits back into the system of conservation of plant genetic resources, into the global plan of action. So I think a system that encourages investment and risk-taking and innovation, that also provides some royalty flows back into the conservation of genetic resources and into the global plan of action is, in fact, the most effective and the most equitable means of encouraging a generation of new varieties for farmers.

Mr. Bernard LE BUANEC, Secretary General, International Seed Federation (ISF), Nyon, Switzerland (Speaker)

If you agree, I will also try to give part of the answer to that very important question raised by Mrs. Gianni. My answer would be that, in fact, it is probably not possible to define what is the best system at international level. The system has to take into account the technical development of a country, the culture of that country, the socio-economic situation of that country. So you cannot say what is the best system for all the countries in the world. In some countries, one system is probably the best and in another country, it will probably be another system. Obviously, you cannot treat the small farmers of the antiplano in Bolivia in the same way as the farmers in the Sierra. You cannot treat the small farmers in Africa as the large farmers in Europe, and the small farmers in Europe as the large farmers in Europe. So, it is up to each country, based on the international instruments that exist, to develop for its own needs, the most efficient system.

Mr. Jeff KUSHAN, Attorney, Sidley, Austin, Brown & Wood, Washington, D.C. (Speaker)

I think the way the question was presented puts these two systems as a choice - either, or - and I think it is important to remember that, in most systems, there is a complimentary combination of two different systems. The patent system has a higher threshold, as I tried to make clear in my talk. It is much higher than you are going to have for obtaining protection under plant variety systems. With that system, also comes a different public benefit. I have heard many debates about the patent system and its pros and cons, but one thing we always forget is that the patent system itself is a very effective system of technology transfer, because it requires immediate publication at 18 months of the application. This is a robust publication, all the technical details of the invention which are flowing immediately into the public for use. That information is how we get advances in technology. The restrictions through the patent on use of the technology in territory of the patent obviously play the economic benefit to the innovator, but there is a significant amount of technology transfer that is part of the equation of the patent system. Just to very briefly summarize, the patent system complements the plant variety system in most environments because of the different activities that qualify for each type of instrument and the patent system itself is perhaps, if I were to rate the two systems, the more effective at promoting technology transfer, at least at the first instance of conveying a lot of technical information through the patent specification and the information you convey through that. I would like to challenge the premise that these are choices that are in conflict, but actually I see these systems working in a very complementary way, each within their own parameters.

Mrs. Karen LEE RATA, Senior Counsellor, Office of the Special Counsel, WIPO

I would like to add my observation to what Mr. Le Buanec, and perhaps what Jeff Kushan has also stated just now. I agree with Jeff's statement that these two systems are not contradictory and, specifically, if the question is rephrased as to which system may be better or more effective in protecting plant varieties, what they have said applies, but in addition we need to remember that these two systems have very different scopes. If I may just recall what Mr. Gerard has said, just by having certain characteristics in a given variety, which may not be protectable under plant variety protection due perhaps to even smaller steps than called for, if we can say it that way, they may be patentable. So there are certain things or steps that can be protected, perhaps incrementally, through patents on one's way to finding improved or different variety. Therefore, in my view, you would need to have both systems, perhaps so that you would be able to protect, in different stages of invention, to the point where you have a new variety. So, I would say again that you need both systems. However, you may want to focus on these two systems differently in your own countries, as Mr. Le Buanec said, depending on what you want to stress or focus and what your needs are, but it seems to me, it is quite clear that you would need both systems, in complementary ways, in each country.

Mr. Rolf JÖRDENS, Vice Secretary-General, International Union for the Protection of New Varieties of Plants (UPOV), Geneva (Speaker)

The UPOV Convention has already tried to strike a balance and to facilitate co-existence of these two systems, for example, through the concept of essentially derived varieties (EDVs). Under the UPOV system, there is room to combine both principles, if this is useful and necessary for technological advancement and progress. However, the breeder's exemption is an invitation to the whole community of breeders, without additional cost and complications to easily use protected varieties in their breeding programs. This is a big advantage. It is relatively evident that the more imagination, the more inventiveness you involve in the process of breeding, the more rapid the process is.

Mr. Peter LANGE, Chairman of the Intellectual Property Committee of the European Seed Association (ESA)

I would like to fully support what Mr. Bernard Le Buanec has said. I really think it should be the choice of the member states to choose between different solutions and, in this respect, one sentence in the speech of Mr. Moufang was interesting. He said referring to the issue of availability of protection that European Law is in practical consequences not so different from national systems, such as systems of the United States of America or Australian, which allow the patentability of plant varieties. But in practical consequences, of course, there are a lot of differences in the scope of protection and we have to consider very carefully if we want to change anything in UPOV. And referring to this, I would like to insist, again, what was referred to already by Mr. Le Buanec, on the position of the International Seed Federation (ISF), which states that it is "strongly attached to the breeder's exemption" and, in line with this statement, this is also the position of the European Seed Association (ESA). We think that the breeder's exemption is really a cornerstone of the UPOV system and any suggestions which would put this cornerstone at risk should be very carefully considered - and that particularly for the following reasons: First, it would raise concerns, in particular in new member states. Second, it would render accession discussions with candidate UPOV member states more difficult. It would encourage countries to develop other ***sui generis*** systems than the UPOV system for the protection of plant varieties. It would render the UPOV system as an effective ***sui generis*** system more vulnerable to attack in the discussions of Article 27.3(b) of the TRIPS Agreement. And last, but not least, it would impair the balance between the UPOV Convention and the International Treaty on Plant Genetic Resources for Food and Agriculture. I would like to ask you to have a look at the Website of ESA, where ESA will issue a statement on this very important and highly political question.

Mr. Huib GHIJSEN, Global Manager Germplasm Protection, Oilseeds Department, Bayer BioScience N.V., Gent

I would like to refer to a remark of Jeff Kushan about the patent requirements. His remark was that one of the requirements putting a threshold on patent granting and that was the inventive step, prevent that easy inventions come available. That is one of the main differences between plant breeders' rights which has a low threshold, so to speak, and the patent system. I have looked into this so-called requirement as applied by the examination of the Patent Office of the United States of America for the invention of plant varieties, so I am not speaking about biotech inventions or industrial inventions, but just the same varieties as used in the UPOV system, and also having applied through the utility patent system in the United States of America and I have come to the conclusion that, in fact, the requirements as applied are lower than the UPOV standards and that the scope of protection is much broader. And I think that that is the key of the problem we are facing at the moment. We are comparing two systems, the UPOV system and the utility patent system. The scope of protection and requirements in the UPOV system are very well balanced. I think the problem in the United States utility patent system is that it is not the case. I think that the discussion has to focus on that problem also.

Mr. Jeff KUSHAN, Attorney, Sidley, Austin, Brown & Wood, Washington, D.C. (Speaker)

When I speak of patent barriers compared between the utility patent system in the United States of America and the plant variety protection system, I do not think only in terms of obviousness. On the question of the requirement of obviousness, the narrower the claim, the less of a hurdle it is, but correspondingly, the patent confers a much narrower scope of protection. The other variable that we have seen much more prevalent in our examination experience has been the application of the written description requirement, the application of the utility requirement and I am speaking in terms of a lot of applications that we have worked on, the Patent Office, to my experience, has not been particularly generous on scope, which on the one hand makes it easier to get a patent issued, but it also makes the effect of that patent much narrower, and that, essentially, the balance that is built into the system. If you ask for broad protection, you are going to have a much higher burden in front of you to get that patent issued. I have seen studies done of US patents and it is almost like to

take the example of a broad patent and you say how could that patent get out? It's not often a good example compared to the types of narrow claims that might get issued more readily. The individual nature of each of the patents in their claims tends to be the major factor you have to look at when you are evaluating how big that hurdle is. But, in principle, it is not just the obviousness requirement that is the additional burden relative to the UPOV system, it is the additional disclosure requirement. It is also more expensive, it is also more time consuming, although our PVP experience has not been speedy! There are a number of variables, as you have mentioned.

Mr. Huib GHIJSEN, Global Manager Germplasm Protection, Oilseeds Department, Bayer BioScience N.V., Gent, Belgium

Just some additional words. I have just mentioned the non-obviousness, but I also mean the other requirements such as industrial application and description that can be placed just by depositing a sample.

Mr. René ROYON, Secretary General, International Community of Breeders of Asexually Reproduced Ornamental and Fruit-Tree Varieties (CIOPORA), Bois de Font Merle, France

I would like to revert to the question asked by the delegate from Argentina. I believe that the answer cannot be given as long as we do not make a distinction as to the subject matter of protection. In biotechnological inventions, it is clear that you do not have a choice. The only possibility to protect is by a patent, because the patent will define the claim and through the claim the scope of the protection that you want to obtain. If the subject matter of protection is a variety, then we know that there are two courses possible, either patents or plant breeders' rights, and in that matter, you have to consider two viewpoints. The viewpoint from the breeder and the viewpoint from the user of new varieties. The viewpoint of the breeder will, of course, depend upon what kind of scope of rights he receives under each system. So far it is clear that under the 1978 Act of the UPOV Convention, the breeder does not receive an effective protection for many reasons that I will not develop here, but which are well-known to most of the people present here. Concerning the 1991 Act, the effectiveness has been improved, but it has certainly not gone as far as the broader patent protection, notably as far as the use of the variety is concerned. While use of a patented subject matter is protected under a product patent protection, use of a variety is not specified in the scope of the breeder's right defined by the 1991 Act of the UPOV Convention. So, we believe that concerning breeders, we still need an improvement of the 1991 Act of the UPOV Convention. Coming back to the users, I believe that licensing or obtaining a license, whether under a patent or under a breeder's right certificate, does not make much difference, although the scope of the right may have some influence. The main thing, however, is the control of the conditions for licensing, and I believe that all of the anti-trust laws or anti-competitive laws existing worldwide cover both licensing under patents and licensing under plant breeders' rights.

Mr. Gerard DOWNES, Researcher, Department of Politics and Public Administration, University of Limerick, Limerick

I would like to ask the panel how much flexibility do countries have in the implementation of the effective ***sui generis*** provision in Article 27.3(b) of the TRIPS Agreement. I am thinking in particular, of India, which implemented the Plant Variety Protection and Farmers' Rights Act of 2001. From my reading, I have ascertained that India's attempted legislation has provoked the ire of ISF and has not enamoured itself to UPOV. Could you enlighten me a little about how much flexibility countries have under the ***sui generis*** provision in 27.3(b)?

Mr. Adrian OTTEN, Director, Intellectual Property Division, World Trade Organization (WTO), Geneva (Speaker)

I do not know how much I can enlighten you, but I can attempt to respond. You are familiar of course with the language of Article 27.3(b) of the TRIPS Agreement, which talks about members

protecting plant varieties by patents or by an effective ***sui generis*** system or a combination of the two. Now, we have no authoritative further guidance as to what that means-jurisprudence or decisions of the members. This issue has not been the subject of any dispute settlement proceedings which might lead to rulings or findings which could at least provide some guidance as to how the appellate body or panels would understand it, nor has it been the subject of collective decisions of the World Trade Organizaton (WTO) members, and that is the only way in which authoratative interpretations can come about. As I mentioned this morning, this is one of the topics that is under discussion in the TRIPS Council in the context of the review of Article 27.3(b). I mentioned, I think, a non-exhaustive list of some points which have come up. There is a range of views amongst members. I mentioned the responses to the questionnaire and we have had responses from 37 members so far, mostly developed and transition economies, and a few developing countries, which actually gives a fairly consistent picture of what have been the practices of those members. But we have not gone further in studying systematically or in a comparative way the legislation of members to give effect to this requirement. So we do not have a body of information which would crystallize the different ways in which members have chosen to understand and implement this provision. I am afraid that that is as much as I can offer.

Mr. Bernard LE BUANEC, Secretary General, International Seed Federation (ISF), Nyon, Switzerland (Speaker)

As ISF was quoted, I think I have also to give some comments. Yes, ISF was not happy with the Law in India. Probably for two main reasons. The first reason is that we consider that that Law is not an effective system for protecting plant breeders' rights. There are several articles that are not, from our view, consistent with the 1978 Act of the UPOV Convention, but there is one major point and that is that there is the right for the farmer to sell seeds under another denomination. These two items are contrary to the UPOV Convention. First of all, they have the right to sell -this is not acceptable-and according to the Convention, when a variety has got a denomination, it has always to be sold under that denomination. So there are two huge breeches and if you have the right to sell farm-saved seeds, where is the efficiency of the protection? The second reason is that we consider that it is completely confusing to wish to organize in the same Act, very different goals, like farmers' rights, breeders' rights, benefit-sharing and so forth. Yesterday, the Council of UPOV has also adopted a paper indicating that it was probably not the best solution to try and have all the different problems regulated in one law, but it would be preferable to have different pieces of law. Those are the two main reasons, but obviously, the Indian Law is not an effective ***sui generis*** system for plant breeders' rights.

Mr. Rolf JÖRDENS, Vice Secretary-General, International Union for the Protection of New Varieties of Plants (UPOV), Geneva (Speaker)

It is probably useful to explain the situation with the Indian Law in respect of UPOV. The Government of India has expressed the wish to have this Law examined by the Council of UPOV for conformity with the 1978 Act of the UPOV Convention in view of India's accession to UPOV. India wants to accede to the UPOV Convention. This examination has started, but is not yet finished. We are in contact with the Indian Government to clarify certain questions, but there is no position taken with regard to the conformity of this Law with the UPOV Convention to date.

Mr. Oscar DOMINGO, Director, Relmó, Buenos Aires (Speaker)

I see that we have an academic discussion on protection systems. But there is another system which is the real system. RR doesn't have any protection in Argentina and there is no company that has used the gene or registered varieties without the permission of the owner or the holder. I do not think that any company can afford to do that. They would have been just outlawed and I do not think they would have been able to stay in the market.

Mr. Anthony TAUBMAN, Acting Director and Head, Traditional Knowledge Division, Office of Legal and Organization Affairs and PCT System, WIPO

I would like to go back to the question of effectiveness and equity. I think the last intervention put a very important perspective before us. That is to say, effectiveness and equity are ultimately practical matters as well. It is a question, of course, of what is on the statutory books, what the laws look like. But equity also depends on what is actually delivered in practice. For me, at least, one of the insights of a number of the presentations today was that they highlighted some of the areas where effectiveness and equitable outcomes are also bound up with practice, and with the capacity and the skills that lead to equity in practice. I think, in as much as the patent system is concerned for example, there are two core issues: one is the nature of the right as granted and the process that leads to a decision to grant; and the other is the life of the granted patent in the market place, the way it is used, the way it is traded with the licensing and negotiation that surround it. In both cases, there are very important practical matters, as well as the theoretical and legal concepts that structure the pre-grant process. We have heard discussion about the need for the examination process to adhere to core patent principles, a need for patent processing to cleave, as far as possible, to the ideal that is expressed by patent criteria. Now we all know as a matter of inevitable practice, that no decision making process can be perfect in the patent area. No patent examiner is omniscient and indeed, when patents are tested in court, they are not infrequently found to be invalid because of the vastly greater universe of information that is made available during the litigation process. So, one practical matter is to maximize the possibility or likelihood that a patent, as actually granted, will indeed be valid, that it will approach, as far as possible, the ideal that is represented by the criteria of novelty, inventive step and utility. There are necessary practical steps to improve that situation. One includes, for example, a greater focus on improving the prior art base, in as much it is relevant to genetic resources and traditional knowledge and there are a number of practical initiatives underway in that regard. This has gone to the heart of some of the basic tools of the patent system - the International Patent Classification and the minimum documentation of the Patent Cooperation Treaty, by way of example. And looking also at the post-grant situation, for me at least, the most informative and insightful material came forward with the practical examination of how rights are actually used in the marketplace and what regulatory mechanisms are applied in the case that patent rights are misused in the marketplace. It was interesting, too, to see a certain degree of self-correction and mutual self-interest, if you like, where differing commercial players have a common interest in having their respective complementary technologies brought through successfully to the market, and the cooperation that that induced. So I think, Mr. Chair, some of the important insights that certainly I can take away from the discussions relate to the very practical aspects of actually delivering equity and actual effectiveness in achieving public policy outcomes, as against some of the theoretical debate.

* * * *

Closing Remarks

H.E. MR. ALEJANDRO JARA
Ambassador and Permanent Representative of Chile, Geneva

Ladies and gentlemen,
Friends and colleagues,

As we are approaching 5.00 p.m. we must bring this Symposium to a close.

I would like to say a few general remarks. They must be general as my understanding of the issues, though greatly improved, is still inadequate. Fortunately there is no right to reply, so no one can criticize me, in public!

We face big challenges and questions in this increasingly interdependent globalized world, and those challenges will increase. They relate to very important and key public policy issues.

To come up with the appropriate answers to these questions and challenges, we need new knowledge, and thus we need to invest in new knowledge. In this regard effective intellectual property protection is of the essence. We have heard today of some experiences, national and regional, as well as some success stories in developing countries. But we have been reminded that much needs to be done.

The two systems, one of patents and the other of plant variety protection, have evolved over time and will continue to evolve. This takes place in and made possible by a flexible framework contained in Article 27.3(b) of the TRIPS Agreement. We have also been made aware that, in the end, there is no perfect or a best system; there are different realities and cultures to which the systems have to adapt.

These are extremely complex issues in terms of public policy choices such as private rights, investment incentives, incentives to improve varieties, questions of sustainable development, implementation problems of both a legal and institutional nature and good governance.

The two systems have co-existed out of necessity. This relationship of co-existence needs to improve over time in the light of some grey areas which will have to be settled and defined by legislators or by regulators or by the Courts, depending on the particular national system in which you are operating. At the end of the day we have an evolving world, we have big challenges that we have to convert into big opportunities. We need, I believe, more work - more and better data and analyses, not only of a legal nature, but also from the point of view of sound economics.

I shall leave my remarks to that and, on behalf of Dr. Kamil Idris, in his capacity as Director General of WIPO and Secretary-General of UPOV, I would like to thank you all, to thank the participants that have congregated here and the speakers who have contributed to a decisive extent to enlighten discussions on the subject. From an organizational point of view, a particular thanks to those who, without being particularly mentioned, have put their efforts into this Symposium, to the interpreters for their efficient work. Finally, I would like to thank, on behalf of you all, WIPO and UPOV for organizing this event. This has attracted a large number of participants, over 200 including speakers and Secretariat.

I would like to remind you that the presentations will be posted immediately in the WIPO and UPOV Websites. The transcriptions of the discussion will be posted in the near future and participants will receive an electronic notification to this effect.

I would like to thank you all once again and bring this Symposium to a close. For those of you who come from far away, I wish you a safe journey back home.

List of Participants

* Les noms et titres qui figurent dans la liste ci-après sont reproduits tel qu'ils ont été communiqués au Secrétariat jusqu'au 25 octobre 2002.

* Names and titles in the following list are reproduced as communicated to the Secretariat by October 25, 2002.

* Los nombres y cargos que figuran en la presente lista están reproducidos tal y como fueron comunicados a la Secretaría hasta el 25 de octubre de 2002.

AFRIQUE DU SUD / SOUTH AFRICA / SUDÁFRICA

Shadrack R. MOEPHULI, Assistant Director-General: Agriculture Production, Department of Agriculture, Pretoria

Joan SADIE (Mrs.), Principle Plant and Quality Control Officer, Directorate: Genetic Resources, Stellenbosch

ALGÉRIE / ALGERIA / ARGELIA

Kamel LATROUS, directeur général, Centre national de contrôle et de certification (CNCC), Ministère de l'agriculture et du développement rural, Alger

Abdelkarim OULD RAMOUL, Sous-Directeur des homologations, Direction de la Protection des Végétaux et des Contrôles Technique (DPVCT), Alger

ALLEMAGNE / GERMANY / ALEMANIA

Udo VON KRÖCHER, President, Federal Office of Plant Varieties, Hanover

Michael KÖLLER, Head of Legal Section, Federal Office of Plant Varieties, Hanover

Ulricke KASSNER (Ms.), Assistant Head of Division, Federal Ministry of Consumer Protection, Food and Agriculture, Berlin

ARABIE SAOUDITE / SAUDI ARABIA / ARABIA SAUDITA

Shayea A. AL SHAYEA, Director General, General Directorate of Patents, King Abdulaziz City for Science and Technology (KACST), Riyadh

ARGENTINE / ARGENTINA

Marcelo LABARTA, Director de Registro de Variedades, Secretaría de Agricultura, Ganadería, Pesca y Alimentos (SAGPyA), Ministerio de la Producción, Buenos Aires

Carmen Amelia M. GIANNI (Sra.), Directora de Asuntos Jurídicos, Secretaría de Agricultura, Ganadería, Pesca y Alimentos (SAGPyA), Ministerio de la Producción, Buenos Aires

AUTRICHE / AUSTRIA

Josef HINTERHOLZER, Head of Plant Variety Protection Office, Federal Office of Food Security, Vienna

Reinhold MOSSER, Austrian Patent Office, Vienna

BELGIQUE / BELGIUM / BÉLGICA

Camille VANSLEMBROUCK (Mme), ingénieur, Office de la propriété intellectuelle, Bruxelles

BRÉSIL / BRAZIL / BRASIL

Vera Lúcia DOS SANTOS MACHADO (Sra.), Servicio Nacional de Protección de Cultivares (SNPC), Ministerio de Agricultura, Ganadería y Abastecimiento, Brasilia, D.F.

BULGARIE / BULGARIA

Panayot DIMITROV, Head, Chemistry, Biotechnology, Plant Varieties and Animal Breeds, Patent Office of the Republic of Bulgaria, Sofia

CANADA / CANADÁ

Valerie SISSON (Ms.), Commissioner, Plant Breeders' Rights Office, Canadian Food Inspection Agency (CFIA), Ottawa,

Glyn CHANCEY, Director, Plant Production Division, Canadian Food Inspection Agency (CFIA), Ottawa

Cameron MACKAY, First Secretary, Permanent Mission, Geneva

CHILI / CHILE

Rosario SANTANDER KELLY (Sra.), Jefa de Gabinete del Director Nacional, Servicio Agrícola y Ganadero (SAG), Santiago

Rosa MESSINA CRUZ (Sra.), Directora, Departamento de Semillas, Servicio Agrícola y Ganadero, Ministerio de Agricultura, Santiago

Enzo CERDA, Jefe Subdepartamento Registro de Variedades, Departamento de Semillas, Servicio Agrícola y Ganadero (SAG), Ministerio de Agricultura, Santiago

CHINE / CHINA

LI Yanmei (Mrs.), Project Administrator, Department for International Cooperation, State Intellectual Property Office (SIPO), Beijing

GUO Ruihua, Deputy Director, Office for Protection of New Varieties of Plants, Ministry of Agriculture, Beijing

LIN Xiangming, Director, Science, Technology and Education Department, Ministry of Agriculture, Beijing

ZHAO Yangling (Mrs.), First Secretary, Permanent Mission, Geneva

COLOMBIE / COLOMBIA

Ana Luisa DÍAZ JIMÉNEZ (Sra.), Coordinador Nacional, Derechos de Obtentor de Variedades y Producción de Semillas, Instituto Colombiano Agropecuario (ICA), Bogotá

CONGO

Delphine BIKOUTA (Mme), premier conseiller, Mission permanente, Genève

CROATIE / CROATIA / CROACIA

Ruzica ORE (Mrs.), Head of Plant Variety Protection and Registration, Institute for Seeds and Seedlings, Osijek

DANEMARK / DENMARK / DINAMARCA

Jette PETERSEN (Mrs.), Chief Adviser, Ministry of Food, Agriculture and Fisheries, Copenhagen

Kent HARNISCH, Head of Section, Ministry of Food, Agriculture and Fisheries, Copenhagen

ÉGYPTE / EGYPT / EGIPTO

Ahmed ABDEL-LATIF, Third Secretary, Permanent Mission, Geneva

ESPAGNE / SPAIN / ESPAÑA

Ricardo LÓPEZ DE HARO Y WOOD, Director, Oficina Española de Variedades Vegetales (OEVV), Ministerio de Agricultura, Pesca y Alimentación (MAPA), Madrid

Luis SALAICES, Jefe de Área del Registro de Variedades, Oficina Española de Variedades Vegetales (OEVV), Ministerio de Agricultura, Pesca y Alimentación (MAPA), Madrid

Javier MANSO TOMICO, Técnico Superior Examinadaor, Departamento de Patentes, Oficina Española de Patentes y Marcas, Ministerio de Cienca y Tecnología, Madrid

ESTONIE / ESTONIA

Pille ARDEL (Mrs.), Head of Department, Variety Control Department, Plant Production Inspectorate, Viljandi

ÉTATS-UNIS D'AMÉRIQUE / UNITED STATES OF AMERICA / ESTADOS UNIDOS DE AMÉRICA

Paul M. ZANKOWSKI, Commissioner, Plant Variety Protection Office, Agricultural Marketing Service, United States Department of Agriculture (USDA), Beltsville

Karen M. HAUDA (Mrs.), Patent Attorney, Office of International Affairs, United States Patent and Trademark Office (USPTO), Washington

FÉDÉRATION DE RUSSIE / RUSSIAN FEDERATION / FEDERACIÓN DE RUSIA

Yuri A. ROGOVSKIY, Deputy Chairman, Chief of Methods Department, State Commission of the Russian Federation for Selection Achievements Test and Protection, Moscow

Madina OUMAROVA (Mrs.), Expert of Methods Department, State Commission of the Russian Federation for Selection Achievements Test and Protection, Moscow

FINLANDE / FINLAND / FINLANDIA

Arto VUORI, Director, Plant Variety Rights Office, Ministry of Agriculture and Forestry, Helsinki

FRANCE / FRANCIA

Nicole BUSTIN (Mlle), secrétaire général, Comité de la protection des obtentions végétales (CPOV), Ministère de l'agriculture et de la pêche, Paris

J.P. MULLER, Département des brevets, Institut national de la propriété industrielle (INPI), Paris

GRÈCE / GREECE / GRECIA

ZAGGILIS, Directorate of Inputs for Crop Production, Section A, General Directorate for Plant Production, Ministry of Agriculture, Athens

HONGRIE / HUNGARY / HUNGRÍA

Mária PETZ-STIFTER (Mrs.), Patent Examiner, Hungarian Patent Office, Budapest

IRAN (RÉPUBLIQUE ISLAMIQUE D') / IRAN (ISLAMIC REPUBLIC OF) / IRÁN (REPÚBLICA ISLÁMICA DEL)

Hekmatollah GHORBANI, Permanent Mission, Geneva

IRLANDE / IRELAND / IRLANDA

John V. CARVILL, Controller of Plant Breeders' Rights, Plant Variety Rights Office, Department of Agriculture and Food, National Crop Variety Testing Centre, Leixlip

ISLANDE / ICELAND / ISLANDIA

Hólmgeir BJÖRNSSON, Senior Scientist, Agricultural Research Institute, Reykjavik

JAMAHIRIYA ARABE LIBYENNE / LIBYAN ARAB JAMAHIRIYA / JAMAHIRIYA ARABE LIBIA

Khames IHDAYB, Libyan Central Intellectual Property Office, National Board for Scientific Research, Tripoli

Ibrahim H. ZAEDEE, Biotechnology Research Center, Tripoli

Abdelhamid S. HAMEID, Biotehnology Research Center, Tripoli

JAPON / JAPAN / JAPÓN

Jun KOIDE, Deputy Director, International Affairs, Seeds and Seedlings Division, Ministry of Agriculture, Forestry and Fisheries (MAFF), Tokyo

LITUANIE / LITHUANIA / LITUANIA

Rimvydas NAUJOKAS, Director, State Patent Bureau of the Republic of Lithuania, Vilnius

LUXEMBOURG / LUXEMBURGO

Marc WEYLAND, Chef de Service de la production végétale, Administration des services techniques de l'agriculture, Luxembourg

MALAISIE / MALAYSIA / MALASIA

W.A.Y. WAN ABDUL RASHID, Second Secretary, Permanent Mission, Geneva

MAURICE / MAURITIUS / MAURICIO

Hemraj JALIM, Technical Officer, Plant Pathology Division, Ministry of Agriculture, Food Technology & Natural Resources, Reduit

MEXIQUE / MEXICO / MÉXICO

Enriqueta MOLINA MACÍAS (Sra.), Encargada del Despacho de la Dirección, Servicio Nacional de Inspección y Certificación de Semillas (SNICS), Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA), Tlalnepantla

Mauricio GARCÍA, Representante, Secretaría de Medio Ambiente y Recursos Naturales, Misión Permanente ante la Organización Mundial de Comercio (OMC), Ginebra

Jesús VEGA HERRERA, Instituto Mexicano de la Propiedad Industrial (IMPI), México

Karla Tatiana ORNELAS LOERA (Sra.), Tercera Secretaria, Misión Permanente, Ginebra

NICARAGUA

Patricia CAMPBELL GONZÁLEZ (Sra.), Primera Secretaria, Misión Permanente, Ginebra

NORVÈGE / NORWAY / NORUEGA

Haakon SØNJU, Registrar, Plant Variety Board, Aas

Grethe EVJEN (Ms.), Senior Advisor, Royal Ministry of Agriculture, Oslo

Veslemoy-Susanne GUNDERSEN (Ms.), Legal Advisor, Royal Ministry of Agriculture, Oslo

OUGANDA / UGANDA

Denis T. KYETERE, Director of Research, Coffee Research Institute (CORI), Ministry of Agriculture, Animal Industry and Fisheries, Mukono, Kituza

PANAMA / PANAMÁ

Lilia CARRERA (Mme), analyste de commerce exterieur, Mission permanente auprès de l'OMC, Genève

Katia CASTILLO (Mme), attaché Agricole, Mission permanente auprès de l'OMC, Genève

PARAGUAY

María Estela OJEDA GAMARRA (Sra.), Jefa, Departamento Registro de Cultivares, Dirección de Semillas (DISE), Ministerio de Agricultura y Ganadería, San Lorenzo

PAYS-BAS / NETHERLANDS / PAÍSES BAJOS

Chris M.M. VAN WINDEN, Manager Propagating Material, Ministry of Agriculture, Nature Management and Fisheries, The Hague

Krieno Adriaan FIKKERT, Secretary, Board for Plant Breeders' Rights, Wageningen

Sabina VOOGD (Ms.), Senior Policy Advisor, Ministry of Foreign Affairs, s'Gravenzande

PÉROU / PERU / PERÚ

Alejandro NEYRA SÁNCHEZ, Tercero Secretario, Misión Permanente, Ginebra

POLOGNE / POLAND / POLONIA

Edward S. GACEK, Director General, Research Centre for Cultivar Testing (COBORU), Slupia Wielka

Julia BORYS (Ms.), Head, DUS Testing Department, Research Centre for Cultivar Testing (COBORU), Slupia Wielka

PORTUGAL

Carlos PEREIRA GODINHO, Jefe, Centro Nacional de Registro de Variedades, Dirección General de Protección de Cultivos (DGPC) Ministerio de Agricultura, Desarrollo Rural y Pesca, Lisboa

RÉPUBLIQUE DE CORÉE / REPUBLIC OF KOREA / REPÚBLICA DE COREA

CHOI Keun-Jin, Examination Officer/Senior Researcher, Plant Variety Protection Division, National Seed Management Office (NSMO), Anyang City

RÉPUBLIQUE ARABE SYRIENNE / SYRIAN ARAB REPUBLIC / REPÚBLICA ÁRABE SIRIA

Mohammad-Ghiath IBRAHIM, Attaché, Mission permanente, Genève

Mohammad KHAFIF, conseiller, Mission permanente, Genève

RÉPUBLIQUE DE MOLDOVA / REPUBLIC OF MOLDOVA / REPÚBLICA DE MOLDOVA

Dumitru BRINZILA, President, State Commission for Crops Variety Testing and Registration, Ministry of Agriculture, Chisinau

RÉPUBLIQUE TCHÈQUE / CZECH REPUBLIC / REPÚBLICA CHECA

Daniel JUREKA, Director, Plant Variety Division, Central Institute for Supervising and Testing in Agriculture (ÚKZÚZ), Brno

Jirí SOUCEK, Head of Department, Department of Plant Variety Rights and DUS Tests, Central Institute for Supervising and Testing in Agriculture (UKZUZ), Praha

RÉPUBLIQUE-UNIE DE TANZANIE / UNITED REPUBLIC OF TANZANIA / REPÚBLICA UNIDA DE TANZANÍA

Irene KASYANJU, Counsellor, Permanent Mission, Geneva

ROUMANIE / ROMANIA / RUMANIA

Adriana PARASCHIV (Mrs.), Head of Division, Examination Department, State Office for Inventions and Trademarks (OSIM), Bucharest

Mihaela Rodica CIORA (Mrs.), Deputy Executive Director, State Institute for Variety Testing and Registration, Ministry of Agriculture, Food and Forestry, Bucharest

Ruxandra URUCU (Ms.), Legal Adviser, Legal and International Affairs Division, State Office for Inventions and Trademarks (OSIM), Bucharest

SERBIE-ET-MONTÉNÉGRO / SERBIA AND MONTENEGRO / SERBIA Y MONTENEGRO

Jovan VUJOVIC, Counsellor, Division for Seed and Seedlings, Ministry of Agriculture and Water Management, Belgrade

SUISSE / SWITZERLAND / SUIZA

Martin GIRSBERGER, co-chef, Service juridique Brevets et Dessins, Division Droit et Affaires internationales, Institut fédéral de la propriété intellectuelle, Berne

Eva TSCHARLAND (Mme), assistante juridique, Office fédérale de l'agriculture, Berne

Marie WOLLHEIM (Mme), conseillère juridique, Institut fédéral de la propriété intellectuelle, Berne

SUÈDE / SWEDEN / SUECIA

Carl JOSEFSSON, Deputy Director, Ministry of Justice, Stockholm

Marianne SJÖBLOM (Mrs.), Senior Administrative Officer, Ministry of Agriculture, Food and Fisheries, Stockholm

TUNISIE / TUNISIA / TÚNEZ

Mounir BEN REJIBA, conseiller, Mission permanente, Genève

TURQUIE / TURKEY / TURQUÍA

Metin SEHITOGLU, Chief, General Directorate of Protection and Control, Ankara

Kamil YILMAZ, Director, Variety Registration and Seed Certification Centre, Ministry of Agriculture and Rural Affairs, Ankara

UKRAINE / UCRANIA

Valentyna ZAVALEVSKA (Mrs.), First Deputy Chairman, State Service on Right Protection for Plant Varieties, Kyiv

Kateryna VASCHUK (Mrs.), Member of Parliament of Ukraine, Head of Faction of Agrarian Party of Ukraine, Kyiv

Olena SAVYTSKA (Mrs.), Head, Department of Agroindustrial Management, Social and Labor Relations, Kyiv

Oksana ZHMURKO (Mrs.), Head, International Cooperation Department, Department of Scientific and Technical Provision for International Integration and Publishing Activity, Ukrainian Institute for Plant Variety Examination, Kyiv

URUGUAY

Gustavo BLANCO DEMARCO, Asesor, Ministerio de Ganaderia, Agricultura y Pesca

Carlos RODRÍGUEZ DU HAUTBOURG, Instituto Nacional de Semillas (INASE), Canelones

Alejandra DE BELLIS (Sra.), Primera Secretaria, Misión Permanente, Ginebra

ZIMBABWE

Bellah MPOFU (Mrs.), Registrar of Plant Breeders' Rights, Department of Research and Specialist Services, Seed Services, Ministry of Agriculture, Harare

II. ORGANISATIONS INTERNATIONALES INTERGOUVERNEMENTALES / INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS / ORGANIZACIONES INTERNACIONALES NO GOBIERNAMENTALES

ORGANISATION DES NATIONS UNIES POUR L'ALIMENTATION ET L'AGRICULTURE (FAO) / FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS (FAO) / ORGANIZACIÓN DE LAS NACIONES UNIDAS PARA LA AGRICULTURA Y LA ALIMENTACIÓN (FAO)

Nuria URQUÍA FERNÁNDEZ (Ms.), PGR Officer, Seed and Plant Genetic Resources Service, Plant Production and Protection Division, Agricultural Department, Rome

ORGANISATION MONDIALE DU COMMERCE (OMC) / WORLD TRADE ORGANIZATION (WTO) / ORGANIZACIÓN MUNDIAL DEL COMERCIO (OMC)

Jayashree WATAL (Mrs.), Counsellor, Intellectual Property Division, Geneva

Xiaoping WU (Mrs.), Legal Affairs Officer, Intellectual Property Division, Geneva

COMMUNAUTÉ EUROPÉENNE / EUROPEAN COMMUNITY / COMUNIDAD EUROPEA

Bart KIEWIET, President, Community Plant Variety Office (CPVO), Angers

Jacques GENNATAS, chef de Secteur - Droit d'obtenteurs, Direction générale santé et protection des consommateurs, Unité E1, chef du Secteur "Plant Variety Property Rights," Commission européenne, Bruxelles

Jean-Charles VAN EECKHAUTE, Directorate General: Trade, Unit F1, European Commission, Brussels

Mark CANTLEY, Advisor, Directorate for Biotechnology, Agriculture and Food, European Commission, Brussels

Martin EKVAD, Head of Legal Affairs, Community Plant Variety Office (CPVO), Angers

Patrick RAVILLARD, Counsellor, Permanent Delegation to the International Organizations, Geneva

CONSULTATIVE GROUP ON INTERNATIONAL AGRICULTURAL RESEARCH (CGIAR)

Victoria HENSON-APOLLONIO (Mrs.), Manager, Central Advisory Service on Intellectual Property (CAS), c/o International Service for National Agricultural Research (ISNAR), The Hague

INSTITUT INTERNATIONAL DES RESOURCES PHYTOGÉNÉTIQUES (IPGRI) / INTERNATIONAL PLANT GENETIC RESOURCES INSTITUTE (IPGRI) / EL INSTITUTO INTERNACIONAL DE RECURSOS FITOGENÉTICOS (IPGRI)

Marie-Eve MARTEL (Ms.), Intern - Policy, Maccarese

OFFICE EUROPEÉN DES BREVETS (OEB) / EUROPEAN PATENT OFFICE (EPO) / OFICINA EUROPEA DE PATENTES (OEP)

Pierre TREICHEL, Directorate Patent Law 5.2.1, Munich

ORGANISATION AFRICAINE DE LA PROPRIÉTÉ INTELLECTUELLE (OAPI) / AFRICAN INTELLECTUAL PROPERTY ORGANIZATION (OAPI) / ORGANIZACIÓN AFRICANA DE LA PROPIEDAD INTELECTUAL (OAPI)

Wéré Régine GAZARO (Mme), chef du Service des brevets et titres dérivés, Yaoundé

ORGANISATION DE COOPÉRATION ET DE DÉVELOPPEMENT ÉCONOMIQUES (OCDE) / ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD) / ORGANIZACIÓN DE COOPERACIÓN Y DESARROLLO ECONÓMICOS (OCDE)

Jean-Marie DEBOIS, administrateur principal, codes et systèmes agricoles, Division des échanges et marchés agricoles, Direction de l'alimentation, de l'agriculture et des pêcheries, Paris

III. ORGANISATIONS NON GOUVERNEMENTALES / NON-GOVERNMENTAL ORGANIZATIONS / ORGANIZACIONES NO GUBERNAMENTALES

Asociación Ixacavaa de Desarrollo e Información Indígena (IXACAVAA)
Odir BLANCO CRUZ, Consultor indígena, San José

Association des obtenteurs horticoles européens (AOHE) / Association of European Horticultural Breeders (AOHE) / Asociación de Obtentores Hortícolas Europeos (AOHE)
Pierre TRIOREAU, secréraire général, c/o Société nationale d'horticulture de France (SNHF), Association des obtenteurs horticoles européens (AOHE), Paris
Sonia MEILLAND (Ms.), Meilland International, Le Luc-en-Provence

Centre d'études internationales de la propriété industrielle (CEIPI) / Centre for International Industrial Property Studies (CEIPI) / Centro de Estudios Internacionales de la Propiedad Industrial (CEIPI)
François CURCHOD, Professeur associé, Université Robert Schuman de Strasbourg, Genolier

Communauté internationale des obtenteurs de plantes ornementales et fruitières de reproduction asexuée (CIOPORA) / International Community of Breeders of Asexually Reproduced Ornamental and Fruit-Tree Varieties (CIOPORA) / Comunidad Internacional de Obtentores de Variedades Ornamentales y Frutales de Reproducción Asexuada (CIOPORA)
René ROYON, secrétaire général de CIOPORA, Bois de Font Merle
Maarten LEUNE, President of CIOPORA, Royalty Administration International (RAI), s'-Gravenzande

Agence européene des semences (Esa) / European Seed Association (Esa)
Joachim WINTER, Secretary General of ESA, Brussels
Garlich VON ESSEN, Director, European Seed Association (ESA), Brussels
Peter LANGE, Chairman of the Intellectual Property Committee of ESA
Claude GRAND, R.A.G.T. Génétique, Rodez, France

Association internationale pour la protection de la propriété Industrielle (AIPPI) / International Association for the Protection of Industrial Property (AIPPI) / Asociación Internacional para la Protección de la Propiedad Industrial (AIPPI)
S. Claire BALDOCK (Mrs.), Member Q114: Biotechnology, Zurich

Les amis de la terre - France / Friends of the Earth - France
Cédric CABANNE, chargé de campagne agriculture, Montreuil

Comité consultatif mondial des amis (CCMA) / Friends World Committee for Consultations (FWCC) / Comité Mundial de la Consulta de los Amigos (CMCA)
Jonathan HEPBURN, Programme associate, Geneva

Fédération internationale des semences (ISF) / International Seed Federation (ISF) / Federación Internacional De Semillas (ISF)
Radha RANGANATHAN (Ms.), Technical Director, Nyon
Werner BASTIAN, Senior Patent Attorney - Head Patents Basel, Syngenta, Basel
Marcel BRUINS, Manager Plant Variety Protection, Seminis Vegetable Seeds, Intellectual Resource Protection and Regulatory Affairs, Wageningen
Richard CROWDER, Chief Executive Officer, American Seed Trade Association (ASTA), Alexandria
Jean DONNENWIRTH, Pioneer Overseas Corporation, Brussels
Huib GHIJSEN, Global Manager Germplasm Protection, Oilseeds Department, Bayer BioScience N.V., Gent
Christopher HERRLINGER, German Association of Plant Breeders, Bonn
Thomas KRAMER, Responsible for Intellectual Property Protection, Seminis Vegetable Seeds, Wageningen
Peter LANGE, Head, Legal Department, KWS Saat AG, Einbeck
Martine MARCHAND (Mme), secrétaire général, SEPROMA, Paris
Kees NOOME, IPR Manager, Advanta BV, Kapelle
Pierre ROGER, directeur de la propriété intellectuelle, Groupe Limagrain Holding, Chappes
Walter SMOLDERS, Head of Biotechnology Patenting, Intellectual Property, Syngenta Crop Protection AG, Basel
Marick VAN DIJK (Mrs.), Plantum NL, Gouda
Peder WEIBULL, Svalof Weibull, Sweden

Association internationale d'essais de semences (ISTA) / International Seed Testing Association (ISTA) / Asociación Internacional para el Ensayo de Semillas (ISTA)
Michael MUSCHICK, Secretary General, Bassersdorf

Institut Max Planck pour la propriété intellectuelle (MPI) / Max Planck Institute For Intellectual Property (MPI) / Instituto Max Planck para la Propiedad Intelectual (MPI)
Eva WILLNEGGER (Mrs.), Munich

IV. PARTICULIERS* / INDIVIDUALS* / PARTICULARES*

(dans l'ordre alphabétique des noms français des États)
(in the alphabetical order of the names in French of the States)
(por orden alfabético de los nombres en francés de los Estados)

AFRIQUE DU SUD / SOUTH AFRICA / SUDÁFRICA

Mark LAING, Professor and Chair, Plant Pathology, University of Natal, Pietermartizburg

ALLEMAGNE / GERMANY / ALEMANIA

Ludwig WILLNEGGER, Ludwig-Maximilian-Universitat, Munich

Eslah STARK (Mrs.), Consultant, GTZ, Munich

BULGARIE / BULGARIA

Ivan IVANOV, President, IP Consulting Ltd., Sofia

CAMEROUN / CAMEROON / CAMERÚN

Madeleine NGO LOUGA (Ms.), Economist, Executive Coordinator, Health and Environment Program, Yaoundé

DANEMARK / DENMARK / DINAMARCA

Kurt HJORTSHOLM, Director, Sejet Plant Breeding, Horsens

ÉGYPTE / EGYPT / EGIPTO

Walter FROELICH, Team Leader, GTZ, Cairo

FRANCE / FRANCIA

Claire NEIRAC-DELEBECQUE (Mme), Juriste (propriété intellectuelle), CIRAD, Montpellier

Barry GREENGRASS, Chilly

IRLANDE / IRELAND / IRLANDA

Gerard DOWNES, Researcher, Department of Politics and Public Administration, University of Limerick, Limerick

NORVÈGE / NORWAY / NORUEGA

Morten Walloe TVEDT, Research Fellow, The Friotjof Nansen Institute, Oslo

---

* Grouped according to place of work/country of residence.
Groupés selon le lieu du travail et/ou pays de résidence.
Agrupados según el lugar de trabajo/país de residencia.

PAYS-BAS / NETHERLANDS / PAÍSES BAJOS

Klaas DE HAAN, Legal Affairs, De Ruiter Seeds, Bengschentoek

SUISSE / SWITZERLAND / SUIZA

Yohan ARIFFIN, maitre d'enseignement et de recherche, Université de Lausanne, Lausanne

Jacqueline FOSSATI (Mme), Ingénieurs du Monde, Genève

Alfred KÖPF, Patent Attorney, Feldmann & Partner AG, Glattbrugg

Promila KAPOOR-VIJAY (Mrs.), CSK HP Agriculture University, IWS Zurich University, Geneva

Vinenza TRIVIGNO (Ms.), Senior Advisor Economic Affairs, Syngenta, Basel

ROYAUME-UNI / UNITED KINGDOM / REINO UNIDO

Muriel LIGHTBOURNE (Mrs.), Senior Researcher, Queen Mary Intellectual Property Research Institute, London

URUGUAY

Guzman FERNÁNDEZ, Attorney-at-Law, O'Farrell Schmuckler, Montevideo

V. CHAIRMAN / PRÉSIDENT / PRESIDENTE

H.E. Mr. Alejandro JARA, Ambassador and Permanent Representative of Chile, Geneva

VI. ORATEURS / SPEAKERS / CONFERENCIANTES

Oscar DOMINGO, Director, Relmó, Buenos Aires, Argentina

John GERARD, President, Access Plant Technology, Inc., Plymouth, Indiana, United States of America

Jeffrey KUSHAN, Sidley, Austin, Brown & Wood, Washington, D.C., United States of America

Bernard LE BUANEC, Secretary General, International Seed Federation (ISF), Nyon, Switzerland

Rainer MOUFANG, Legal Member, Boards of Appeal, European Patent Office (EPO), Munich, Germany

Alexander OCHEM, Research Assistant, Molecular Biology, International Center for Genetic Engineering and Biotechnology, Trieste, Italy

Adrian OTTEN, Director, Intellectual Property Division, World Trade Organization (WTO), Geneva, Switzerland

Philip PARDEY, Science and Technology Policy, Department of Applied Economics, University of Minnesota, United States of America

Stephen SMITH, Research Fellow/Germplasm Security Coordinator, Pioneer Hi-Bred International Inc., DuPont Crop Agriculture and Nutrition, Johnston, United States of America

Arnold VAN WIJK, Head, Plant Variety Research Centre for Genetic Resources (CGN), Wageningen, Netherlands

Thanda WAI (Ms.), Intellectual Property Rights Specialist, International Rice Research Institute (IRRI), Laguña, Philippines

Qinfang WANG (Ms.), Associate Professor, Deputy Director of Research Management Division, Biotechnology Research Institute, Chinese Academy of Agricultural Sciences,
Beijing, China

VII. SECRÉTARIAT DE L'OMPI / WIPO SECRETARIAT / SECRETARÍA DE LA OMPI

Francis GURRY, Assistant Director General, Office of Legal and Organization Affairs and PCT System

Yoshiyuki TAKAGI, Senior Director, Office of Strategic Planning and Policy Development

Antony TAUBMAN, Acting Director and Head, Traditional Knowledge Division, Office of Legal and Organization Affairs and PCT System

Richard KJELDGAARD, Senior Counsellor, Biotechnology and Genetic Resources, Traditional Knowledge Division, Office of Legal and Organization Affairs and PCT System

Karen LEE RATA (Mrs.), Senior Counsellor, Office of the Special Counsel

VIII. SECRÉTARIAT DE L'UPOV / UPOV SECRETARIAT / SECRETARÍA DE LA UPOV

Rolf JÖRDENS, Vice Secretary-General

Peter BUTTON, Technical Director

Raimundo LAVIGNOLLE, Senior Counsellor

Makoto TABATA, Senior Counsellor

Yolanda HUERTA (Mrs.), Senior Legal Officer

Paul Therence SENGHOR, Senior Program Officer

Vladimir DERBENSKIY, Consultant

* * *