THE WORLD BANK

Intellectual Property Rights

Designing Regimes to Support Plant Breeding in Developing Countries

Agriculture and Rural Development Department

REPORT NO. 35517-GLB

Intellectual Property Rights

Designing Regimes to Support Plant Breeding in Developing Countries

THE WORLD BANK
AGRICULTURE AND RURAL DEVELOPMENT DEPARTMENT

© 2006 The International Bank for Reconstruction and Development / The World Bank
1818 H Street, NW
Washington, DC 20433
Telephone 202-473-1000
Internet www.worldbank.org/rural
E-mail ard@worldbank.org

All rights reserved.

This volume is a product of the staff of the International Bank for Reconstruction and Development/The World Bank. The findings, interpretations, and conclusions expressed in this paper do not necessarily reflect the views of the Executive Directors of The World Bank or the governments they represent. The World Bank does not guarantee the accuracy of the data included in this work. The boundaries, colors, denominations, and other information shown on any map in this work do not imply any judgment on the part of The World Bank concerning the legal status of any territory or the endorsement or acceptance of such boundaries.

The material in this publication is copyrighted. Copying and/or transmitting portions or all of this work without permission may be a violation of applicable law. The International Bank for Reconstruction and Development/ The World Bank encourages dissemination of its work and will normally grant permission to reproduce portions of the work promptly.

For permission to photocopy or reprint any part of this work, please send a request with complete information to the Copyright Clearance Center, Inc., 222 Rosewood Drive, Danvers, MA 01923, USA, telephone 978-750-8400, fax 978-750-4470, http://www.copyright.com/.

All other queries on rights and licenses, including subsidiary rights, should be addressed to the Office of the Publisher, The World Bank, 1818 H Street NW, Washington, DC 20433, USA, fax 202-522-2422, e-mail pubrights@worldbank.org.

Contents

Tables

Figures

Boxes

Acronyms and Abbreviations

AATF	African Agricultural Technology Foundation
AFLP	Amplified fragment length polymorphism
AICCIP	All-India Coordinated Crop Improvement Programs
ARIPO	African Regional Intellectual Property Organization
BIOEARN	Eastern Africa Regional Network on Biotechnology
BRI	Biotechnology Research Institute (China)
Bt	*Bacillus thuringiensis*
CAAS	Chinese Academy of Agricultural Sciences
CBD	Convention on Biological Diversity
CEO	Chief Executive Officer
CGIAR	Consultative Group on International Agricultural Research
CIAT	Centro Internacional de Agricultura Tropical (International Center for Tropical Agriculture)
CICR	Central Institute for Cotton Research (India)
CIMMYT	Centro Internacional de Mejoramiento de Maíz y Trigo (International Maize and Wheat Improvement Center)
CORPOICA	Corporación Colombiana de Investigación Agropecuaria (Colombian Corporation for Agricultural Research)
CRI	Cotton Research Institute (China)
DNA	Deoxyribonucleic acid
DPL	Delta and Pineland
DUS	Distinctness, uniformity, stability
EDV	Essentially derived variety
Embrapa	Empresa Brasileira de Pesquisa Agropecuária (Brazilian Agricultural Research Corporation)
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FEDEARROZ	Federación Nacional de Arroceros (National Federation of Rice Producers) (Colombia)
FLAR	Fondo Latinoamericano para Arroz de Riego (Latin American Fund for Irrigated Rice)

FtO	Freedom to operate
GDP	Gross domestic product
IARC	International Agricultural Research Center
ICA	Instituto Colombiano Agropecuario (Colombian Institute for Agriculture and Livestock)
ICAR	Indian Council of Agricultural Research
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
INASE	Instituto Nacional de Semillas (National Seed Institute) (Argentina)
IPR	Intellectual property right
IR	Imidazolinone resistant
IRRI	International Rice Research Institute
IT PGRFA	International Treaty for Plant Genetic Resources for Food and Agriculture
IVF	Institute for Vegetables and Flowers (China)
KARI	Kenya Agricultural Research Institute
KEPHIS	Kenya Plant Health Inspectorate Service
KIPI	Kenya Intellectual Property Institute
KSC	Kenya Seed Company
MAS	Marker assisted selection
MNC	Multinational corporation
MoA	Ministry of Agriculture
MTA	Material transfer agreement
NARI	National agricultural research institute (generic)
NARO	National Agricultural Research Organization (Uganda)
NBPGR	National Bureau for Plant Genetic Resources (India)
NBRI	National Botanical Research Institute (India)
NGO	Nongovernmental organization
NPTs	National Performance Trials (Kenya)
NSCS	National Seed Certification Service (Uganda)
OAPI	African Organization for Intellectual Property
OECD	Organization for Economic Cooperation and Development
OPV	Open-pollinated variety (as opposed to hybrid – in this report used for both normally out-crossing and self-fertilizing crops)
PCT	Patent Cooperation Treaty
PBR	Plant Breeders' Rights
PIPRA	Public Intellectual Property in Agriculture
PMA	Plan for the Modernization of Agriculture (Uganda)
PVP	Plant variety protection
RAPD	Random amplified polymorphic DNA
RFLP	Restriction fragment length polymorphism

PCR	Polymerase chain reaction
RR	Roundup Ready
SADC	Southern African Development Community
SIPO	State Intellectual Property Office (China)
SPLT	Substantive Patent Law Treaty
TRIPS	(WTO Agreement on) Trade Related Aspects of Intellectual Property Rights
UPOV	International Union for the Protection of New Varieties of Plants
USA	United States of America
USPTO	U.S. Patent and Trademark Office
V-GURT	Genetic use restriction technology operating at variety level
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Acknowledgments

This report was prepared by Rob Tripp (ODI), Derek Eaton, and Niels Louwaars (Wageningen University, NL) under the overall supervision of Eija Pehu (Task Team Leader) and Riikka Rajalahti (ARD).

The task team would like to extend thanks to Willem Janssen (SAR) and Indira Ekanayake (LCR) for their helpful comments on the manuscript. The team would also like to thank Jonathan Agwe (ARD), Kym Anderson (DEC), Carlos Braga (PRMTR), Charles Di Leva (LEGEN), Danielle Malik (LEGEN), Berhane Manna (AFR), Gayane Minasyan (EAP), David Nielson (AFR), Sari Soderstrom (EAP), Carl Pray (Rutgers University), and Michael Halewood (IPRGI) for their comments and suggestions during the preparation of this report.

The task team thanks Kevin Cleaver (Director, ARD) and Sushma Ganguly (Sector Manager, ARD) and the ARD Management Committee for their support and guidance. The team acknowledges Kelly Cassaday for editing and formatting the report, and Melissa Williams and Marisa Baldwin for their help with the logistics and production of the report.

Executive Summary

Increased attention has been given in the past few years to strengthening intellectual property rights (IPRs) in plant breeding. The number of countries that grant such rights has grown, the types of inventions that can be protected have expanded, and the scope of protection offered by extant IPR systems in different countries has also broadened. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS 1993) of the World Trade Organization (WTO) requires all WTO members to introduce at least a minimum level of protection in their national laws for plant varieties and inventions in biotechnology. Least Developed Countries recently managed to extend the deadline to 2013 for bringing their national IPR laws fully up to the TRIPS standards. Even so, this extension does not diminish the pressure to develop IPR legislation for plant varieties in several countries, because bilateral trade negotiations between developing countries and the USA or EU often include requirements that go beyond the TRIPS requirements (the so-called "TRIPS-plus" requirements). These developments towards strengthened IPRs arise from a trade perspective rather than from a perspective of increasing innovation in the developing countries concerned.

The TRIPS agreement is not the only international agreement related to regulatory systems affecting plant breeding. Others include the Convention on Biological Diversity, the International Treaty on Plant Genetic Resources for Food and Agriculture, and the discussions in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore of the World Intellectual Property Organization (WIPO). In addition, the development of a Substantive Patent Law Treaty (SPLT) as discussed within WIPO is likely to reduce the current flexibility to protect plant varieties (Wallø Tvet 2005). This report concentrates on the requirements arising from the TRIPS Agreement and IPR-related trade discussions, and it refers to the other agreements only when they relate directly to IPRs.

Plant breeding research and seed provision are vital industries that need to be fostered and stimulated. Plant breeding is important for food security at the local and global levels; the ability of adapted varieties to cope with environmental stresses contributes to strategies for sustainable agriculture, and the provision of productive options for commercial farming is essential for wider economic development. The twin challenges are first to understand the degree

to which stronger IPRs in plant breeding can help stimulate these industries and second to determine whether the IPR systems for plant varieties that have been developed in industrialized countries can contribute to development objectives.

This report is based on a field study of the impact of strengthened IPRs on the breeding industries in China, Colombia, India, Kenya, and Uganda. The analysis also makes use of secondary data and interviews with stakeholders from other countries.

IPRs AND PLANT BREEDING

Although a range of attempts have been made to provide some type of IPRs for plant varieties, only within the last several decades has a mechanism for plant variety protection (PVP) firmly taken hold in industrialized countries. The UPOV (International Union for the Protection of New Varieties of Plants) Conventions provide the most widespread model for PVP, and most countries of the Organization for Economic Cooperation and Development and a growing number of developing countries have implemented legislation compatible with one of these Conventions. However, UPOV is not the only possible option for designing a PVP system, and even within the UPOV Conventions there is a fair degree of flexibility that developing countries must appreciate and take advantage of if they are to design IPR regimes for plant breeding that meet their specific conditions and priorities. Of particular importance are issues related to farmer seed saving and exchange and issues concerning access to protected varieties for further research and development.

Increasingly, IPR regimes for plant breeding include attention to patent systems, particularly for biotechnology. Most of the genes and tools used in the development of transgenic crops are patented. Even many of the diagnostic and selection processes used in conventional plant breeding are patented, and their protection has implications for researchers' ability to use these tools and release varieties developed through these techniques. Developing countries still have relatively limited experience in managing patents for biotechnology.

It is also important not to lose sight of the fact that other mechanisms can protect the rights of plant breeders and seed producers and provide incentives for commercial seed system development, even in the absence of IPRs. Among the more important examples are biological (hybrid technology), regulatory (seed law and, more recently, biosafety law), legal (contract law), and commercial (business practices) mechanisms.

PLANT BREEDING AND SEED SECTORS IN DEVELOPING COUNTRIES

Until fairly recently in most developing countries, seed was supplied through the public sector. Recent private sector involvement has been a function of policy change. Any assessment of the specific impact of IPR regimes on seed industry performance and investment must be seen in the context of these wider changes in the commercial and policy environment. In the majority of developing countries, most of the plant breeding and some seed production still depend on the public sector, particularly national agricultural research institutes (NARIs), often supported by international agricultural research centers (IARCs).

Plant breeding and seed production are already subject to a set of national regulations on variety release and seed quality control. These regulations have played an important part in determining the current evolution of seed systems in developing countries. Recently established IPR systems in the seed sector are meant to act in concert with conventional seed regulations, and in some cases they are the impetus for further changes in national seed regulations.

IPR LEGISLATION AND MANAGEMENT FOR PLANT BREEDING

Relatively few developing countries have any significant experience with protecting varieties. The preliminary evidence indicates that the application of PVP in these countries tends to reinforce major domestic trends in the development of commercial seed systems rather than to open major new avenues or opportunities. In systems where there is heavy emphasis on hybrid varieties and considerable commercial competition, such as those in China and India, most interest centers on PVP for parent lines and hybrids. Where a market in commercial open-pollinated varieties (OPVs) is already established, the PVP system provides welcome additional protection for those markets.

In some cases in which a domestic seed industry is just emerging, companies may not feel it is worthwhile to take advantage of PVP. In countries where the production of ornamental plant materials is important, these materials dominate PVP applications.

Even though developing countries have relatively little experience with PVP, the systems that are in place demonstrate a fairly wide range of approaches to issues such as seed saving, the range of crops and varieties eligible for protection, and the treatment of Farmers' Rights. The case studies also indicate that many issues concerning the administration of PVP in developing countries remain to be addressed. For example, establishing facilities and providing staff to test varieties for distinctness, uniformity, and stability (DUS) represents a significant investment. No comprehensive guidance exists on how to set charges for PVP, and it is likely that current fee rates do not provide an optimal set of incentives for national plant breeding industries. There is also little experience with the enforcement of PVP.

IMPACTS OF IPRs ON SEED COMPANIES

The literature analyzing the impact of IPRs on plant breeding in the North provides only patchy evidence that PVP regimes have a significant influence on the size or nature of investments in the commercial seed sector. Thus it should not be surprising that it is difficult to document many instances in which a developing country's involvement with PVP has led to marked changes in direction for its domestic seed industry. One problem in looking for such relationships is the fact that the commercial seed sector in most developing countries is undergoing significant change because of government liberalization policies, making it difficult to attribute any changes to the establishment of an IPR regime.

Nevertheless, it is possible to demonstrate some positive contributions from recently established PVP systems in developing countries. Where domestic seed companies produce OPVs for commercial farmers, PVP helps stabilize the industry and protect companies from their competitors. Where parental lines of commercial hybrids are subject to misappropriation, PVP provides additional protection and makes companies more confident about their research investments. A PVP system may also make foreign seed companies more confident in sharing varieties with domestic partners. Even so, commercial seed industries have developed in the absence of IPRs (other than trademarks) in several countries, including India and Uganda. In the near future, PVP can be expected to have only a modest impact on the direction of domestic commercial seed markets, given that most PVP systems in developing countries cannot control farmer seed saving and possess very limited enforcement capabilities (because of inadequacies in legal systems, insufficient regulatory staff, and insufficient experience in the companies themselves).

The protection of transgenic crops has proven particularly difficult in developing countries. Most experience with transgenic crops revolves around Roundup-Ready soybean and Bt (*Bacillus thuringiensis*) cotton and shows that the presence of IPR systems is not necessarily correlated with the effectiveness of controlling access to seed of transgenic varieties. Indeed, the most effective control has been achieved through contracts in controlled output markets and the application of seed and biosafety regulations. The experience with transgenic crops emphasizes the importance of learning how to use a judicious combination of seed regulation, biosafety, and IPRs to provide a reasonable degree of protection to the providers of transgenic technology.

IMPACTS OF IPRs ON PUBLIC SECTOR PLANT BREEDING AND SEED PRODUCTION

The advent of IPRs for plant breeding has significant implications for public sector plant breeding in developing countries, yet very few NARIs have well-developed IPR policies or staff that are capable of dealing with these complex issues. One of the principal attractions of IPRs for NARIs is the possibility of using them to raise revenues, especially when NARIs increasingly are expected to generate a portion of their income. However, there are concerns about whether NARIs that focus on earning royalties can compete effectively (for staff and market share) with private sector plant breeding. There is also concern over how the focus on revenue will affect NARIs' public task. Some NARIs are beginning to apply for patents on some

of their innovations. The added revenue raises important administrative challenges about the division of royalty income within the NARI to reward innovators sufficiently while maintaining incentives for research that is less likely to be protected. The NARIs also need to know how to negotiate access to protected technologies and how to make the best use of their own innovations in the bargaining process.

The IARCs all have IPR policies, although most of these are still subject to adjustment and elaboration. The increased use of IPRs has caused IARCs to reevaluate their modes of interaction with both NARIs and seed companies. Varied approaches have been taken to ensure that NARI germplasm reaches the farmers for whom it is intended. Although IARCs make use of many protected technologies, they have very limited experience in assessing their freedom to operate or in knowing how and when to pursue patent protection for particular inventions.

LESSONS

IPRs should not be considered a silver bullet for commercial seed industry development. Because seed systems differ widely among countries and also within countries, between crops, and across regions, blueprint advice cannot be given to policy makers on how to design the ideal IPR system for plant breeding. Rights that are excessively broad in scope may obstruct the flow of technologies to resource-poor countries and farmers. On the other hand, IPRs may contribute to the development of commercial seed systems in certain sectors, and they may assist in the creation of effective public-private partnerships. This outcome will materialize, however, only when other conditions for business development are favorable.

Pressure to strengthen IPRs in plant breeding in developing countries presents both immediate and long-term challenges to policy makers and donors. The immediate challenges are related to framing and implementing appropriate legislation that is consistent with TRIPS and that supports national agricultural development goals. The longer-term challenges are derived from the fact that an IPR regime, on its own, is not likely to provide the incentives that elicit the emergence of a robust plant breeding and seed sector; attention to other institutions and the provision of an enabling environment are also necessary.

National policy makers must give immediate attention to the establishment and implementation of appropriate IPR legislation for plant breeding. Several *sui generis* models are available, including the UPOV Conventions, but even reliance on a model requires a number of choices. The most important parameters to determine are related to seed saving, seed exchange, the scope of protection, the breadth of coverage, and the relation of PVP and patents to the concerns of Farmers' Rights. These parameters deserve careful consideration before a decision is made on the use of a particular model for national legislation. Policy makers must also consider cost-effective means for implementing an IPR regime and ensuring that the IPR system is consistent with enforcement capabilities.

If they are to have their intended effect, IPR systems in plant breeding must be tailored to the conditions of national seed systems. Even within a single country, the requirements and conditions of different crop production systems are not uniform, and countries may consider legal options that address this variability. For example, strong protection may be provided for export agriculture and weak or no protection for noncommercial sectors that primarily cater for subsistence farmers. The absence of commercial incentives in noncommercial sectors, however, creates a (continued) responsibility for public investments in plant breeding and seed support systems.

Systems for PVP contain flexibility to balance benefits for breeders and farmers—a flexibility that is much more difficult to create within patent systems. Some patent systems have created openings for flexibility, however, either by excluding certain inventions from patentability or certain claims from being honored, or by providing explicit exemptions when protection may unduly affect farmers.

Developing IPRs for biotechnology in plant breeding requires greater attention to strengthening capacities in national patent offices. Countries that use transgenic varieties will need to ensure adequate protection, although in many cases credible enforcement of the right combination of biosafety regulations, seed laws, and PVP may offer adequate protection for transgenic varieties, at least in the early stages of their availability in developing countries.

Policy makers must recognize that the development of a commercial seed sector depends on

attention to other factors in the enabling environment, including seed regulations and the growth of agribusiness. Particular attention is also needed to ensure that policies encourage NARIs to fulfill their public sector mandate while taking advantage of IPRs to gain access to technology, guide the diffusion of their varieties, and, where appropriate, earn royalties.

The World Bank can assist developing countries by providing immediate support to national efforts at developing and implementing PVP legislation as well as by instituting longer-term strategies that foster the development of seed sector institutions. In the short term, the Bank can support opportunities for national (or, where relevant, regional) forums that promote debate and discussion about the shape of PVP legislation and its implementation. Discussions should emphasize (1) the necessity of structuring IPR regimes to evolve in concert with national seed systems, including the possibility of providing different levels of protection to different crops, and (2) the importance of key parameters within IPR models. The Bank can also sponsor meetings and other activities that explore possibilities for regional collaboration in the administration and management of PVP, and it can encourage stronger regional mechanisms for patent applications, including those in biotechnology. In addition, the World Bank can support further research that monitors experience with IPRs in developing countries and that examines issues related to the cost-effective management of IPR regimes.

There are also longer-term opportunities for the Bank to support the growth of seed sector institutions. Capacity building in national PVP and patent offices, as well as support for effective seed regulatory regimes, will be useful. Capacity building for regional collaboration is needed in both the IPR and seed regulatory domains. Bank-supported agribusiness projects should include reviews of IPR regimes and their implications for project success. World Bank support for NARIs should help develop adequate IPR policies and strategies, encourage more effective interaction with the private seed sector, and build competence in accessing protected technology.

1 Introduction

THE STRENGTHENING OF IPRs

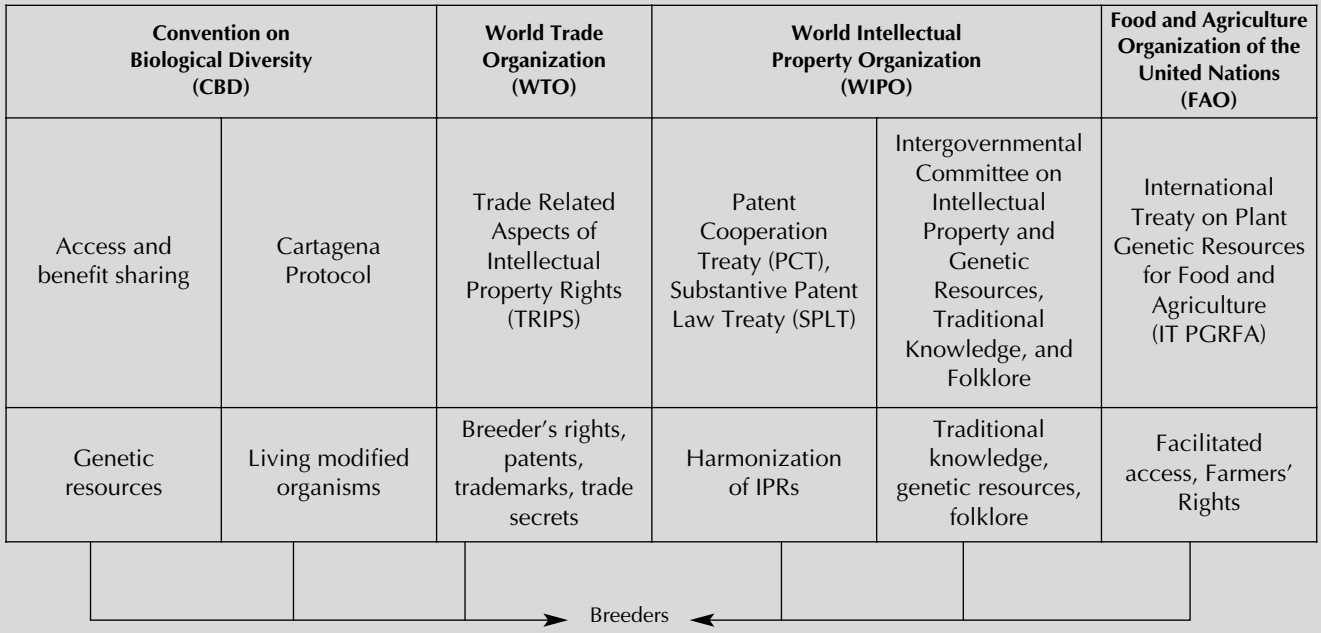
The past few years have seen increased attention to the strengthening of intellectual property rights (IPRs) in plant breeding. The number of countries that grant such rights has grown, the types of inventions that can be protected have expanded, and the scope of protection offered by extant IPR systems in different countries has broadened as well. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS 1993) of the World Trade Organization (WTO) dramatically changed the importance of IPRs in developing countries by requiring all WTO members to introduce at least a minimum level of protection of intellectual property in their national laws. Article 27.3(b) of the TRIPS Agreement asks all members to provide some form of protection for plant varieties. Patent protection needs to be available for all other inventions, including those in plant biotechnology.

The nature and scope of IPRs for genetic resources, including plant varieties, are also discussed in the frameworks of the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (IT PGRFA), which entered into force in 1993 and 2004, respectively. Additional pressure to protect plant varieties in developing countries (beyond the minimum requirements of TRIPS) is being exerted in bilateral trade negotiations between developing countries and the USA or EU. The importance of IPRs for plant breeding and the seed industry has been further enhanced by the development of plant biotechnology, which not only has engendered patents for the genes, tools, and processes that are an increasingly common part of modern plant breeding but has spurred the introduction of utility patents for plant varieties and hybrids in some countries.

IPRs are just one set of regulations based on international agreements that impact plant breeding and seed production. Although other international agreements influence plant breeding and seed production (figure 1.1), such as agreements over rights to traditional knowledge or national sovereignty over plant genetic resources, this report concentrates on the introduction of IPRs in developing countries as a result of the TRIPS Agreement. It refers to aspects of other agreements and organizations only when they are important to the discussion.

Systems for IPRs have been recognized for more than a century, yet until recently IPRs have not been an issue in the plant breeding and seed sector in most developing countries. Although IPR regimes

Figure 1.1 International Agreements that affect Plant Breeding



Source: Authors.

for agricultural inventions have been used widely in industrialized countries for decades, most developing countries are in the early stages of implementing and/or enforcing IPRs related to plant varieties. The use of IPRs in plant breeding in developing countries raises a number of important issues, including smallholders' access to technology, the role of public agricultural research, the growth of the domestic private seed sector, the status of farmer-developed varieties, and the growing North-South technology divide that restricts access to plant germplasm and research tools. Since access to seed and new crop varieties is fundamental for agricultural development and rural welfare, it is important to understand the impact of these legal systems on the breeding and seed sectors in developing countries.

IPRs IN PLANT BREEDING

Conventional IPRs protect printed text, inventions, industrial designs, trademarks, geographical indications, and trade secrets, all of which have different regimes for registration, scope, and duration of protection. Since none of these property rights is considered adequate for certain other sectors, additional, so-called "*sui generis*" systems have been developed for the protection of integrated computer circuits, databases, and plant varieties (Plant Breeders' Rights). Plant varieties present several important challenges for an IPR system. First, they are biological products that are easily reproduced and whose very use entails multiplication. Second, the users (and potential "copiers") of the technology are millions of individual farmers whose compliance with any protection regime is difficult and expensive to monitor. Third, the agricultural sector involves cultural values and food security and, in many countries, affects the livelihoods of the rural poor, making the imposition of any controls a sensitive political issue. Fourth, the inherent diversity of plant varieties makes it difficult to apply the narrow technical criteria of novelty and reproducibility used in the conventional patent system, whereas the use of standard breeding methodologies may frustrate the application of the "inventive step" criterion. Finally, the development of new plant varieties has always relied to some extent on public research, partly in response to the traditional public good nature of crop germplasm, and the application of IPRs to the products of a publicly funded endeavor can be problematic.

The advent of modern biotechnology has brought additional challenges for the application of IPRs in plant breeding. Not only do some countries allow

the use of patents to protect plants, varieties, and genes, but the majority of the tools and processes of molecular biology and genetic transformation can be patented as well (Appendix A). Many of the techniques of biotechnology, which are an increasingly important part of conventional plant breeding, are also protected, raising implications for the ownership of any variety resulting from such research. Finally, because biotechnology allows a much more precise understanding of the genetic makeup of any crop variety, it opens the door to sophisticated screening and reverse engineering techniques, which in turn offer new possibilities for utilizing protected varieties, leading to pressure for more stringent protection.

IPRs AS A POLICY ISSUE

Plant breeding research and seed provision are vital industries that need to be fostered and stimulated. Plant breeding is important for food security at the local and global levels. The ability of adapted varieties to cope with environmental stresses contributes to strategies for sustainable agriculture, and the provision of productive options for commercial farming is essential for wider economic development. IPR regimes for plant breeding can play a part in agricultural development, but the challenge is to strike the right balance between incentives for innovation and access to productive resources. An IPR regime in plant breeding should perform two basic roles. First, in the interest of the public, the IPR regime should ensure that knowledge and materials enter the public domain at some point, and it should stimulate improvements and innovations that increase the choices available to farmers and consumers. Second, in the interest of the rights holder, the IPR regime should provide opportunities for breeders to recoup their investments, which may include the rights:

- to keep farmers from saving seed of the protected variety, sharing the seed with neighbors, or engaging in informal sale of the seed;
- to keep competing commercial seed producers from multiplying and marketing the protected variety without a license; and
- to keep competing plant breeders from using a protected variety or technology in the development of a new variety.

The role of IPRs in agriculture is an exceptionally controversial subject. The debates involve complex arguments defended by a range of interest groups. The optimum design of IPR regimes will vary according to local economic, institutional, and agricultural circumstances and will change as these determining conditions evolve. It is unrealistic to believe that there are any simple, uniform, or permanent formulas that will provide ready-made solutions. It is important to recall that IPR regimes are rights and privileges that are granted at the national level in order to contribute to the public good. It is therefore the responsibility of policy makers to define the particular societal goals that IPRs in agriculture are meant to address and to develop appropriate legislation.

THE ORIGINS OF THIS REPORT

This report is based on an empirical analysis of the conduct and performance of IPR regimes for plant breeding in developing countries. It attempts to draw useful lessons to guide national policy makers and donors who are concerned with establishing effective and relevant IPR systems. This report is based on a study that was commissioned by the World Bank in late 2003 and carried out in 2004. The preliminary results and conclusions were discussed with World Bank staff and specialists in agricultural IPRs in November 2004, and a summary of the study has been published (Louwaars et al. 2005).

Because relatively few developing countries have experience with IPRs in plant breeding, and because an assessment of that experience requires in-depth fieldwork, a wide range of evidence had to be sought in a small number of developing countries that have started implementing IPR regimes in agriculture. The five countries chosen for case studies represent major segments of developing country agriculture, geographical spread, and levels of experience with IPRs (box 1.1).

A team of nine researchers from Europe and the case study countries worked on the study. They reviewed the literature and developed interview protocols for the case study countries to obtain comparable sets of data. Interviews were conducted with large numbers of stakeholders in each country, representing public plant breeding and seed production, the private seed sector, IPR and regulatory agencies, and farmers and farmer groups. Data and reports were also collected and analyzed, and interviews were conducted with representatives of the commercial seed sector in industrialized countries.

Box 1.1 Countries Included in the Study

China is among the most important agricultural economies in the world and has experience in implementing most relevant IPR systems over the past several years. It has a substantial domestic capacity in plant breeding and biotechnology. The seed industry is developing rapidly through private investment (local and foreign) and through the commercialization of a large number of public research and seed enterprises at the national, provincial, and prefectural levels. China is a market that attracts investors and inventors from all over the world. The country also has a significant area planted to transgenic crops.

Colombia is one of the Latin American countries with the most experience with IPRs in the breeding and seed sectors. It has a diverse agriculture, ranging from subsistence farming to several important agricultural exports, and an emerging use of transgenic crops. Different crops attract different seed production systems, with local companies investing in a number of food crops and multinational investments in cotton, maize, and flower seed production.

India has a very well developed agricultural research capacity in breeding and biotechnology, and its large market attracts considerable interest from abroad. It has a thriving private seed sector, with many small- and medium-scale local companies and a number of joint ventures with multinationals, existing alongside an extensive public seed production and research infrastructure. India's approach to agricultural IPRs has resulted in recently enacted legislation that has a number of unique characteristics and is the product of prolonged and wide-ranging public debate.

Kenya is the Sub-Saharan African country with the longest experience with IPRs in the breeding and seed sector after South Africa. Its very diverse agriculture ranges from subsistence to export sectors, and Kenya maintains a relatively open policy towards biotechnology. Its national seed company faces growing competition from local and foreign companies. The horticultural industry—encompassing both flower and vegetable crops—established the presence of foreign providers of planting materials and seed in the country.

Uganda does not yet have an operational IPR system in the breeding and seed sector, but it has a diversifying commercial agricultural sector. It may be considered a representative of the large number of developing countries that are still in the process of establishing an IPR regime. Its public seed enterprise has been privatized and is losing market share to emerging private seed companies. Seed production of field crops for export is emerging, as is the flower industry, which depends on Kenya-based suppliers of planting materials.

More detailed information on the seed systems of these countries is presented in Appendix B.

Source: Authors.

The present document summarizes the findings from the study, includes relevant information from other developing countries, and draws lessons for policy makers who are concerned with designing and operating appropriate IPR regimes for their countries.

THE STRUCTURE OF THIS REPORT

Following this brief opening chapter, Chapter 2 introduces the major examples of IPR regimes for plant breeding, focusing on plant variety protection (PVP) and patents, and discusses other mechanisms that provide similar incentives for the breeding industry. Chapter 3 reviews the institutional setting for seed system development in developing countries. Chapter 4 examines the establishment and management of IPR regimes in plant breeding in developing countries. Chapter 5 reviews the impacts of IPR regimes on seed companies, and Chapter 6 examines their effects on public research in developing countries. The final chapter presents a set of lessons for policy makers and donors who are responsible for guiding the establishment of IPRs for plant breeding.

2 IPRs and Plant Breeding

Various attempts have been made to establish IPR systems for plant varieties, but the concept of PVP and the possibility of plant patents emerged just under a century ago. This chapter summarizes the historical development of IPR systems for plant varieties and looks at the major factors that distinguish them from other intellectual property systems. More detailed information can be found in Appendix C. Although the patent system has been in operation for a much longer time, it still must be adjusted to the field of plant biotechnology so that appropriate and equitable incentives become available. This chapter outlines some of the major areas of concern, especially in relation to supporting agricultural production in developing countries. The discussion emphasizes that formal IPR regimes are not the only method for protecting the interests of plant breeders and seed producers, and it reviews some of the major alternatives.

THE PROTECTION OF PLANTS AND VARIETIES

The evolution of IPRs for plant varieties

Almost from the beginning of modern plant breeding, there have been arguments for establishing some mechanism to reward the creativity inherent in new crop varieties and to establish plant breeder's rights. European efforts eventually culminated in the Convention for the Protection of New Varieties of Plants (Paris, 1961), which also established UPOV (the Union for the Protection of New Varieties of Plants) to support the implementation of the harmonized system and to expand it to more crops and countries. UPOV provides protocols for assessing and describing the unique characteristics of a new variety, ensuring that it is distinct, uniform, and stable (DUS). These standards are adapted to the mode of reproduction of the protected species: cross-fertilizing crops admit a wider tolerance than the relatively strict requirements for uniformity in vegetatively propagated crops. Any variety that fulfills the DUS criteria and that is "new" (in the market) is eligible for protection, and there is no need to demonstrate an inventive step or industrial application, as required under a patent regime. A DUS examination involves growing the candidate variety together with the most similar varieties of common knowledge, usually for at least two seasons, and recording a comprehensive set of morphological (and in some cases agronomic) descriptors.

The UPOV system—revised in 1972, 1978, and 1991—has gradually strengthened the rights of the breeder. The rights defined under UPOV are known as "plant variety protection" (PVP). By late 2005, 59 countries (plus the EU) had ratified a UPOV Convention (32 countries follow the 1991 Convention, 25 the 1978 version, and 2 still operate under older versions). Most countries of the Organization for Economic Cooperation and Development (OECD) are members of UPOV, and a growing number of developing countries, particularly in Latin America, have joined. The UPOV system is the major example of a *sui generis* method for the protection of plant varieties, and it is seen by many as the most straightforward choice for countries wishing to comply with the TRIPS Agreement. UPOV offers important harmonization functions because members use the same technical guidelines for DUS testing, even though UPOV member countries may provide quite different levels of protection for plant varieties. UPOV makes it easier for countries to share information and may reduce transaction costs. Countries that now wish to join UPOV need to comply with the rules of the latest Convention (1991). However, countries that want to comply with TRIPS do not have to become a member of UPOV. They can either design their own "effective *sui generis* system" or design a system based on one of the older versions of UPOV. For example, Indonesia has a PVP system based on the 1978 Convention. Even though it is not eligible to join the Union, Indonesia considered the flexibility provided by the older Convention more appropriate for its agricultural conditions. India, on the other hand, has designed a law incorporating several features that are dissimilar to any UPOV Convention.

An alternative to PVP is provided by the utility patent system in a limited number of countries. A 1985 U.S. court decision (reaffirmed in 2001) ruled that plants were eligible for utility patents, opening the door to a flood of applications for this higher level of protection (Evenson 2000; Supreme Court of the United States 2001). Only plant varieties invented or discovered "in a cultivated area" are eligible for patents, thus limiting the possibility of patents on wild relatives. Under the 1978 UPOV Convention, a variety could not be protected by both a patent and PVP, but the 1991 Convention allows this double protection. Only a few other countries (for example, Australia and Japan) allow patents for plant varieties. In Japan, the patent system is used only for plant varieties that are considered innovative and not merely a product of normal plant breeding. The EU does not issue patents for plant varieties, although the effective scope of protection of its biotechnology patents may include a variety or group of varieties. Based on the study conducted for this report, utility patents for plant varieties are not considered a reasonable option for developing country IPR systems. Nevertheless, aspects of patents for plant varieties are discussed throughout this report because of the pressure from some parts of the seed industry to move in this direction and because this option is included in some of the bilateral trade negotiations between the USA and several Latin American countries.

A number of important parameters must be considered in designing an appropriate IPR system for plant varieties. The major parameters of the most common *sui generis* protection systems and the utility patent system are listed in table 2.1. The most prominent issues in the *sui generis* systems involve the so-called "farmer's privilege" and "breeder's exemption." The farmer's privilege provides the farmer with some exemptions to IPRs, ranging from the right to save seed for his or her own use to the right to exchange or sell seed, depending on the national law. The issue of seed saving is a good example of how IPRs in plant breeding must be tailored to the conditions of national seed systems. Even within a single country, the requirements and conditions of different crop production systems are not uniform, and countries could consider legal options that address this variability. The breeder's exemption provides that any person is allowed to use a protected variety for further breeding without requiring the consent of the rights holder. Under some laws, a newly bred variety may be considered an "essentially derived variety" (EDV), and the IPRs to that variety then depend on the rights to the original variety.

The patent system does not include such exemptions, even though the EU Directive 98/44/EC on this matter has specifically included a farmer's privilege provision, in the event that the scope of a biotechnology patent extends to a group of plant varieties. Some countries in Europe explicitly include a breeder's exemption in such cases.

The farmer's privilege should not be confused with the concept of "Farmers' Rights," which has been codified in the IT PGRFA (2001) and in some national laws. There is no uniform interpretation of Farmers' Rights in relation to IPRs on plant varieties.

Table 2.1 Comparison of Major Intellectual Property Systems for Plant Varieties

Criterion	UPOV 1978	UPOV 1991	Utility patents (USA)
Protection	Varieties of species or genera as listed	Varieties of all genera and species	Sexually reproduced plants (and genes, tools, methods to produce varieties)
Exclusion	Nonlisted species	None	First-generation hybrids, uncultivated varieties
Requirements	Novelty (in trade) Distinctness Uniformity Stability	Novelty (in trade) Distinctness Uniformity Stability	Novelty (in public knowledge) Utility Nonobviousness Industrial application
Disclosure	Description (DUS)	Description (DUS)	Enabling disclosure Best mode disclosure Deposit of novel material
Rights	Prevent others from commercializing propagating materials	Prevent others from commercializing propagating materials and, under certain conditions, using harvested material	Prevent others from making, using, OR selling the claimed invention or selling a component of the invention
Seed saving	Allowed for private and noncommercial use	For use on own holding only (for listed crops only)	Not allowed without consent of patent holder
Seed exchange	Allowed when noncommercial	Not allowed without consent of rights holder	Not allowed without consent of patent holder
Breeder's exemption	Use in breeding allowed	Use in breeding allowed (but sharing rights in case of EDV)	Not allowed without consent of patent holder
Duration	15-20 years (depending on crop)	20-25 years (depending on crop)	20 years from filing or 17 years from granting (prior to June 1995)
Double protection (PVP and patent)	Not allowed	Allowed	Allowed

Source: Adapted from Helfer (2002), Krattiger (2004), and van Wijk et al. (2003).

Further details on differences between protection systems, on Farmers' Rights, and on the protection of biotechnological inventions can be found in Appendix C.

ADDITIONAL STRATEGIES THAT PROTECT THE INTERESTS OF THE PLANT BREEDER

Policy makers considering the design of IPR legislation for the plant breeding industry must recognize that a number of other mechanisms are available to protect the interests of plant breeders and contribute to the development of a competitive and dynamic national seed sector. Decisions on IPRs should not be made without understanding and considering the other instruments that are available to promote plant breeding and seed production. The alternatives include biological processes, conventional seed law, contract law, biosafety regulations, brands and other IPRs (such as trademarks), and trade secrets. As with patents and PVP, the effectiveness of these alternatives depends on the local capacity for enforcement.

Biological protection

The oldest mechanism for protecting a plant variety is hybridization. Hybrids are the products of a cross between two (or more) parent lines or populations. The discovery of the phenomenon of hybrid vigor in the early 20th century opened new possibilities for producing high-yielding and uniform varieties of cross-fertilizing crops and offered two distinct advantages for protecting the interests of commercial seed provision. First, seed of hybrid origin will lose some yield potential and other

valuable characteristics (such as uniformity) in subsequent generations, which reduces farmers' incentives for saving seed. Second, competing seed companies cannot duplicate a particular hybrid variety if they do not have access to the inbred lines used to develop the hybrid variety. If the inbreds can be physically protected, they have the character of a trade secret. In contrast, companies can easily duplicate an open-pollinated variety (OPV) by obtaining seed of that variety. The use of hybrids thus provides a steady demand for seed, overcoming much of the uncertainty in the conventional seed market, where factors such as the weather determine how much seed is saved on the farm and hence the demand for fresh seed. Hybrid seed is more expensive to produce than seed of OPVs, but if the hybrid varieties are superior in yield potential and homogeneity, substantially higher seed prices can be charged.

A more recent example of biological protection mechanisms is the introduction of genetic use restriction technologies, operating at the variety level (V-GURTS) (Louwaars et al. 2002). In the absence of special treatments, plants containing these technologies produce sterile seed, thereby ensuring that farmers cannot save commercial seed of self-fertilizing crops like wheat and beans for subsequent planting. The technologies also make it difficult for other breeders to use the protected germplasm. Companies are using the methods of genetic transformation to develop several such protection mechanisms. None are commercially viable yet, but the possibility of this so-called "terminator technology" has led to widespread debate and concern in the popular press and has caused the technology to be specifically banned in India's Protection of Plant Varieties and Farmers' Rights Act.

Seed laws

Conventional seed law can provide opportunities for controlling access to plant varieties, even in the absence of IPR legislation. Seed laws usually specify the extent to which seed must be certified and define the types of variety that may be offered for sale. A certification scheme defines seed classes of specified origins, so that any certified seed can be traced back to a seed lot produced by the maintainer of the variety (usually the breeder). Where seed certification is compulsory, the breeder may determine who is producing seed by controlling access to breeder's (or pre-basic) seed. Any unauthorized multiplication will not be acceptable to the certification agency. These requirements mean that a public or private breeder can establish an exclusive contract with a seed company for the production of specified varieties, even in the absence of IPRs. When a variety is not protected by PVP (for example, after the rights have expired), the authorities can assign one or more maintainers to meet the continued demand for seed. Seed certification requirements can also be used to limit informal seed sales, especially when they occur on a large scale.

Where seed law specifies that a variety must be approved (through a registration process or on the basis of performance tests) before entering commercial seed production, this provision can also prohibit the sale of a released variety under a different name. In this way, the law limits the extent to which a competing company can market seed of a protected or an essentially derived version of a released variety, including the unauthorized use of a transgene.

Contract law

Various types of contracts can be effective in providing legally enforceable agreements that restrict the use of a breeder's variety and offer complements or substitutes to IPRs. Such contracts are effective only if the provider of the genetic materials has exclusive access or established rights to the materials or can offer particular benefits to the other contracting party. The contracts are ineffective if third parties have easy access to the varieties or genes. Some contracts are aimed primarily at preventing seed saving and multiplication, whereas others are aimed at protecting the germplasm from being used in competitors' breeding programs.

One type of contract that is increasingly prevalent in the U.S. seed market is the grower contract, or "bag tag." This simple (unsigned) agreement restricts the farmer from using or disposing of any part of the harvest as seed. Farmers are considered to comply with the provisions of such contracts when they open the seed bag.

If it is possible to control the market for the harvested product, then another type of contract can be enforced. The breeder can oblige a grower to use the plant variety in certain ways and can impose restrictions on the saving or multiplication of planting material. For example, in the cut flower industry, the vast majority of the output is sold in a limited number of wholesale markets in the North.

If a flower variety is protected in the country where a major wholesale market is located, growers in other countries may have to sign contracts limiting multiplication or unauthorized sale of that variety, or they risk being denied further access to the major market. This type of contract can be effective even if the flower-growing country has no IPR system.

Control of output markets can also be used to regulate access to certain field crop varieties. Chapter 5 presents several examples of how access to transgenic crop varieties is controlled.

Access to germplasm may also be controlled through material transfer agreements (MTAs), which may be seen as another form of contract regulating the use of breeding material. When MTAs are established between genebanks or other public institutions and private breeders, they can establish exclusive access, stipulate the type of benefit sharing in the case of commercialization, and prohibit legal protection by the recipient of the materials "in the form received." Commercial firms may also use MTAs (box 2.1).

Biosafety regulations

Biosafety regulations are not meant to serve as IPRs but are intended primarily to protect the environment and promote the safe use of biotechnologies. Even so, aspects of the biosafety system can create property-like rights. For example, in cases where national IPR systems do not provide adequate protection, biosafety regulations may be used to prohibit the sale of varieties that include the unauthorized use of a privately owned transgene. In addition, biosafety data themselves may be valuable property. The biosafety system generates data from extensive testing to demonstrate environmental and food safety. Such testing can be very expensive, especially when feed and food trials are necessary, and most of the costs are paid by the company that wants to register the transgene. Regulations in some countries require biosafety analysis for each new transgenic variety, even if the variety is based on a previously approved "event" (the introduction of a particular construct in a particular place in the genome). Since such data are usually confidential, they have great commercial value and create the basis for contracts that effectively create rights over genes. Although biosafety regulations may help control the unauthorized use of transgenic varieties in countries without relevant IPRs, it is important to recognize that a biosafety agency's mandate, budget, and personnel are directed towards environmental protection and not the enforcement of rights or access to biotechnology.

Brands and trademarks

Brands and trademarks are part of intellectual property law, but their utility in the seed industry is often overlooked in the policy debate about IPRs. Seed companies frequently register their brands and trademarks as a way of distinguishing their products from those of their competitors and building up a loyal customer base. In the absence

Box 2.1 MTAs and the Seed Industry

MTAs and other contractual arrangements can be used by private companies to control access to genes or transgenic varieties that are protected by IPRs in one country, even if the recipient country does not recognize the particular IPR. For example, when a national agricultural research organization contracts with a major biotechnology company to use particular proprietary transgenes, the contract may specify how the national organization is to use the genes, the rights to anytechnologies that are produced, and the company's obligations (for example, to provide training or other assistance). In some developing countries, multinational corporations (MNCs) may find that commercialization of their own transgenic varieties requires too much attention to marketing seed, policing violations, and enforcing rights, and they may prefer to license the rights to a transgene to local seed companies. Access to various tools and processes of biotechnology, such as genetic transformation techniques or diagnostic methods, is also usually subject to contracts specifying limitations on their use and the rights of the provider in relation to commercial products.

Source: Authors.

of other intellectual property instruments, the development of a strong brand image and reputation can protect a company from some types of competition. While trademarks can be effective in communication with customers (farmers), they do not protect a breeder from competitors who "steal" the variety and include it in their own (branded) product portfolio.

It is much less common for crop varieties to be trademarked. Usually there is a prohibition against using a variety name registered under PVP as a trademark, but in some cases a trademarked variety name may be very useful. For instance, flower breeders often register a variety through PVP under one name but market it under a second, trademarked name, which can be used and protected long after the PVP expires. Some countries prohibit the use of separate trade names and prescribe that the name registered in the PVP or seed law lists is to be used in commerce.

Trade secrets

In some instances, secrecy is an effective way to protect certain technologies, and the choice between patenting and secrecy may depend on the type of technology and the size of the firm. Trade secrets may not be included in a separate body of law but come under standard trade law. In plant breeding, the primary example of a trade secret is the protection of the inbred lines used to produce a hybrid. The ability to exploit this type of secrecy depends to an important extent on the degree of physical security that can be provided to plant breeding facilities and seed multiplication plots. Registration requirements (under PVP or seed law) may require the breeder to provide information on the pedigree (e.g. the specific inbred lines that are "the formula" for breeding the hybrid) or even deposit samples of the different parent lines. This requirement can nullify the trade secret unless the registration authority can keep the information and materials confidential. Advances in biotechnology make this type of secrecy more difficult to maintain, as reverse engineering of new varieties becomes easier. Even though such actions might be covered by the enforcement of provisions on EDVs, they help to explain the pressure from some parts of the seed industry for further limitations on the breeder's exemption. Trade secrets are also useful for protecting certain aspects of plant biotechnology, particularly procedures or techniques that cannot be detected in the final product, such as markers and regeneration methods.

3 Plant Breeding and Seed Sectors in Developing Countries

This chapter provides a brief introduction to the major actors in national seed systems. These systems encompass formal institutions engaged in research and plant breeding, seed multiplication, and seed marketing and use. They also include informal seed sectors based on the saving, exchanging, and selling of seed among farmers. Seed systems are usually subject to some control from regulatory regimes. Seed systems involve individuals and organizations in the public domain, the private sector, and civil society. The overview of seed systems in this chapter concentrates on trends and differences in the developing world and touches only briefly on industrialized countries. Appendix B summarizes information on the seed sectors in the five case study countries, illustrates some of the differences among developing countries, and provides background references on some of the institutions and organizations featuring in the examples cited throughout this report.

SEED SYSTEMS IN INDUSTRIALIZED COUNTRIES

In industrialized countries, seed multiplication, marketing, and distribution are almost solely commercial operations. The situation in plant breeding is somewhat more complex. Commercial enterprises dominate the market for high-value seed crops like maize, cotton, soybean, vegetables, and grasses, and companies that initially earned most of their revenue from seed multiplication and marketing now invest heavily in plant breeding to maintain their market position. For lower-value seed crops, such as small grains and legumes, public institutions such as universities and government research institutes still have an important position in plant breeding in some countries. Basic research in plant breeding, such as the development of selection methods or research on the genetic control of important characteristics, used to be the task of public institutions. However, with the application of biotechnology to plant breeding and the associated opportunities for patenting, private industry has been very active in these areas since the early 1980s. This activity has been accompanied by a significant consolidation of many conventional seed companies into a few large multinational enterprises. For these companies, research is not only a service unit to maintain the firm's position in the seed market but is also a profit center in its own right. In some cases, companies may detach themselves from the seed market,

leaving operations in seed production and marketing to specialized companies to whom they license the technology.

SEED SYSTEMS IN DEVELOPING COUNTRIES

In most developing countries, scientific plant breeding has largely been the responsibility of the public sector, often stimulated by the results of international agricultural research centers (IARCs). Plant breeding has received significant emphasis since the so-called "Green Revolution" in the 1960s and 1970s, and it has been viewed as contributing to rural development and national food security and thus as a public responsibility. Similarly, seed production and distribution have been seen as vehicles for technology transfer rather than as commercial operations. For these reasons, governments have largely been responsible for organizing and funding plant breeding research and seed multiplication.

More recently, some countries have stimulated commercial seed supply by privatizing public seed production programs, encouraging the development of domestic seed enterprises, and opening up their seed markets to foreign investors. Developing countries currently show a wide range of public and private responsibilities in the seed sector, although basic research and breeding for most crops remain public responsibilities while a variety of public, parastatal, and private enterprises cater for seed production and marketing.

Farmers' seed systems usually operate alongside formal seed systems. Farmers' systems are characterized by traditional methods of selection within and among varieties, on-farm seed multiplication, and informal diffusion of seed from farmer to farmer (Almekinders and Louwaars 1999). These systems still provide the vast majority of all crop seed used by farmers in most developing countries. Despite the fact that farmers' seed systems are built on traditional methods and processes, they often involve modern varieties, some of which may be associated with IPRs.

RESEARCH AND PLANT BREEDING

Almost all developing countries maintain national public organizations for agricultural research, which are referred to here as national agricultural research institutes (NARIs). Plant breeding has traditionally been a key research area of the NARIs. In many smaller countries, NARIs depend heavily on IARCs for much of the germplasm and methods used for breeding field crops. Smaller NARIs concentrate on selecting material from IARC "nurseries," which are collections of potentially useful germplasm that can be tested under local conditions. More advanced NARIs receive assistance in the design and operation of their breeding programs, including the selection of parents, the creation of genetic variation, and the development of efficient methods for selecting germplasm possessing desired characteristics. A relatively small number of stronger NARIs have more capacity for basic research.

Many NARIs have faced gradual reductions in their direct financing from government, in line with overall reductions in public expenditure, and many have also been affected by declining donor support. The IARCs have been instrumental in building the capacity of the NARIs, but budgets for these support activities have also declined. The breeding programs in most IARCs have been reduced in size over the past two decades as overall research funding has declined and as plant breeding has faced growing competition from other research activities within IARCs.

SEED PRODUCTION AND MARKETING

National seed programs were established in most developing countries following the first successes of the Green Revolution in the 1970s. Many seed sector development initiatives were supported through the Seed Development Program of the Food and Agriculture Organization (FAO), which provided assistance for the development of basic seed farms, seed conditioning facilities, and contract grower schemes. These seed programs were designed to help spread high-yielding varieties to as many farmers as possible by making seed available to government extension services and rural development projects, often under subsidy schemes. In a few countries, notably Kenya and Zimbabwe, seed production was initiated by organizations serving the needs of large commercial farmers, but these operations were later brought under more direct government control.

Seed policies gradually changed in the 1980s and 1990s as seed production was increasingly considered a potentially commercial economic activity.

Some national seed programs were transferred to government corporations (parastatals), which had different levels of freedom to develop their businesses. In addition to putting public seed programs on a more commercial basis, many countries also began to support the development of local seed companies and in many cases also opened their doors to regional or global seed companies.

Countries differ widely in the success of these approaches to develop a competitive commercial seed sector. Larger countries such as China and India tend to be able to attract a more diversified commercial seed sector, whereas smaller countries may be able to provide incentives only for a few commercial seed suppliers. Multinational seed companies tend to concentrate on a very few seed crops (such as maize or cotton), whereas local companies tend to offer a wider range of products. Many local seed companies depend on NARIs for their varieties, while others develop their own breeding programs for a few important crops. A number of crops that are critical for national food security, such as small grains and legumes, are not very profitable seed products, however. They attract much less attention than vegetable and hybrid seed crops.

SEED USE

Despite all the emphasis on seed industry development, most seed in developing countries is still produced by farmers themselves. The level of farm-saved seed depends on a number of factors, including the crop and the wealth of the farmer. Crops with a low seed rate that are produced mainly for the market will be more likely to attract frequent seed purchase. Farmers with more resources are more likely to use the commercial seed market. Seed that cannot be stored easily or that tends to carry seed-transmitted diseases is also purchased more regularly.

Farmers' seed systems can be very effective in providing seed of adapted varieties at the right time and at low cost, but they can be vulnerable to natural and man-made disasters. These systems are also the only way that farmers' varieties can be maintained and further developed, so they make a valuable contribution to agro-biodiversity. Modern varieties are also multiplied and shared in farmers' seed systems, and in many countries it may even be official policy to stimulate farmer-to-farmer exchange of new varieties so that those varieties can reach remote and resource-poor farmers. More recently, a range of programs, often sponsored by donors and nongovernmental organizations (NGOs), have supported farmers' seed systems and local seed multiplication and distribution.

SEED POLICIES AND REGULATIONS

IPRs are not the only type of legislation relevant to the seed industry. Both public and private seed systems are subject to national seed legislation. As mentioned, seed laws commonly include a variety approval system and a seed certification and quality control system, managed by various bodies and committees.

A variety approval (or release) system identifies varieties that have value for farmers and establishes a system by which the varieties are named and described. Official variety release is usually (but not always) a prerequisite for commercial seed

Table 3.1 Costs (US$) of Variety Release in Case Study Countries

Country	Procedures and cost
China	Agronomic trials in one or more agroecological zones: US$ 150 per season
Colombia	Agronomic trials in one or more agroecological zones: US$ 1,718 per zone for supervision
India	Private sector entries in All-India Coordinated Crop Improvement Programs (AICCIP) trials: US$ 217 per location per year
Kenya	DUS test required: US$ 600 per variety or inbred National Performance Trials (NPTs): US$ 500 per year, per zone
Uganda	Private sector entries in NARO trials: US$ 120 per site (5-7 sites)

Source: Compiled by authors from information obtained from national authorities.

sale. The costs of testing for variety release may be substantial (and are independent of the costs of testing for PVP, discussed in chapter 4). Costs of variety release for the five case study countries are presented in table 3.1.

The certification system introduces strict generation control for seed production, in which breeder's or pre-basic seed is multiplied through a prescribed number of generations to produce commercial seed. The breeder is in most cases designated as the maintainer of the variety and the sole source of this seed. The seed certification process also usually involves testing for seed quality (germination percentage, cleanliness, and other quality characteristics). Seed certification systems may be compulsory or voluntary.

The conditions established by seed laws and policy greatly influence opportunities for private enterprise, and seed policy changes and regulatory reforms are the subjects of continuing discussion in many developing countries (Tripp 1997; Louwaars 2002). There are important interactions between seed regulation and IPRs for plant breeding. Because both seed regulatory regimes and IPR systems can control access to—and utilization of—seed, it is important that they are compatible and complementary. Seed regulatory frameworks and IPR regimes also share a dependence on enforcement capacities. Seed regulation is usually managed and enforced by the state, although limited resources often mean that state responsibilities may not be addressed adequately.

More recently, biosafety regulations have been developed to guide the introduction of genetically modified crops (Traynor and Komen 2002). These regulations are also an important part of the regulatory environment of the plant breeding industry, determining what type of transgenic varieties may be available and specifying conditions for their multiplication and sale.

4 IPR Legislation and Management for Plant Breeding

This chapter examines the experience to date with the establishment and administration of IPR legislation for plant breeding in developing countries. Such an examination is limited by the fact that relatively few countries have yet to enact relevant legislation, so many of the examples are drawn from the case study countries. The chapter looks at the implementation of PVP legislation in developing countries, the scope of protection that is offered, and the administration of PVP systems. The chapter also briefly discusses the current status of biotechnology patents in developing countries.

THE CURRENT STATUS OF PVP IN DEVELOPING COUNTRIES

IPR legislation

A study of the current state of play for IPRs in plant breeding in the South shows that few countries have operational PVP systems (box 4.1). A recent review shows that although more than two-thirds of low-income countries are members of WTO, only 8 percent are members of UPOV (adapted from Koo et al. 2004). However, it is important to understand that national legislation significantly pre-dates an application to join UPOV, that legislation is not necessarily based on UPOV models, and that there are cases (most notably India) where the compatibility of national legislation with UPOV Conventions or with Article 27.3(b) of the TRIPS Agreement has yet to be tested.

Developing countries must also pay increasing attention to biotechnology patents. The majority of developing countries have functioning patent offices, but only a few have any experience in dealing with inventions related to plant biotechnology.

The establishment of PVP legislation

Pressure for the establishment of PVP in the South has come from different sources. In Kenya, for example, the protection of plant varieties was already included in the 1977 seed law, but this protection was not implemented until that law was substantially revised in 1994. The major thrust towards implementing PVP in Kenya came from the flower industry, which currently accounts for the lion's share of applications. A special office for PVP was established within the Kenya Plant Health Inspectorate Service (KEPHIS), and the country joined UPOV in May 1999.

Box 4.1 Developing Country Responses to TRIPS

Many developing countries have felt the pressure of the deadline specified in TRIPS and have tabled their laws at the last moment. Most exceptions are in Latin America, where 10 countries followed the 1994 example of Argentina and Uruguay and had become UPOV members by 1999. The African Intellectual Property Organization (OAPI), comprising 16 (mostly francophone) countries in West and Central Africa, initiated procedures to join UPOV 1991; OAPI's individual members have also agreed to produce legislation consistent with the 1991 Convention. Most Asian countries with PVP laws have not become UPOV members, even though in several cases their laws reflect the main components of the UPOV 1978 system. Others, such as India, have applied for membership, which is still under consideration by the UPOV Secretariat. India's 2001 Act for the Protection of Plant Varieties and Farmers' Rights includes an exceptionally liberal allowance for farmers to save, use, and exchange seed of protected varieties. Farmers or farming communities can also register their own varieties. Some of the provisions seem to go beyond the UPOV 1978 clauses, but UPOV is awaiting the implementation rules to judge whether the Indian system is in conformity with the 1978 Convention. (India received a dispensation to accede to UPOV under the old Convention.) An authority is currently being established under the Ministry of Agriculture to administer the Act.

Least Developed Countries have more time to develop their systems; as of the publication of this report, the deadline for compliance with the most relevant aspects of TRIPS had been extended to July 2013. The debate in these countries is complicated by growing pressure to combine the protection of varieties with concepts from the CBD and the IT PGRFA, as in the African Model Law. The Indian law is an appealing model for some, but other countries cannot judge the adequacy of this legislation until it is implemented.

Harmonization is a special and important issue in the design of laws related to Plant Breeders' Rights (PBR). All countries of the Andean Community (Bolivia, Colombia, Ecuador, Peru, and Venezuela) have agreed to a common PVP regime, but the actual implementation and enforcement of PVP varies by country. Although the former East African Union intends to harmonize its seed sector regulations, there are considerable differences between the Kenyan, Tanzanian, and (draft) Ugandan PVP legislation.

Source: Authors.

In other countries, crop breeders in public research institutes initiated the pressure to introduce PVP. In Uganda the first discussions started in 1991, organized by the public research system, which saw opportunities to earn revenues and compensate for declining public expenditures. This situation has been repeated in a range of developing countries.

A third impetus for the establishment of PVP is the TRIPS agreement, which specifies the minimum requirements for protection. Several developing countries started national debates to design appropriate laws. While these debates remained within expert circles in some countries, in others—notably the Philippines and Thailand—the issue was picked up by NGOs, which influenced the decision-making process. In India, the government itself, together with some leading NGOs, organized a wide consultation covering all states and a wide range of stakeholders. After long debate, in 2001 India passed its Act for the Protection of Plant Varieties and Farmers' Rights. The original impetus for the Act came from India's commercial seed sector, and draft bills produced in 1993, 1996, and 1999 were opposed by NGOs. A Joint Committee of Parliament then traveled through the country collecting the views of the industry, NGOs, farmers' groups, and others and redrafted the bill in 2000 for introduction to Parliament (Ramanna 2003). The bill was also widely debated in India's press.

Identifying institutional responsibilities

There is a time lag between the adoption and actual implementation of a national PVP law. This time is used to draft implementation rules, to establish a PVP office, and to assign responsibilities for variety testing. This period may also be used to publicize

the operation of the new law among all stakeholders, including the courts. In China, the first applications were submitted two years after the law was adopted in 1997; in India, the first applications were received in 2005, four years after the passage of the law.

Two common options for the location of a PVP office are to use existing facilities in the patent office or to establish a new office within the Ministry of Agriculture (MoA), as in most UPOV member countries. (In China, the Ministries of Forestry and Agriculture take responsibility for PVP for woody species and other crops, respectively). Both options have advantages and disadvantages. The patent office is conversant with administrative procedures for granting IPRs, but it has no experience with the biological nature of plant varieties. The MoA commonly lacks the legal expertise to operate such an office, but it knows the seed sector and is familiar with plant science. It is generally easier for the MoA to acquire the legal expertise than for the patent office to acquire skills in biology.

Variety testing is done under the responsibility of the PVP office. Some countries have developed a completely new network of testing stations (for example, 15 stations in China under the MoA). In other countries, the task is combined with other regulatory tasks in agriculture (for example, KEPHIS in Kenya), and in yet other countries, such as India, existing research stations test the applicant varieties. Smaller countries with limited human resources in the fields of taxonomy and breeding tend to assign responsibility for variety testing to the national breeding program. This procedure has the great disadvantage that an institute may be called upon to test its own varieties for protection. This conflict of interest can be avoided by establishing a separate DUS testing unit, often connected to the seed certification agency, which can combine DUS testing with the post control operations for certification. Alternatively, varieties from a particular research institute may be tested by another institute in the same country or abroad. The examples of the USA, where breeders performs their own DUS testing, or Canada and Australia, where breeder testing occurs under different levels of official supervision, are not commonly followed in developing countries.

One way to reduce costs and the burden on the limited human resource base for breeding and variety testing is regional cooperation in variety testing. This option is used in the EU, where responsibilities for particular crops are shared among countries. Alternatively, countries (especially UPOV members) can accept test reports from other countries based on bilateral agreements. This option is used in Kenya and Colombia, which use Dutch reports for flower crops to grant PVP nationally.

Initial range of crops

Most developing countries that have started to implement PVP are doing so for a limited number of crop species and genera, mainly because the procedures differ by crop and because testing agencies have to be able to handle applications. For example, China currently offers protection for 41 species, including many important field crops but excluding cotton and important horticultural species. India has developed procedures for 40 species but does not have any practical experience yet. The UPOV Convention does not require countries to provide protection for all crop species immediately. Taking time to build facilities, reducing the administrative costs, or maintaining a more open playing field for certain crops may all be reasons for initially limiting the range of protected crops. Countries tend to give priority to major field crops in developing their protection systems, yet it may also make sense to concentrate on crops for which protection would create the best incentive for investments in breeding—in most cases, the more commercial horticultural species.

It should be noted that the length of protection available for varieties can vary. The UPOV Conventions establish minimum periods for protection (15 years for field crops under the 1978 Convention and 20 years under the 1991 Convention). Colombia recently extended its protection period to 20 years as part of its law, modeled on UPOV 1978. Many countries establish coverage for 15 years for field crops, but Uganda's draft legislation contemplates 20 years.

Extant varieties

Another decision that must be taken in establishing a PVP system concerns the status of existing varieties. Although PVP is offered for new varieties only, it is considered acceptable to offer protection for varieties that are released just before the system comes into force. Countries take different positions on this issue (box 4.2). In most developing countries enacting PVP legislation,

Box 4.2 Differential Treatment of Extant Varieties

Some countries (for example, see Uganda's draft legislation) offer no protection for extant varieties. In others, extant varieties may be allowed limited coverage. China allowed protection for varieties released up to four years before the legislation (although the impact does not seem significant). Colombia allowed a one-year amnesty for applications, but any protection granted would cover a period beginning with the original release date. The Colombian Institute for Agriculture and Livestock (ICA) chose not to act on this provision because it felt that its varieties were already in the public domain, but many private applications (mostly for ornamentals) took advantage of the amnesty. India's legislation permits PVP for public and private varieties that are already released and notified. Coverage begins on the original notification date, which is similar to the position taken by several countries in the Commonwealth of Independent States.

The most controversial case regarding extant varieties has arisen in Kenya, which announced an amnesty that allows a full period of protection (15 years) for any released variety. This amnesty would cover, for instance, maize hybrids that were released in the 1960s and remain in commercial production. Most of the eligible varieties are the property of the Kenya Agricultural Research Institute (KARI), and although KARI has already signed royalty agreements with the Kenya Seed Company (KSC) for many of them, the amnesty would mean that KARI could collect royalties from any other seed producer for a wide range of its crop varieties. The issue has raised considerable controversy, and the amnesty has not yet been gazetted.

Source: Authors.

a number of crop varieties will have been through the official release process; in many cases these will be public varieties, sold by either public or private seed companies. A decision to extend protection to such extant varieties in effect provides a windfall profit for the breeder (often a NARI) in the form of royalties. Royalties may provide a welcome source of revenue but might in some cases discourage further seed production. In cases where PVP legislation includes some restrictions on farmer's privilege or breeder's exemption, the use of the variety in local seed systems or formal breeding programs may also be affected.

Early experience with PVP

The three case study countries that have established PVP systems illustrate wide divergence in the types of crops and varieties that are protected (table 4.1).

China received 1,150 applications for PVP between 1999 and 2003. Of these, 411 have been granted. Although many applications from as far back as 1999 have not yet been acted upon, the average time to grant an application is 17 months (Koo et al. 2003). The vast majority of the applications are for field crops; maize and rice account for 45 and 32 percent of the applications, respectively. More than three-quarters of the maize applications in the MoA office are for hybrids, and more than three-quarters of the rice applications involve either hybrids or inbred lines. Wheat, soybean, and rapeseed are the other major examples of field crops seeking PVP. Two-thirds of the applications come from public research institutions, mostly at the provincial and prefectural level. (Applications at the Ministry of Forestry PVP office are mainly for roses.)

Colombia has received 785 applications for PVP since 1996, and 448 had been granted by mid-2004. The vast majority of the applications are for ornamentals; roses alone account for 62 percent of all applications. The major examples of PVP for agricultural crops are rice (12 applications to date; 6 granted) and cotton (25 applications; 8 granted). Applications for other field crops include soybean, tobacco, and potato, all from the private sector. Although hybrid maize is an important crop in Colombia, sold by several local firms and MNCs, there are no PVP applications for maize. Other important agricultural crops, including beans and wheat, are similarly unrepresented.

Between 1997 and 2003, Kenya received over 600 applications for PVP, but by mid-2004 only

Table 4.1 Numbers of PVP Applications and Certificates Issued in Case Study Countries

	China		Colombia		Kenya	
Crop	**Applications**	**Granted**	**Applications**	**Granted**	**Applications**	**Granted**
Beans					27	1
Cabbage	15	7				
Cassava					2	0
Coffee	[a]				4	0
Cotton			25	8	2	0
Fruits	18	8			5	0
Groundnut	10	5				
Macadamia	[a]				11	0
Maize	520 = *50%*	248			54 = *10%*	0
Pasture grasses					10	0
Potato	7	1	5	3	4	0
Peas					7	0
Pepper	10	1				
Pyrethrum					23	23
Rapeseed	38	11			14	0
Rice	365 = *34%*	82	12	6		
Roses	[a]		448 = *62%*	279	248 = *42%*	61
Sorghum					7	6
Soybean	30	19	8	2	7	0
Sugarcane			5	5	6	2
Sunflower					10	0
Tea	[a]				33	0
Tobacco			4	3		
Wheat	84	21			30	0
Other ornamentals	[a]	214 = *29%*	139	61 = *11%*	15	
Other	53	8	6	6	31	0
Total number of varieties	1,050	411	727	451	569	108

Source: Compiled from Louwaars et al. (2004:76-78).
a. Data from China on woody species, including ornamentals, not included in this study.

108 certificates had been granted, 70 percent of them for ornamentals, especially roses and alstroemeria. Among field crops, maize has the highest number of applications (accounting for 10 percent of the total); all of these applications are for hybrids from either the public sector or the parastatal Kenya Seed Company (KSC). The rise in domestic applications is partly due to the amnesty granted in 2001 to previously released public varieties. The fact that this ruling is being contested is one of the explanations for the relatively low number of PVP grants issued so far.

The experience of these three countries with PVP is quite varied, but it illustrates some general principles. Not surprisingly, the major interest in PVP is for those crops whose seed or planting material represents an important commercial market. In Colombia and Kenya, the applicants are predominantly foreign breeding firms producing ornamentals (table 4.2), and European DUS testing reports are used for registration. The high interest in PVP for these crops reflects their commercial value, their great diversity, and their ease of reproduction. A review of PVP grants in all UPOV member countries showed that ornamentals account for more than 51 percent of all grants and that ornamental and other horticultural species combined account for 70 percent of PVP grants worldwide (Srinivasan 2004). Even in the case of field crops, commercial interests affect the likelihood of PVP application. In industrialized countries, where hybrid technology usually offers sufficient protection, hybrids may not be submitted for PVP. On the other hand, the majority of PVP applications in China are for hybrid varieties that already have a certain degree of in-built biological protection but which require additional legal safeguards in a very

Table 4.2 Sources of Applications for PVP in China and Kenya

Source	China	Kenya
Public research institutions (%)	67	22
- National (%)	3	
- Provincial (%)	28	
- Prefectural (%)	29	
- University (%)	7	
Private sector (%)	33	69
- National (%)	32	11
- Foreign (%)	1	58
Joint public-private (%)		9
Total (number of applications)	*1,150*	*602*

Source: Compiled from Louwaars et al. (2004:76-78).

competitive commercial seed market (table 4.2). Rice is the field crop that attracts the most PVP applications in Colombia because of the competitive and profitable domestic rice seed market. The public sector may be slower to apply for PVP for many of its varieties, especially those without well-established seed markets; the surge in public applications in Kenya following the announcement of the amnesty is the exception that proves the rule. Thus although PVP can strengthen established seed markets and provide incentives for further investment, it is more difficult to prove that PVP—at least at the level illustrated in the case study countries—is a sufficient cause of new commercial seed activity.

THE SCOPE OF PVP IN DEVELOPING COUNTRIES

Even though two countries may both be members of the same UPOV Convention, their enabling legislation may be quite different. For example, issues addressed in the three case study countries with PVP legislation include the regulation of farmer seed saving and seed exchange; the breeder's exemption; the range of crops to be included in the early stages of the program; the treatment of extant varieties; and the wider issues raised by Farmers' Rights provisions. Questions also arise about the relationship between conventional seed law (variety registration and seed quality control) and PVP legislation.

Seed saving and exchange

Farmer seed saving is one of the most contentious issues related to PVP. China's PVP legislation provides a broad farmer's privilege for saving and reusing one's own seed, which is seen as important in a country dominated by smallholder farmers. The degree to which farmers can sell or provide seed of protected varieties to others is not well defined, and there is a great deal of informal trade in certain varieties. Kenya also permits farmers to save seed of protected varieties, but KEPHIS has expressed interest in moving closer to compliance with the more restrictive 1991 UPOV Convention. One particular concern is that many wheat farmers (some of whom cultivate quite large areas) either save seed or acquire it from neighbors. Although there is considerable farmer-to-farmer sale and exchange of seed, this activity is illegal for any major field crop (whether it is subject to PVP or not) because of Kenya's strict seed certification requirements.

As mentioned in chapter 2, EU countries that prohibit seed saving generally exclude small farms from the rule. In Colombia, a recent ruling (Resolution 2046 of July 2003) prohibits farmers with holdings greater than 5 hectares from saving seed of protected varieties. Those with smaller farms may save such seed, but they are required to report to a local ICA office and give details of how home-saved seed will be processed and used. The sale of farm-produced seed of protected varieties is not permitted, although a certain amount of seed selling does occur and is of particular concern to the rice seed industry.

India's recently passed legislation is exceptionally liberal in its definition of farm-level seed saving, allowing farmers to save, use, exchange, or sell *nonbranded* seed of protected varieties just as they have done previously. It appears that selling seed to a neighbor is permitted as long as the transaction is conducted informally and the seed is not sold with any commercial denomination or packaging.

These cases illustrate a wide range of regulation and practice with respect to farmers' utilization of saved seed of protected varieties. Decisions regarding seed saving and exchange must be based on an assessment of the needs and conditions of the nation's farmers, the capacities of the seed industry, and the possibilities of enforcing particular regulations. Like many aspects of IPR management, initial legislation can establish broad guidelines

and then further adjustments can be made as conditions warrant.

Breeder's exemption

There is less evidence on how the use of protected germplasm in other breeding programs has been affected by PVP. UPOV 1978 establishes no restrictions on such use, and the private plant breeding industries in most developing countries are not sufficiently well established for this issue to have appeared as important. There are no special arrangements for EDVs in the case study countries, although China and Kenya are considering modifying their legislation to address this issue. The International Seed Federation is debating proposals to limit the breeder's exemption, mainly to protect commercial interests in the most competitive markets in Europe and the USA. This issue could emerge in developing countries as well when MNCs start to use the national PVP systems in the South.

Farmers' Rights

Both the CBD and the IT PGRFA describe countries' obligations to provide mechanisms for sharing benefits from the use of plant genetic resources with farming communities, but they do not spell out precise mechanisms or legal instruments. There are concerns about possible contradictions between what Article 9 of the IT PGRFA describes as "Farmers' Rights" and some aspects of PVP legislation. There is also some debate over whether a single piece of legislation might try to link PVP with benefit sharing. Several countries have enacted PVP legislation that does not address these broader aspects of Farmers' Rights, while others have combined the two (box 4.3).

The relation of PVP to national seed law

When countries design and enact PVP legislation, they need to review its relation to national seed law. Chapter 3 discussed the fact that in many cases national seed law (governing variety release and seed quality control) may complement (or even substitute for) PVP legislation. Some countries find that their seed laws must be revised to come into line with PVP legislation. In India, for instance, public plant varieties have always needed to be officially released and notified, a process that includes testing agronomic performance and recording descriptors (sufficient for seed certification, although not DUS testing). But private firms could sell their varieties as "research varieties," without complying with these release procedures, although they needed to meet minimum seed quality standards and clearly specify the variety name on the package. Now that most new varieties, public or private, are likely to apply for PVP, a revised Seeds Bill establishes a National Register of Seeds, which applies to all varieties offered for sale and includes performance testing. Thus private companies in India have traded their freedom to sell varieties without passing performance tests (but without legal recourse if competitors appropriate their varieties) for an obligation for registration and testing linked to a legal system of protection. There is considerable debate in India

Box 4.3 Farmers' Rights and PVP

One of the most prominent examples of combining Farmers' Rights and Breeders' Rights in one law is India's Protection of Plant Varieties and Farmers' Rights Act, which includes the possibility that farmers or farming communities may register their own varieties; the expectation that farmers can claim compensation if a variety does not perform in the manner described by the breeder; and benefit sharing through a National Gene Fund.

The model PVP legislation developed under the auspices of the Organization of African Unity places particular emphasis on farmer and community rights and the protection of the environment. Uganda's draft PVP legislation includes treatments of community rights to local plant varieties and sharing of benefits from the utilization of local germplasm (through a national "community gene fund").

Source: Authors.

over whether the strict new Seed Bill sufficiently supports Farmers' Rights.

Both PVP and seed law may be used to limit the extent of informal (for example, farmer-to-farmer) seed sale. If the objective is to ensure that legitimate seed companies are not undermined by large-scale informal sales of protected varieties, a reasonable definition of "commercial sale" in a PVP law may be more feasible than a full-blown mandatory seed certification scheme that assumes, often unreasonably, that a country can provide efficient and effective certification to serve seed producers in all parts of the country. Such a definition of commercial sale may be specified by crop type or other criteria and does not necessarily imply acceding to the strictures of the UPOV 1991 Convention.

THE ADMINISTRATION OF PVP

Costs of PVP

It is important to recognize that a PVP system entails significant costs, particularly related to DUS testing and assessment. A candidate variety must be grown in carefully controlled and monitored trials, usually for at least two seasons, to ensure that it is novel and distinct from other varieties and that its traits are uniform and stable. This process requires access to good experimental sites and adequate laboratory facilities. In addition, confirmation of distinctiveness requires the capacity to maintain and grow reference varieties for comparison as well as access to databases describing similar varieties. All of these activities imply the availability of well-trained personnel, who in reality may be in short supply in developing countries and whose assignment to PVP responsibilities may entail considerable opportunity costs.

The costs of applying for and maintaining PVP in selected countries are presented in table 4.3, along with comparative data from the EU and USA. It should be noted that the costs of application are substantial; in addition there are significant transaction costs (justifying the use of agents to facilitate the application procedure in countries like China and Colombia). The maintenance fees rise steadily over the full or initial period of protection in most countries; in Kenya there is a flat annual fee for maintenance. It is important to remember that these are *only the costs of obtaining PVP.* Other expenses related to variety testing and release can be substantial and also must be met (representative costs for variety release, for example, are presented in table 3.1).

High fees for PVP can act as a disincentive for application, but little guidance is available on how to structure PVP fees (box 4.4). In China, maintenance fees for PVP are substantial, although some

Table 4.3 Costs (US$) of PVP Applications and Maintenance

Item	China	Colombia	Kenya	EU	USA[a]
Application	217	233	200	1,115	432
Testing	556	1,396 (155 if done abroad)	600	1,265-1,490 (depending on type of crop)	3,220
Granting of rights	-	39	240	-	682
Annual maintenance fee (by year)	(1-3): 181 (4-6): 236 (7-9): 306 (10-12): 398 (13-15): 517 (16-18): 672 (19-20): 874	(1): 78 (2): 155 (3): 233 (4-20): 311	(1-20): 200	(1-20): 540 (beginning 2006)	None

Source: Louwaars et al. (2004), updated with data from PVP office websites.
a. The USA does not charge annual maintenance fees. In addition, in the USA testing is undertaken by the breeder and results supplied to the Plant Variety Protection Office; the testing fee in the table refers to an examination fee.

Box 4.4 Determining PVP application and Renewal Fees

Establishing the appropriate fees for PVP is an important challenge. High fees create a barrier to widespread participation, especially for public institutes or smaller firms. On the other hand, low fees may produce insufficient revenue for the registration and testing authorities, leading to reduced efficiency or rent seeking. In each case it is important to decide the extent to which the government should insist on cost recovery or, alternatively, be willing to subsidize the agency as a stimulus to national plant breeding activity. The need to cover the costs of variety protection has to be balanced by the need to establish effective incentives for stimulating widespread invention.

Different options may be considered for establishing the fee structure:

- One option assumes that the cost of the authority's activities will be shared equally among all applicants and crops. This option will involve a certain amount of cross-subsidizing between crops (for example, few applications and high costs in testing sesame can be compensated by many applications and relatively low-cost registration work in rice).
- Alternatively, countries may establish different fee levels for separate crop groups (based on the actual costs of evaluation). This option may lead to acceptable fees for crops with large numbers of applications each year, such as major cereal crops, but it can lead to prohibitive fees if special facilities need to be maintained, and charged accordingly for crops with few applications per year, such as minor vegetable crops.
- A third option would be to base the fees on the value of the protection for the applicant. Fees for varieties with a larger (more lucrative) potential market can be higher; hybrid rice might attract higher fees than conventional rice varieties, or highly commercial crops like maize would attract higher fees than minor crops like pigeon peas. Considerations of market size also illustrate why it is difficult to make comparisons between countries; the potential market for a variety may be many times greater in China than in a small country like Rwanda.
- Finally, it is also possible to establish different fee levels for different types of applicant. In the USA, for example, patent application and maintenance fees for individuals, small businesses, and nonprofit organizations are only half the fees charged to larger firms.

Source: Authors.

subsidies are offered for public sector applications. Nevertheless, many public plant breeding institutes, particularly at the prefectural level, find they do not have the funds to apply for PVP (Huang et al. 2003). Research managers estimate that the cost of a PVP application for a single variety may be the equivalent of half a researcher's annual budget. The private sector in China also complains about the high costs of PVP. Breeders of ornamentals point out that they need to protect a number of varieties of a particular species to start commercial production. The local market for flowers does not yet sustain such investments, and several foreign breeders avoid sending their elite materials to China for this reason.

Another strategy for cost saving is to consider possibilities for cost sharing and cooperation (Louwaars et al. 2003). There are several options for managing DUS testing. The PVP authority itself may provide all the staff and facilities for DUS testing; this alternative provides a neutral source of expertise, but it requires hiring and training specialized personnel. Another option is to leave the testing to the breeders (whether in public organizations or private firms), with the PVP authority responsible only for monitoring and evaluation. This option can lower the costs of establishing a public institution, but it assumes that the breeding organizations themselves have the capacity to carry out DUS testing. (In Australia, breeding firms often collaborate to manage joint DUS trials, to save money.) Various combinations of these systems are also possible. Finally, a national PVP office can contract another authority to conduct the tests. In Colombia, all the DUS testing for ornamentals is done abroad, while testing for field crops is done in-country by ICA staff with part-time responsibility for DUS testing.

The latter option suggests the potential of regional collaboration. In the EU, for example, a DUS certificate valid in all member countries can be obtained, based on one DUS test done at the request of the Community Plant Variety Office in one member state. Breeders still have the option to apply in one EU member state if they plan to commercialize in that country only. Regional collaboration for DUS testing deserves exploration by many developing countries. For example, the members of the Southern African Development Community (SADC) are developing a system of regional variety release which could be expanded to include regional PVP management. This kind of regional collaboration in DUS testing does not necessarily mean that national PVP laws must be fully harmonized.

Confidentiality

An additional concern regarding the management of a PVP system is the requirement for depositing germplasm, especially the inbred lines used to create hybrids. Hybrids can be protected by PVP on the hybrid itself and/or on the inbred lines. In the first case, procedures in many countries require the applicant to reveal "the formula"—the parent lines and their combination. Because inbred lines are a type of trade secret (whose confidentiality can be maintained well after the expiry of a PVP certificate), companies may be reluctant to turn them over to a testing authority, even though they value the extra protection of the hybrid afforded by PVP. In India, current law requires that the National Bureau for Plant Genetic Resources (NBPGR) take samples of imported germplasm for deposit. This law has been an impediment for some firms wishing to import inbreds and germplasm under development (as in shuttle breeding programs, for example), because the owners may worry about the security of such deposits. India's new PVP law requires the deposit of protected varieties and the inbreds of protected hybrids, and opinion in the seed industry is divided. Some companies feel that the requirement will cause no problems, while others are wary about the prospect and anxious to see how the system will be implemented.

Enforcement

To be effective, a PVP system must include adequate mechanisms for enforcement. It is important to recognize that PVP is a private right and that the rights holders are thus responsible for collecting royalties and detecting violations of their rights. PVP offices themselves generally are not involved directly in enforcement, although they may be called as witnesses or experts in actions taken by breeders. In a recent example in Colombia, a seed company asked the PVP office to examine particular fields and confirm that the cotton variety being grown was the company's. The company could show that the seed was not acquired legally and used the PVP office testimony to obtain an out-of-court settlement. Colombian rice seed companies are concerned about the scale of seed saving and informal seed sales among large-scale producers, and they hope that the new resolution that limits saving seed of protected varieties to smaller farms will provide some relief. But the companies recognize that they will have to identify the violators themselves and bring cases to court. They are concerned that Colombian PVP law currently has no description of penalties for violations.

The experience of the courts is also an important factor in effective enforcement. Chinese plant breeding institutes often produce seed of their own (protected) varieties themselves for fear of losing control of them if they attempt to contract out. Seed management stations under county agricultural administration departments can check licenses, and some are apparently supporting breeders in claiming their rights and imposing fines. But many breeders complain that the knowledge of the courts is often insufficient to enforce these rights effectively.

PATENTS

Patents are national in scope, and an inventor must apply for a patent in each country where this protection is desired. Multiple applications are facilitated through the Patent Cooperation Treaty (PCT), which offers a simplified filing system in 124 member states. The PCT facilitates the application process and encourages the joint technical examination of applications. A single application is made, with the level of fees corresponding to the number of countries in which protection is sought. Similarly, regional patent organizations in Africa—the African Regional Intellectual Property Organization (ARIPO), mainly in Southern and Eastern Africa, and OAPI in West and Central Africa—take much of the burden of processing

Box 4.5 Experience in Patenting for Plant Breeding and Biotechnology

China has the most experience of the case study countries. Patents are administered by the State Intellectual Property Office (SIPO), which is an independent organization. China now has more than 20 years of experience with its patent system; 100,000 applications were filed in 2003. Although living organisms such as plant and animal varieties are not eligible for patents, genes may be patented. By 2003 there were more than 100 applications for gene patents related to agriculture. Biological processes, such as transformation methods, are also patentable. In addition, "methods of breeding" can be patented, which effectively allows patent protection of hybrid varieties. A number of such patents have been granted, but the scope of allowable claims and the impact of these patents is not well known. It appears that the supply of examiners with sufficient biological expertise for considering biotechnology applications is not a constraint in China.

India provides a sharp contrast. Although India has a well-established patent system, the law has specifically excluded the protection of "methods of agriculture." The amended law (January 2005) extends protection to areas such as agrochemicals and the products of biotechnology. It allows the protection of microorganisms (as required by TRIPS Article 27) and genes, although case law will have to determine the extent to which agricultural exemptions will limit the inclusion of plant varieties in the scope of protection. In the period preceding the recent amendment, inventors could deposit an application for a patent in a so-called "mailbox" procedure, which enabled these applications to be considered as soon as the new amendment came into effect.

In Colombia, the patent office under the supervision of the Ministry of Commerce received 1,209 applications in 2003, the majority of which were filed through the PCT. The office employs 15 examiners, one of whom works on biotechnology. Genes and plant varieties cannot be patented (in accordance with an Andean Community agreement), but microorganisms "not found in nature" and transgenic varieties are eligible for patents.

In Kenya, patent applications are handled by the Kenya Industrial Property Institute (KIPI), which employs 20 examiners, several of whom have experience in biotechnology. Kenyan law allows the issuance of both process and product patents in biotechnology but excludes patents on plant varieties. In Uganda, the national patent office has a very limited capacity to examine applications in biology. Most of its work concentrates on examining ARIPO and PCT reports, and it has not yet approached many of the issues related to biotechnology patents.

Source: Authors.

patent applications from the offices of the member countries. However, mechanisms such as PCT and ARIPO leave the final responsibility for granting or rejecting applications with the individual national patent office. The OAPI is a multinational system in which one application can be filed and result in a patent that is automatically effective in all member states.

Only a few developing countries have experience with patents related to plant breeding (box 4.5). No developing country recognizes plant variety patents, and most are just beginning to consider how to approach decisions on the protection of research tools and genetic material used in biotechnology. The case study countries illustrate a wide range of approaches and capacities in patenting related to biotechnology.

Because there are few patents related to plant breeding in most developing countries, there is little experience with enforcement. However, unlike PVP, patents in agriculture can draw upon experiences with enforcing patents of industrial applications. Many countries have law firms with experience in pursuing cases of patent infringement, and extensive international experience and the threat of future claims can affect behavior. For instance, India's National Botanical Research Institute (NBRI) decided not to go forward with licensing its Bt (*Bacillus thuringiensis*) gene construct to local seed companies in 2004 because it was uncertain if the construct's components offered sufficient freedom to operate in the climate of the country's revised patent law and in light of the legal capacities of MNC patent holders.

5 Impacts of IPRs on Seed Companies

There are expectations that new or strengthened IPR regimes for plant breeding in developing countries will provide increased incentives for private seed sector activity. It must be remembered that there has been significant commercial seed production in many developing countries for a number of years without any IPRs, so the challenge is to identify the ways in which new IPR regimes might affect the priorities and strategies of the commercial seed sector. This chapter examines experiences in the commercial seed sector with PVP and the protection of biotechnology.

PVP AND PRIVATE SEED PRODUCTION IN DEVELOPING COUNTRIES

Impact in industrialized countries

There is a limited literature on the impact of IPRs on the seed industry. A full review is beyond the scope of this report (see Lesser 1997; Srinivasan 2001; Eaton 2002), but the studies provide only limited evidence of the effects of PVP in industrialized countries. Studies in the USA have examined the trends in variety release and have surveyed breeders' perceptions. Taken as a whole, these studies indicate that private sector breeding in a number of nonhybrid crops increased following the PVP Act of 1970, but in the case of most crops it would appear that PVP has played only a moderate role in stimulating this activity (Perrin et al. 1983; Butler and Marion 1985; Kalton et al. 1989; Butler 1996; Frey 1996; Alston and Venner 2002). For wheat, Alston and Venner (2002) found that private sector investments in the USA have remained static, while those of the public sector increased.

Studies in other countries are also inconclusive about the effects of PVP. Penna (1994) found an increase in the development of some horticultural varieties but not of others in the UK after the introduction of PVP. In Canada, a survey of breeders following the introduction of PVP reported some increased breeding activity in horticultural crops but less in grains or oilseeds (Canada Food Inspection Agency 2001). In Spain, Diez (2002) found a correlation between the number of PVP certificates granted per crop species and the availability of protection, through either PVP or the potential to develop hybrid varieties. Even when there are relationships, however, alternative explanations are possible. It is thus difficult, if not impossible, to attribute increased breeding investments to PVP alone because of the long-term changes

involved and the role played by a number of factors, such as developments in markets and other policies.

There is not sufficient experience with PVP in developing countries to allow any kind of statistical analysis of impact (box 5.1). Even so, a review of recent events in those countries that have established PVP provides some indication of what might be expected as PVP is instituted more widely.

Company attitudes towards PVP in developing countries

The attitude of the private seed sector towards new IPR regimes in a particular country depends to a considerable extent on the recent history of the domestic seed sector's development.

In India, an exceptionally diverse and dynamic seed sector has developed over the past two decades, supported by quite liberal seed laws. Indian private seed companies are well aware of the new PVP law, and most hope to register their varieties despite what they generally consider to be weak protection. But there is considerable uncertainty about what such registration will entail, and to what extent it will be regulated by seed law or PVP law. Some industry representatives are concerned about the costs and efficiency of managing the large-scale DUS testing that will be required. Many companies welcome the possibility of protecting their hybrids (especially for controlling the theft of inbreds), yet some express reservations about the requirement for depositing protected inbreds with NBPGR. In addition, many Indian companies hope that the establishment of PVP will usher in a new policy that provides greater access to public germplasm. Most Indian companies express an interest in this possibility and a willingness to pay for access to such material.

In China, PVP is only one aspect of major policy changes in the past decade that encourage private sector participation in the seed sector and eliminate the monopoly of the public seed companies. Many smaller, start-up companies have appeared and several larger ones are seeking partnerships with foreign companies. Attitudes towards IPRs differ depending on the size and nature of the company. The larger, well-resourced companies, usually with origins as public corporations, are devoting professional staff to IPR management, primarily PVP and trademarks.

Private seed companies have appeared only recently in Kenya, following the reversal of policies that supported a monopoly of the partially public KSC. Kenya established PVP at about the same time that it started to liberalize the seed market. Local companies have not yet applied for PVP for their varieties, even for maize OPVs, partly because they view the process as involving high transaction costs. Colombia has had a small domestic private seed sector for many years; earlier it depended on public breeding, but it has recently developed its own breeding capacity for a few key crops. It would appear that the major domestic breeding effort that takes advantage of PVP is rice, while MNCs utilize Colombia's PVP for other field crops such as cotton and soybean.

Box 5.1 Early Evidence of the Impact of PVP

An early example of the impact of PVP is found in a study in Argentina, which enacted PBR legislation in the 1970s and joined UPOV (1978) in 1994. As of 1994, 79 percent of the 622 PVP titles issued in Argentina were for OPVs, mostly for field crops such as soybean, wheat, and alfalfa. In the early 1990s, the National Seed Institute (INASE) was created to supervise seed trade; it was a public institute but financed entirely by fees. One of its duties was to enforce PVP, and it was able to police seed sales in the country and impose fines for violations. By mid-1994, INASE had levied 163 fines for violations of PVP. The effect was to greatly reduce the illegal trade in wheat and soybean seed by unregistered dealers and grain elevators and increase the market share for the small domestic seed companies that depended on these crops. These actions have been credited with helping to save this industry, which was otherwise threatened by widespread informal seed sales, but there is little evidence that the private sector has put additional resources into these crops as a result of the establishment and enforcement of PVP.

Source: Jaffé and van Wijk (1995).

The existence of PVP legislation should also make foreign companies more willing to provide their more advanced breeding lines and varieties to a country, but this willingness depends on the effectiveness of enforcement. In India, some local representatives of MNCs say that they still have only restricted access to the parent company's germplasm, while others say that the situation is improving. In China, foreign companies are watching the experiences of domestic competitors in pushing through enforcement cases. Foreign seed companies have been rather cautious about using the new PVP system. They are worried about leakage of their material during the DUS testing, and many are concerned about the effectiveness of enforcement. In many cases, they cite perceived weak enforcement possibilities as a reason for refraining from introducing elite material in the Chinese market or investing in major breeding programs (with partners). The situation with vegetable crops is illustrative. Many domestic companies are applying for PVP protection but still seem to be concentrating on hybrids. Foreign companies, some of whom even use China as a production base for other markets, have generally limited themselves on the local market to introducing older varieties whose original protection elsewhere has almost expired.

Incentives for OPV production

Given that hybrid varieties already offer a certain degree of in-built protection, it might be expected that the major effect of PVP would be to increase incentives for plant breeding and seed production for OPVs. Because most PVP regimes in developing countries do not limit farmer seed saving, however, the potential for repeat sales of protected OPV seed is significantly reduced. This situation helps to explain the apparently modest impact of PVP on private investment in OPVs.

In Colombia, there was already private sector involvement before the establishment of PVP. Companies now seek protection for their rice varieties, but there is not sufficient evidence to demonstrate increased private rice breeding activity due to the IPR regime. Most of the farmers who purchase rice seed manage commercial operations (the average holding is about 32 hectares), and many purchase seed rather than saving it, so the rice seed industry has a reasonable market. Nevertheless, considerable informal seed sales, and the fact that no criminal penalties are described for PVP violations, mean that incentives for seed companies are still limited. The MNCs operating in Colombia apply for PVP on soybean and cotton varieties, but the advent of PVP in Colombia has not seen the emergence of private plant breeding for crops such as OPV maize or beans.

Two Kenyan companies are producing and marketing their own maize OPVs, and KSC also markets public OPVs, but the private companies have so far not applied for PVP for their varieties (and their seed sales for these are modest). Private companies in Kenya are not investing in breeding for other nonhybrid seed crops.

There is not yet much indication of any increased private sector interest in breeding OPVs in China, where PVP was introduced only recently. One of the largest diversified seed companies, China National Seed Group, claims that PVP has not affected its mix of products or breeding strategies. Breeding of OPVs by the private sector (and the marketing of imported OPVs) is minimal and concentrates on small market niches where there is demand from commercially oriented growers who value access to good quality seed. Both domestic and foreign companies indicate that they do not yet have sufficient trust in enforcement possibilities to consider OPVs seriously.

The Indian private seed industry is large and diverse, and no single attitude can be said to characterize its breeding strategies. There is relatively little evidence at this early stage that the new PVP law will elicit much additional breeding activity for OPVs. A few private companies already have their own OPVs (for example, of rice, cotton, and certain vegetable crops); they expect the new legislation will help protect these varieties from competitors, but at this point they have no plans to expand their OPV breeding. A few companies say that if the PVP legislation is effective they may expand into nonhybrid seed, but many others reject the possibility, at least in part because of the very liberal scope for farmer seed saving and exchange. Some seed companies express interest in nonhybrids as a way into the hybrid market. For instance, several companies began conventional rice breeding programs as a way to gain a foothold in what they hope could be a lucrative hybrid rice market.

Industry structure

There is much debate and concern regarding concentration in the seed sector. Economic research on

the seed industry for grains and oilseeds in North America has identified the increased scope of IPRs as one factor contributing to this trend (for example, see Lesser 1998; Fulton and Giannakas 2001; King 2001; Fernandez-Cornejo 2004). Most attention has focused on the crop sectors in which patents play an important role, due to the application of modern biotechnology. There is less attention to the effects of PVP (Lesser 1997), and even basic statistics on market shares are difficult to gather, except for publicly listed companies. Srinivasan (2004) recently examined the degree to which the ownership of PVP certificates in industrialized countries is concentrated. He finds that although the share of certificates owned by a few seed companies is not indicative of exceptional concentration at a global level, individual country statistics show concentration for particular crops. Much of this concentration is a result of the many mergers that took place in the seed sector in the 1990s. But the concentration of ownership of PVP certificates is more a measure of the number of product lines available to farmers, and actual market shares may be more or less concentrated. Whether the level of concentration found in industrialized countries is a matter of concern is open to debate (for example, see Mooney 2000), but it illustrates trends that bear scrutiny in developing countries.

IPR regimes for plant breeding have not been in effect in developing countries for enough time to allow any examination of the impact on the structure of the seed industry. Indeed, many countries find their commercial seed sectors in a position of expansion and diversification in response to liberalization policies, with or without PVP. But the possible effects of PVP on industry structure deserve monitoring. In India, PVP will likely eliminate many of the companies that sell varieties developed by other firms under different names and the fly-by-night operations that sell seed of uncertain origin. Yet if the new PVP and seed laws raise the costs of bringing a new variety to market, small companies that specialize in niche markets will have fewer incentives to operate. (It has already been noted that small seed companies in Kenya currently avoid PVP because of its costs, a practice that could allow larger competitors to appropriate their varieties.) Another concern in India is the role of very small private operations, often farmers, who are linked to public breeding institutes and play an important role in the initial production and popularization of new public rice varieties, particularly in more marginal environments (Pal et al. 2000). Whether such a system will continue under the new PVP and seed laws remains to be seen.

In Uganda, a number of national seed companies are emerging in the absence of PVP, which may be explained more by the gradual decline of the public seed enterprise (now privatized) during the past decade than by the prospect of protection.

Enforcement

Seed companies are learning that most of the responsibilities for enforcing PVP fall to them. In some of the larger Indian firms, new staff positions have been created for monitoring and advising on intellectual property issues. Some companies have tried to deal with particular violations of their intellectual property (such as the imitation of brand names or theft of inbreds) by hiring lawyers and occasionally pursuing court cases, but company intellectual property skills have not grown stronger as a result. Companies that are part of larger commercial holdings can draw upon the legal capacities of the parent company. Several large companies in India have developed genetic fingerprint data for court cases regarding variety theft, but they have not yet been able to get such evidence admitted.

Many smaller Chinese companies, on the other hand, have established themselves in order to produce and sell seed of competitors' varieties illegally, reportedly without knowledge of restrictions imposed by IPRs. Some of the larger companies describe the current situation as a learning phase for a market that does not have a long history of IPRs. The CEO of one major domestic seed company explained that they pursue as many PVP infringement cases as possible, because they feel it is necessary to "educate" their competitors, as well as the legal system, about the new rules of the game.

THE USE OF OTHER METHODS OF PROTECTION

Hybrids

Despite the biological protection offered by hybrids, the majority of attention for PVP in China is on hybrids or inbred lines, accounting for about two-thirds of the PVP certificates issued to date for field

crops. Plant breeders are concerned about the lack of physical security for their inbreds in seed production plots and hence are willing to invest in PVP. Even though PVP can help improve the protection of their hybrids, some companies continue to use (modified) three-way crosses that lower the possibilities that competitors can acquire their inbreds.

The situation is similar in India, where seed companies are anxious to apply for PVP for their hybrids. There are many private seed companies, and seed production usually takes place with contract farmers in specific areas of the country that have appropriate agronomic conditions and grower experience for efficient seed production. The juxtaposition of many small seed producers for competing firms and the impossibility of providing strict monitoring means that inbreds and other germplasm may be stolen or traded. Some observers estimate that one popular cotton hybrid has leaked from the company that developed it and is now produced and sold under different names by as many as a dozen competitors. The hope is that the new PVP and seed laws will allow companies more control over their inbreds.

In countries where the physical protection of inbreds is less problematic (either because crosses are made outside the country or because commercial competition is less intense), PVP for hybrids is less of an issue. This seems to be the case in Colombia, where neither MNC nor domestic maize hybrids have sought PVP. The situation in Kenya is more complex. The public (and parastatal) maize hybrids are seeking protection, in part because of the possibility of royalties, but the maize hybrids of the small domestic companies have yet to apply for PVP. In Uganda, where a local seed company produces maize hybrids on contract for Monsanto, the current lack of PVP means that the operation must be very closely supervised (all inbred parent seed provided by the company has to be planted and all the males destroyed immediately after pollination), which adds to the cost of the seed.

Seed laws

Seed law can also be used by private companies to protect their rights. In Uganda, exclusive license contracts with seed producers to produce National Agricultural Research Organization (NARO) maize varieties are based not on PVP but on a gentlemen's agreement about NARO's ownership of the varieties, backed by seed certification requirements. Companies cannot produce commercial seed when they cannot demonstrate access to NARO-supplied breeder's seed. This requirement may not stop them from commercializing such varieties abroad, but any such attempt may exclude them from access to future NARO releases.

In China, companies are also able to control some illegal sales of their varieties through seed regulations that require seed companies to be certified. Thus smaller, fly-by-night propagators or vendors can be shut down, or bags of seed can be removed from shops, by bringing violators to the attention of the local (county or city) office of the Administration of Industry and Commerce.

Contracts

The importance of contracts for enforcing rights to plant varieties is best illustrated by the cut flower industry, which is able to manage production by contract growers in countries with and without IPR regimes. Most flower producers in Colombia and Kenya are only vaguely aware of the PVP offices in their own countries, but they are well acquainted with the royalties that they pay on planting material, negotiated with the flower breeding companies in Europe or elsewhere.

Given the possibility of controlling illegal production through the withdrawal of contracts and the relative ease of monitoring wholesale markets, it is fair to question the role of PVP regimes in producer countries for the flower industry. Many producers in Colombia and Kenya say they saw no particular change in their conditions or markets when their countries joined UPOV. On the other hand, these producers may not be aware of the degree to which their choice of varieties (presented in catalogues to the growers) may be influenced by the breeding company's confidence in the business climate of those countries with PVP legislation.

The case of Uganda illustrates that a country can attract a buoyant flower production industry without a PVP regime. If the flower varieties are protected through PVP in the country of destination (or if they are trademarked), then PVP in the country of origin may be irrelevant. The flower industry in the Netherlands is lobbying for strong IPRs in the main production countries, however, to create additional ways to tackle infringements. This protection is particularly important where a domestic market and additional wholesale markets develop, such as direct exports from Kenya to the Middle

Box 5.2 Protecting Biotechnology: Roundup-Ready Soybean

Several countries in South America produce RR soybeans, although much cultivation is illegal because of bans on transgenic crops (for example, in Brazil and Paraguay). These soybeans were first introduced to Argentina, where they contributed to an expansion in soybean cultivation and exports. Although genes can be patented in Argentina, Monsanto was unable to make an application in time, so its RR soybean varieties are protected by PVP only. The great popularity of RR soybean varieties was counterbalanced by the black market for seed; only a small proportion of farmers bought seed from legitimate sources, and Monsanto temporarily stopped selling soybean seed in Argentina in early 2005.

Similar problems are evident in Brazil. Owing to debates and delays regarding official approval for the cultivation of transgenic varieties, all of the country's substantial RR soybean harvest is illegal and based on black market seed, much of it brought across the border from Argentina. At one point Monsanto suggested levying royalties from shippers in Argentina and Brazil, which provoked much debate. Monsanto has now taken steps to enforce its patent rights on Argentinean shipments of soybeans arriving in Denmark. It appears that the most likely solution is to charge a royalty based on grain sold at harvest, to be collected by grain dealers, cooperatives, and processors. Negotiations are in progress with producers' organizations and ministries of agriculture, although there is still considerable opposition, especially with regard to charging royalties on farm-saved seed. Monsanto has said that it will not provide advanced soybean technology to these countries until a satisfactory royalty system is established.

Source: Authors.

East and other parts of Africa. Some producers in Colombia believe their industry is better positioned than that of neighboring Ecuador (which does not have a functioning PVP system).

Business practice

Business practices can also help to combat the illegitimate use of company varieties. The seed industry in India has had to contend with high competition and very little legal protection for its germplasm for nearly two decades. Many companies place great emphasis on the importance of developing a brand image as a way of encouraging farmers' loyalty and protecting themselves from imitators. But following up on the misuse of a brand requires time and resources. One company has faced repeated instances of people selling "seed" in falsified bags, but it has been able to catch perpetrators only twice, and the only case that made it to court resulted in just a small fine.

The MNCs are particularly experienced in using other business practices to help protect their varieties. The most important of these practices is the selection of local partners in the initial stages for marketing and possibly also production. Companies repeatedly stress this issue in interviews. While they will reinforce these agreements with contracts, they want to minimize the risk that they will end up in a dispute with their business partner. The MNCs generally have low expectations of enforcing contracts in the study countries, and in any case once material has leaked out it is too late.

PROTECTING BIOTECHNOLOGY

The MNCs have made exceptionally large commitments to the development of transgenic crops and are anxious to protect their investments. In industrialized countries, the effective enforcement of patents and PVP is sufficient to limit the appropriation of genetic material by competitors (although a number of complex court cases are concerned with determining the actual ownership of some of this technology). Prohibiting seed saving by farmers has proven somewhat more difficult, and Monsanto invests significant resources in detecting violations, initiating a number of lawsuits in North America related to seed saving of its transgenic varieties. Nevertheless, the illegal use of seed of transgenic crops is very modest in these countries.

The situation is different for developing countries, where IPR regimes are not necessarily in place, enforcement capabilities are often poor, and the range of informal seed transactions is wide.

Box 5.3 Protecting Biotechnology: Bt Cotton

China has the longest experience with Bt (*Bacillus thuringiensis*) cotton of any developing country. In China, Bt cotton varieties are available through a joint venture between Monsanto, Delta and Pineland (DPL), and the Hebei provincial seed company. Separate gene constructs and Bt varieties have been developed by the Biotechnology Research Institute (BRI). It was estimated that almost one-third of all of China's cotton area was planted with Bt varieties in 1999, and 58 percent in 2003 (Pray et al. 2002; James 2003). Monsanto has patent protection in China for their transformation methods and the 35S promoter gene, but not for the cry1Ac gene construct. The BRI has patent protection for its two Bt constructs, but it acknowledges that its marketing company (Biocentury) faces problems in enforcing these patents. Cotton varieties cannot be protected by PVP in China. There is widespread illicit production and marketing of Bt seed. DPL's construct reportedly has been crossed into other varieties by farmers. Some observers believe that biosafety regulations provide the most effective means of limiting illicit sales, but there is widespread cultivation of Bt cotton varieties in provinces for which approval has not yet been granted.

India's experience with Bt cotton has also attracted widespread attention. Its first Bt cotton varieties were released through a joint venture between Monsanto and India's largest seed company, Mahyco, which it partly owns. When the varieties were released it was not possible to patent genes in India, nor was the PVP system in force. Mahyco's Bt varieties were approved only for certain states, but a thriving underground market for the seed developed in other areas. There are estimates that half the Bt cotton grown in the country is illegal. Several new Bt cotton varieties were approved in selected states in 2005, including further Mahyco varieties and varieties from two local seed companies that license the Monsanto-Mahyco gene. Monsanto's strategy with respect to Bt cotton in India has now shifted towards technology provision rather than direct marketing. A joint venture (Mahyco-Monsanto Biotechnology Ltd.) is providing the Bt gene for cotton to Indian seed companies. As the company does not "own" the gene in India, the contract is based on access to the biosafety data that are necessary for approving any transgenic variety.

Bt cotton plays a part in the policy of the Colombian Government to revive its cotton industry. Both Monsanto and the Colombian government are anxious that the experiment to introduce Bt cotton in 2004 works well, and considerable care has been taken to avoid unauthorized production. The production and sale of seed of the Bt variety is licensed to a local seed company. Farmers who want to grow Bt cotton must register with a cooperative, through which they sell their harvest. The seed company and ICA monitor cotton fields to ensure that growers comply with the requirements for planting a non-Bt refuge. The Bt variety does not yet have PVP; the Bt gene is not patented in Colombia (which does not allow gene patents), but Resolution 2046 makes it illegal to save transgenic seeds on the farm. The strict enforcement is expected to prevent any illicit activity.

Bt cotton has also been grown in South Africa since 1998 (Thirtle et al. 2003). A DPL cotton variety was introduced under very controlled conditions. The seed is provided by one private company; growers must be registered members of a farmers' organization, and the harvest can be sold only at designated ginneries. Similar controls characterize the cultivation of Monsanto's Bt cotton in Mexico. Farmers have to sign seed licensing contracts which forbid saving or replanting the seed, require sale of the harvest at designated ginneries, and allow Monsanto officials to make spot checks on farmers' fields (Traxler et al. 2001).

Source: Authors.

The MNCs are particularly anxious that developing countries adopt strict IPR regimes. Foreign seed companies operating in India that use biotechnology in their breeding programs expect that the new patent law will provide effective protection after an initial maturation period, and many have filed applications, using a "mailbox" procedure. Such applications are considered at the start of the new patent law. The use of this procedure addresses restrictions on late registration. At the same time, companies are increasingly wary of working with technologies that may contain

components that could be in the "mailbox" and eventually fall under an Indian patent.

But even when IPR regimes are in place, local customs and enforcement inadequacies make the protection of biotechnology a considerable challenge. Nevertheless, MNCs have been particularly anxious to establish a foothold for their transgenic crop varieties in developing countries and have often been willing to risk operating in situations where enforcement possibilities are limited. The gamble has paid off in some instances and provided valuable lessons in others. The two most prominent cases concern Monsanto's technology: herbicide-tolerant Roundup-Ready (RR) soybean and insect-resistant Bt cotton (boxes 5.2 and 5.3).

Controlling transgenic varieties

It is particularly difficult to control seed saving of transgenic varieties by farmers, especially because even those countries with PVP legislation usually allow a farmer's privilege. Latin American farmers' objections to Monsanto's proposed royalty collection at harvest are based on their rights to save seed. Where hybrid technology is available, it can make some contribution. For example, the fact that all of India's Bt cotton varieties to date are hybrids (and most Indian cotton farmers are accustomed to buying fresh seed each season) probably contributes to limiting the degree of informal transfer of Bt cotton seed in India. Specific seed contracts (as in Mexico) or government resolutions forbidding any seed saving of transgenic varieties (as in Colombia) may help, although it remains to be seen whether such contracts are considered legal (because they may contradict the provisions of Farmers' Rights) and whether they can be enforced on a large scale. Where the sale of the harvest can be monitored and controlled, the company can detect the use of unapproved seed, or (as in the case of soybean) royalties can be charged. But these enforcement strategies require considerable administrative capacity, and it is not clear if they are feasible for dealing with large numbers of small growers spread over a wide area.

In countries that have considerable plant breeding capacity and a large number of commercial seed producers (China and India, for example), keeping transgenic varieties from the hands of black market seed producers is a particular challenge. Both PVP and patents address this problem, but the conscientious enforcement of the seed laws could eliminate much of the illicit transgenic seed currently available to farmers. A number of observers in India and China place their hopes on biosafety regulations for controlling the illegal sale of transgenic seed, but this form of control is appropriate only at certain levels. Biosafety authorities are mandated to monitor the environmental and public health aspects of the use of transgenic crops and are not trained or equipped to police seed markets. If unapproved transgenic varieties are detected, sanctions defined in biosafety regulations can be applied, but the biosafety agency is usually not the appropriate source of enforcement.

The problem of controlling the use of transgenes by established competing seed firms would appear to be the least of the worries of technology owners. In most cases, a combination of biosafety regulations (identifying the genetic background and conducting field trials before approval) and simple variety registration requirements would limit many possible instances of misappropriation. Thus adequate protection and incentives for transgenic technology development depend on the appropriate division of responsibilities between seed law, biosafety regulation, and IPR regimes. Overly rigid IPRs are not necessarily the answer, and attention to adequate enforcement of basic regulations is liable to yield larger dividends.

6 Impacts of IPRs on Public Sector Plant Breeding and Seed Production

IPR regimes for plant breeding have important implications for the management of public sector agricultural research. NARIs need to develop policies that help them decide when to use intellectual property for their own inventions, how to enforce these rights, and how to gain access to protected technologies from elsewhere. Strengthened IPR regimes are not the only factor that motivates NARIs to consider strategies for generating revenue, but PVP and patents provide additional opportunities whose management requires careful thought. The possibilities of earning royalties have implications for the ways in which scientists are rewarded, the development of enforcement capacity, and the management of public seed production programs. The pursuit of IPRs for NARI technology also has significant implications for the types of crops, breeding strategies, and targets selected by NARIs.

International agricultural research is also affected by IPR regimes, and IARCs require carefully considered intellectual property policies. They need to consider how this new environment affects their interactions with NARIs and the private seed sector, and they need to make sure that their use of protected technology allows them to deliver products to their clients.

INTELLECTUAL PROPERTY POLICIES IN NARIs

Very few NARIs in developing countries have comprehensive IPR policies. One of the exceptions is Brazil, where the Brazilian Agricultural Research Corporation (Embrapa) has long experience in managing IPRs. In 1996 Embrapa published its policy for managing IPRs, which included the formation of an Intellectual Property Committee that meets twice a year to discuss policies and issues (Sampaio 1999). The policy emphasizes that Embrapa will make maximum use of IPRs through the licensing or transfer of proprietary technology and states that royalty-free licenses will be used only when their use is consistent with Embrapa's public service commitments. Embrapa has also reviewed its licenses for biotechnology tools and has negotiated several agreements with foreign intellectual property holders, some of them based on reciprocal access to Embrapa technology. Embrapa's individual research units each have an IPR committee to deal with specific questions.

Few other large NARIs in the South have advanced this far in defining IPR policy. China's public research institutes have considerable experience with IPRs, but most NARIs in China lack written

policies on intellectual property management. However, most Chinese NARIs have guidelines and rules on IPRs that are understood by employees and management, although the approaches vary widely among institutes. Not surprisingly, institutes working on genetic transformation tend to have more experience with intellectual property management than those whose work is confined to conventional plant breeding.

The Indian Council of Agricultural Research (ICAR) also lacks a written intellectual property policy, and ICAR's constituent institutes look to Council headquarters for guidance and direction on these issues. On its website, ICAR has guidelines for seeking patents, and it is issuing instructions for DUS testing of extant varieties and registration of germplasm. IPRs are currently managed with very limited resources by a small unit at ICAR headquarters. Similarly, most Indian agricultural universities do not have an intellectual property policy.

Smaller NARIs are still developing their own IPR policies. KARI, for instance, divides attention to intellectual property issues between its lawyer and the head of its biotechnology center. In Uganda, NARO recognizes that it needs staff with some intellectual property expertise but is not considering employing its own lawyer. Some institutions in Eastern Africa do have an intellectual property policy, developed under the guidance of the Eastern Africa Regional Network on Biotechnology (BIOEARN); these policies tend to concentrate on maximizing revenue.

REVENUE GENERATION STRATEGIES

IPRs offer possibilities for public institutes to generate revenue. The prospect of raising revenue is welcomed by research administrators who have to contend with inadequate public budgets, but there is considerable uncertainty regarding both the level of income that can be expected and the effects that this revenue might have on research programs (box 6.1).

Revenues on varieties

Chinese research institutes have considerable experience with revenue generation strategies. Many provincial crop research institutes had been selling exclusive rights for hybrid varieties of rice and maize to seed companies before the introduction of PVP. On the other hand, some institutes take responsibility for their own seed production and rely on private companies for marketing only. The Cotton Research Institute (CRI) traditionally has generated revenue by selling the rights to market its seed, and the Institute for Vegetables and Flowers (IVF) has also generated revenue from seed sales, relying on companies for marketing. The introduction of PVP has allowed institutes to request higher prices for their varieties, and in many cases auctions have been organized.

Another arrangement that does not necessarily require IPRs is to collect revenue by selling source seed (breeder's or foundation seed) of public varieties to seed producers. For instance, Andhra Pradesh Agricultural University sells more than 70 tons of breeder seed of its rice varieties every year to private and public seed producers. Access to public breeding lines in India is problematic, and many companies hope that the new IPR regime will lead to greater public-private collaboration. In a few recent instances, however, public institutes or universities have entered into nonexclusive agreements that give seed companies access to breeding lines, following guidelines set down by ICAR for such contracts.

In most cases, NARIs will stand a better chance of attracting licensees if they offer exclusive access to their varieties or breeding lines, but even if it can be demonstrated that an exclusive license provides the most effective delivery route for a variety, such an arrangement may clash with the expectations of public service. The KARI administration favors nonexclusive licensing arrangements for this reason, and it lost the chance to license one of its maize hybrids to a company because of the exclusivity issue. In India, a strong public service tradition makes it unlikely that very many public varieties or breeding lines will be assigned on an exclusive basis, and ICAR believes it has an important role in counteracting trends towards concentration in the commercial seed market.

The potential for generating revenue through royalties on public varieties and sales of breeding lines varies by crop and by country. In countries that have large, technically proficient public breeding programs and diverse, well-developed commercial agricultural sectors, NARIs will certainly have things to offer. Even in these cases, the proportion of the budget that can be covered from such sales may still be quite low.

Box 6.1 Licensing Public Varieties

Kenya has a well-established PVP law, but there are few examples of revenue generation by the public sector to date. An important factor is the continuing uncertainty about the ownership and protection of many of KARI's older varieties, which have been the exclusive province of the KSC. Another factor is that very few KARI crop varieties aside from maize hybrids are of interest to the private sector. The barley varieties used by the beer industry are an exception: KARI has entered into a nonexclusive agreement with Kenya Breweries, which pays a 2.5 percent royalty on the value of the seed of KARI barley varieties that the company provides to its outgrowers. As a result of the brewery's support for barley breeding, PVP is being sought for several new barley varieties, with Kenya Breweries and KARI as joint owners. Although KARI tendered 16 maize hybrids in early 2004, with the expectation that various seed companies would bid for production rights, the outcome was disappointing. Only three of the hybrids were contracted, in each case to very small seed companies.

In Uganda, NARO recently licensed different maize hybrids and OPVs to four different companies that were willing to enter into contracts and agree to pay royalties, even though there is no PVP in Uganda. NARO's legal advisors believe that NARO can demonstrate ownership of these hybrids, and in any case the country's mandatory seed certification law would make it difficult for another company to sell seed of these varieties.

In Brazil, Embrapa has collaborated with the private seed sector since 1989 to market its maize OPVs and hybrids. Access to the varieties is mediated by a consortium of small- and medium-sized seed companies, and the royalties received by Embrapa make an important contribution to the operating costs of its maize program (Garcia 1998).

Colombia has several examples of privately funded commodity research. The cotton growers' association provides some funding for cotton breeding to CORPOICA (the Colombian Corporation for Agricultural Research, an independent corporation created by the Colombian government as part of its effort to privatize research). The growers' association agreed that royalties would go to a fund for cotton research. Given that PVP is well established in Colombia, there are surprisingly few examples of contracts between CORPOICA and the private sector. One of the problems is that many public varieties are OPVs (beans, maize, wheat, oats) that are of little interest to the private seed sector.

Source: Authors.

An additional possibility for NARI plant breeding programs to generate revenue is through interaction with MNCs. In such cases, the NARI provides germplasm in return for a share of royalties on any varieties eventually marketed (nationally or internationally). Several international seed companies are active in India, and in a few cases they have simply purchased nonexclusive access to public breeding lines. Once the PBR legislation is in place, these interactions may be strengthened and formalized. In Kenya, KARI has an agreement with Monsanto to provide maize and cotton breeding lines for possible genetic transformation, in return for a share (as yet unspecified) of royalties on any transgenic varieties that are ultimately developed.

Patents

The patenting of innovations is an additional mechanism for NARIs to generate revenue. Among the case study countries, China's NARIs have the most experience with patents. The BRI owns approximately 10 patents and has another 40 applications pending, of which 2 have been submitted for overseas protection under the PCT. The BRI has patented two Bt genes and commercialized them in cotton varieties through a joint venture with Biocentury Transgene Technology. Although the revenues have been much less than expected (difficulties in enforcing the patent have led to the emergence of a large black market for Bt cotton seed), BRI currently generates about 15 percent of its income from patents and expects to increase this share significantly in coming years.

India's public agricultural research institutes have limited experience in patenting, and policies and modalities are still being established. However, there is growing experience in patenting plant-based products and processes for pharmaceutical uses (locally and abroad). The NBRI used

this experience in the international patent applications for its Bt genes, which have not yet been commercialized. One commercially successful case involves a method for detecting the Bt gene in a plant, developed by a scientist at the Central Institute of Cotton Research (CICR). ICAR did the paperwork to acquire an Indian patent and (through PCT) to pursue patents in several other countries. The detection kit is being marketed by an Indian firm, and royalties go to CICR. Although this is a success story, the public system has no institutional mechanism for pursuing patents or sharing costs and royalties, and there are cases where scientists in agricultural universities are left to their own devices to pursue patents.

Incentives for individual scientists

A particularly important administrative issue for NARIs is the degree to which royalties are shared with individual scientists. Staff promotion is generally determined by a fairly complex set of criteria, usually including research productivity, publications, and service to the institute. For breeders, the number of released varieties is often an important criterion. As NARIs begin to earn royalties from protected varieties, breeders may also share directly in the financial benefits. NARIs are approaching this issue in various ways.

Chinese NARIs have the broadest experience in earning royalties through commercial seed sales, and breeders generally are given a "bonus" related to the level of royalties received. This practice was common even before the introduction of PVP. The BRI receives one-third of the net revenues from its joint venture with Biocentury, with half of this amount going to the research group that developed the Bt cotton genes and 10 percent to the individual scientists. The provincial academies of agricultural sciences and their institutes have developed their own approaches to revenue sharing, although generally they seek to ensure that not only breeders but also other staff benefit from the royalties.

In Brazil, researchers in public institutes may be entitled to as much as one-third of the revenues earned by their institute's protected inventions. In Kenya, KARI has yet to establish a policy, but it is under pressure from the Kenya Plant Breeders Association to accept a formula for dividing royalties (based on the type of crop) with the breeder; the association is even lobbying to have this formula included in the revised Seed Law to apply to both public and private sector breeders. The director of KARI acknowledges that deciding how to divide royalties within the Institute, between and among programs, is a significant management challenge.

ENFORCEMENT

Another administrative challenge for NARIs wishing to take advantage of IPRs is the investment required to enforce agreements. If a NARI sells or licenses a protected variety or technology for a fixed fee, then enforcement is not its problem (although possibilities for enforcement can affect what a company is willing to pay for access to a variety). But royalty collection assumes a capacity for enforcement.

The issue is similar in public research institutions in the North, where various strategies are followed. Early biotechnology inventions, such as particle gun technology, were provided under an exclusive license that required just one negotiation and relieved the owner of the invention (in this case, a university) from further complex intellectual property management and royalty collection tasks. The limitations of exclusive licenses caused a number of U.S. universities to join forces in intellectual property management under the Public Intellectual Property Resource for Agriculture (PIPRA), which intends to support both commercial and humanitarian applications of technology. The management of PVP for publicly developed varieties is often complex because different seed producers want to market the varieties. For example, the Wageningen University and Research Centre employs several marketing staff to look after the commercial interests of the Centre's strawberry varieties.

In China, rice breeding institutes that are oriented towards generating revenue either sell or license their varieties to seed companies, in which they may even have an ownership share. Although some institutes have considerable experience in enforcing their rights, others that have recently acquired their first PVP titles do not. The IVF acknowledges that difficulties in enforcing PVP were a major factor in its decision to continue exclusively with hybrids. Staff from the CRI are deployed to check local shops for illegal seed of their cotton varieties, but this strategy is only partly effective, because illegal copies of CRI's Bt cotton varieties are readily available, even in Anyang, where the Institute is located. In other countries, NARIs have

little experience with enforcement, but NARI administrators acknowledge that extra effort will have to be devoted to establishing agreements with seed companies, collecting royalties, ensuring that adequate seed certification and/or sales data are available to verify seed quantities, checking for unauthorized sales, and pursuing violations.

PUBLIC SEED PRODUCTION

NARI seed production

As an alternative to contracting with private seed companies, NARIs may choose to produce and market seed themselves. Despite several decades of generally unhappy experience worldwide with public seed production schemes, the problems of interesting private companies in seed production (even under strengthened IPR regimes), combined with pressure on NARIs to demonstrate a capacity to generate revenue, have encouraged several NARIs to consider their own seed production strategies (box 6.2).

The situation in China is particularly complex, as many research institutes are expected and also have clear incentives to generate a significant proportion of their own budgets. To maintain control over parent lines, the IVF has always undertaken its own production of vegetable and flower seed, which it sells through retailers. In the cases of cotton and rice, incentives for generating income have led some research institutes to establish their own subsidiary production and marketing companies. Smaller institutes like the Tianjin Cucumber Research Institute have been formally turned into successful commercial enterprises. In other cases, contracts granting exclusive access to new varieties are negotiated with companies that have a special relationship with the institute.

Other public seed production

Public sector seed enterprises have generally declined in developing countries during the past decade. The advent of IPR regimes may further affect the viability of this sector.

India's state seed corporations concentrate almost exclusively on the production of public OPVs, although the public sector still produces some hybrid maize seed. (The Maharashtra State Seed Corporation is an exception in having its own breeding programs in several crops.) As long as state universities and ICAR institutes continue to sell breeder's seed of their varieties to all seed enterprises, most state seed corporations may experience little change from PVP. Independent of PVP, state seed corporations are increasingly challenged by private sector activity. For instance, private companies now supply more than half of the seed of public rice varieties in Andhra Pradesh.

In Kenya, the fate of KSC, which has operated for many years as a successful commercial enterprise with majority shares held by the government, has yet to be decided. Although KSC continues to dominate the market, management problems and irregularities in recent years have left doubts about

Box 6.2 NARI Seed Production Units

KARI established a Seed Unit to ensure that source seed of KARI varieties was readily available to seed producers. An important rationale for creating the Seed Unit was the concern that seed of many "orphan crops" was unavailable to farmers, because commercial seed enterprises took little interest in those crops. It was thought that a more transparent, efficient facility for producing source seed would help generate commercial interest and foster smaller seed enterprises, but the Seed Unit also deals with hybrid maize in cooperation with small seed firms and produces other commercial seed stocks (for example, potato seed). The Seed Unit has been an important player in donor projects that support seed production by local producer groups, but it is unclear if any of these groups can survive commercially. In Colombia, CORPOICA has taken a similar route by establishing a Seed Production Unit that primarily undertakes seed production as part of its public task but also produces some commercial seed. The unit is not always reimbursed by the government programs that request the seed.

Source: Authors.

its role and even about the degree of public ownership. The company has lost its previous monopoly status, but many express the belief that the government will still look to KSC as a guarantor of maize seed sufficiency, and as such the company would expect certain concessions. PVP on its established hybrids could provide KSC with some valuable assets to maintain its strong position in the market.

NARI PLANT BREEDING PRIORITIES AND STRATEGIES

Research investments

The pursuit of royalties for the use of public varieties and breeding lines may have important implications for the nature of public plant breeding. Certain crops are much more likely to attract commercial interest than others, raising concerns that the possibility of earning royalties may shift NARIs' resources to the more commercially attractive crops, even though such a shift might not be in line with their mandate for agricultural development and poverty reduction. Because the private seed industry values hybrids and other seed with commercial potential, NARIs that respond to demand from commercial seed producers may shift their focus away from less commercial seed crops such as beans, cowpea, cassava, and millet and towards more commercial crops such as maize, sunflower, and vegetables. Similarly, research priorities within a particular crop may shift from solving constraints to smallholder agriculture to increasing output in commercial agriculture, with a corresponding shift from OPVs to hybrids. An examination of crop portfolios, breeding objectives, and breeding methods in NARIs gives some indication of these trends, although these shifting priorities cannot be attributed solely to the advent of an IPR regime. Most NARIs find themselves under increased pressure for cost recovery, and the exploitation of IPRs is considered a potentially important strategy for achieving that goal.

The case of NARO presents an interesting example. Uganda's new agricultural policy emphasizes that agricultural research is to be client oriented and market driven. NARO now sees its principal role as contributing to the development of commercial agriculture in Uganda and is prepared to allocate its resources accordingly. This new policy means that priority will be given to such crops as hybrid maize (with the possibility of earning royalties on seed). It also means that priority will be given to any crop for which demand is evident, for example through donor funding for research. Although NARO has released a number of bean varieties, and several are produced on a modest scale by private seed companies (often for sale to relief agencies), no seed company is yet willing to invest in seed production for climbing bean varieties. It remains to be seen if this situation will result in diminished investment in climbing bean breeding within NARO. The emergence of PVP in Uganda thus reinforces a broader, commercially oriented direction for NARO.

Agricultural development policy is less well defined in Kenya, but KARI currently assigns high priority to crops from which it can earn revenue. The fact that past KARI research produced many of the maize hybrids that are planted on more than half of the country's maize area gives KARI confidence that hybrid maize will be a major revenue earner, once new hybrids can be offered to the seed companies operating in the country. The implications for other crops are less clear, although KARI leadership acknowledges its public service mandate and recognizes that Kenyan farmers grow a range of crops that do not figure in current seed company portfolios.

It is difficult to predict how PVP legislation in India will affect the relative distribution of research investment across crops. At present there is no indication that research administrators plan to adjust their portfolios because of potential royalties. ICAR administrators believe that any royalties will be remitted to ICAR headquarters (and to the Treasury), thus limiting incentives for shifting priorities in favor of royalty-earning crops. Administrators of state agricultural universities emphasize their mandate to serve state farmers, which sometimes leads them to give less emphasis to hybrid development (in rice or vegetable crops, for example).

As noted, many crop research institutes in China generated revenue from sales of varieties or seed long before the advent of PVP, so the impact on research priorities may be limited. However, government funding of some institutes depends on adoption targets. For example, the Rice Research Institute of Guangdong receives extra financing based on the area sown with its varieties. Despite that, the Institute is concentrating more on hybrid varieties because of the potential for generating income. The CRI has a mandate to develop open-pollinated cotton

varieties for poorer farmers. The IVF, however, concentrated on hybrid varieties and revenue generation even before the introduction of PVP.

The orientation of public research towards the needs of smallholder farmers, which gained special attention in the 1980s, has led to a wide range of participatory research processes, including participatory plant breeding (Sperling et al. 2001; Almekinders and Louwaars 2002). Most NARIs lack policies that define ownership or benefit sharing arrangements for varieties developed through participatory approaches. When revenue collection becomes a guiding principle in NARIs' research management, it is not certain whether NARIs will continue to invest in approaches that feed only into local seed systems. In such cases, NARIs may consider participatory programs only if they attract donor funding.

Access to patented technology

NARIs need to think much more carefully about the implications of their use of protected technology. Researchers in most NARIs use patented technology for activities such as marker assisted selection or genetic transformation. Few varieties or other products have yet to emerge from this work, but only a minority of bench researchers are aware of the implications of using protected technology. NARIs in the study countries rarely commission (or have the capacity to undertake) an intellectual property audit. Frequently their freedom to operate is not clear, and other potential consequences of using patented technology are not understood or addressed.

The country case studies found two very distinct attitudes in laboratories towards third-party intellectual property: overapprehension and ignorance. An example of the former attitude is that some institutes in ICAR now insist on prior permission for the use of intellectual property in research, including the freedom to commercialize any innovations that are developed. On the other hand, a 1998 survey of agricultural research organizations in Brazil, Chile, Colombia, Costa Rica, and Mexico found widespread use of proprietary biotechnology tools and processes but relatively little knowledge of the IPR implications (Salazar et al. 2000).

When NARIs enter into formal agreements to acquire protected technology, they may or may not be able to bargain effectively. In Kenya, KARI entered into a contract for access to Bt technology. The contract stipulates how the genes can be used and who has rights to any inventions that are based on the technology. It also prescribes that KARI will have to use new versions of the technology (from the same supplier) as soon as they become available. This limits KARI's opportunities to use other sources of Bt technology, such as those that go out of patent. KARI entered into the contract to get training in the use of the technology and to develop future scientific collaboration, even though management knew that the patents on the technology were not valid in Kenya. It is not clear if the potential long-term obligations for KARI balance the short-term value of this arrangement.

IMPACT ON IARCs

Intellectual Property Policies in IARCs

The IARCs within the Consultative Group on International Agricultural Research (CGIAR) have long been able to operate outside the intellectual property debate and produce international public goods that are freely available to primary target groups in developing countries and commercial users in industrialized countries. The emergence of IPRs in the biological sciences and their introduction in developing countries are forcing the IARCs to reconsider their approach. The situation is further complicated by the shifting focus of the NARIs, which are some of the primary partners and initial target groups for the IARCs within the CGIAR system.

All of the IARCs with crop breeding mandates have written intellectual property policies, although some of these policies remain in draft form and their actual implementation is still evolving. Several IARCs now have their own lawyers, whereas others have given staff the responsibility for intellectual property management. The CGIAR has also established the Central Advisory Service on Intellectual Property to assist the IARCs and help share experiences and practices in intellectual property management.

Most of these IARCs have seen their principal role as supporting NARI breeding programs. In many cases, the IARCs do not release their own varieties; NARIs either test and release IARC materials or use IARC germplasm to develop their own varieties. Germplasm, both improved varieties and raw or genebank materials, is moved within and outside the IARCs under

MTAs. The MTAs that accompany genebank materials are standard for all IARCs under their agreement with FAO. These MTAs stipulate that no IPRs can be claimed on the material in the form received. On the other hand, MTAs used with improved germplasm can vary, although they only allow that rights can be taken out if such protection can be shown to stimulate wider distribution and use of the materials. The recipient also may transfer the materials to third parties provided that the same MTA is used (or the same provisions are maintained). This rule has led to discussions about whether it requires farmers participating in on-farm testing of varieties to sign such agreements and whether it is fair for farmers to take responsibility for such reach-through provisions themselves. The main argument against such strict regulation is that farmer-to-farmer exchange of materials is a proven mechanism to reach remote and resource-poor farmers with improved materials. The International Rice Research Institute (IRRI) has introduced MTAs for its farmer-cooperators.

There is a strong fear in several IARCs that their regional nurseries, which share the best varieties (released or under development) among a consortium of NARIs for testing under different environments, may collapse because members will not provide their own materials when protection in all of the participating countries cannot be guaranteed. This concern has arisen in response to the increased commercial attitude of several NARIs, supported by the rise of IPRs.

Different policies are observed by the IARCs with regard to the protection of inventions. Some patent their inventions, either as part of joint research projects with private sector partners in the North or to facilitate future collaborative agreements. In all of these cases, the basic principle is that the inventions must be available for smallholder farmers and be used for poverty alleviation. Another IARC—the International Center for Tropical Agriculture (CIAT)—takes another route; many inventions are published, and CIAT intends to make sure that all its critical inventions emerge in patent searches as prior art by sending publications to national patent offices abroad, notably the U.S. Patent and Trademark Office (USPTO). This strategy is meant to keep IARC inventions in the public domain and to stimulate the use of these inventions in further research. Such "defensive publication" is only effective, however, when the published descriptions are sufficiently broad so that researching "around" the publication and patenting the results becomes difficult.

One newsworthy application of intellectual property policy within the IARCs—covered in the international press—is CIAT's intervention in a U.S. patent application for yellow ("Enola") beans. The patent might interfere with CIAT's bean program in Latin America, where yellow beans are fairly common. In a wider context, this challenge serves as an example that the CGIAR, with its open access to genetic resources, is willing to defend this access policy in a wider context. The effort and costs involved in challenging this patent may serve as an example of how difficult it is for IARCs to deal with the protection of rights relevant for their work.

Interactions with Seed Companies

Most IARCs provide their breeding lines not just to public organizations but also to private seed companies, usually under MTAs that prohibit the protection of the lines as provided. As domestic seed companies in the South develop increased breeding capacity, and as they compete with increasing effectiveness against public seed enterprises, they will become an ever more important conduit for IARC research. The emergence of IPR regimes has encouraged the IARCs to consider various new strategies for interacting with the private seed sector (boxes 6.3 and 6.4). Some continue to provide materials without charge, while others pursue practices that involve either fees or royalties. Sometimes IARCs provide materials to the private sector directly, while other transfers are mediated by NARIs. In the case of maize, the International Maize and Wheat Improvement Center (CIMMYT) provides germplasm to seed companies for use in developing their own commercial varieties. In Southern Africa, CIMMYT licenses its hybrids and OPVs to private companies; the hybrids may be licensed on an exclusive basis for a single country, but the OPVs are always offered on a nonexclusive basis. CIMMYT takes responsibility for obtaining national variety release in these cases but has not pursued PVP and does not collect royalties on these varieties.

When CIAT developed a new variety of Brachiaria (a pasture grass) called Mulato, it found that the most effective way of promoting its diffusion was to license seed production and marketing

Box 6.3 The Latin American Fund for Irrigated Rice

The Latin American Fund for Irrigated Rice (FLAR) was created in 1995 to fill the gap left by CIAT's decision to shift its rice breeding priorities towards virtually exclusive concentration on marginal production zones. FLAR currently has a membership of eight countries (plus CIAT); the budget comes largely from members' contributions. Each country has a single representative, which may be a NARI, a rice producers' association, or a group of seed companies. FLAR manages an extensive regional program of rice breeding, directed by its members. Although FLAR does not produce finished varieties, it gives members access to breeding lines at a relatively advanced stage of development (roughly the F_5 or F_6 stage). CIAT's rice breeding program provides germplasm to FLAR, covered by MTAs. Each representative or constituent member of FLAR is responsible for registering and protecting any varieties it produces from FLAR germplasm. FLAR requires that any varieties based on its germplasm be protected under national PVP, but FLAR does not receive any royalties or additional payments from released varieties. Members can produce seed themselves or license varieties to someone else and collect royalties.

Source: Authors.

to a company in Mexico (because of its commercial and technical capabilities). The Mexican company in turn licenses local seed companies for distribution in Colombia and several other Latin American countries. The Mexican company has to protect Mulato in the name of CIAT in every country where it intends to commercialize it, and it has agreed to pay a royalty to CIAT on seed sales for the first 10 years. A separate agreement provides additional royalty payments to CORPOICA, which participated in the research to develop the variety. The royalties paid to CIAT go into a special royalty fund.

IARCs' access to protected technology

Like NARIs, the IARCs must also be concerned with access to protected technologies. Several

Box 6.4 Millet and Sorghum Commercialized through ICRISAT

The International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) has given such valuable support to India's domestic commercial pearl millet and sorghum seed sector that companies subscribe to consortia to gain access to ICRISAT breeding lines and inbreds. The growth of the hybrid pearl millet and sorghum seed business is one of the great success stories of seed market liberalization in India. Until recently, ICRISAT provided germplasm to any legitimate private company or NARI. In 1999, ICRISAT approached private Indian seed companies to discuss ways in which they could support ICRISAT's research, leading to the creation of two consortia (for pearl millet and sorghum). Each member pays an annual fee for access to breeding lines. The consortia include a range of Indian seed companies, although some of the very largest and smallest players in the hybrid pearl millet and sorghum business are not members. A few companies from other Asian countries are also included in the current membership. It is expected that the Indian companies will apply for PVP for the hybrids they produce once India's PVP law is operational. Members are asked to provide sales figures to ICRISAT in order to assess uptake and impact, but no further royalties or payments are expected. The subscriptions currently cover the entire cost of ICRISAT's hybrid pearl millet and sorghum breeding in India. It should be noted that NARIs in India still maintain full access to ICRISAT's breeding material, but the subscribers to the consortia do not see this as a threat.

Source: Authors.

Box 6.5 IPRs for Striga Resistance in Maize

CIMMYT's work in Kenya to develop maize varieties to resist Striga, a parasitic weed, required considerable attention to IPRs. Research by the Weizmann Institute and CIMMYT indicated that a herbicide coating for seed could effectively control Striga by killing the weed as it germinates in the soil. The innovation would require maize varieties with herbicide resistance, and collaboration was initiated with BASF, the owner of a mutant gene that confers resistance to a herbicide produced by BASF. Because the technology does not involve a transgene, it does not require biosafety clearance, as is the case with most other herbicide resistance traits. BASF facilitated access to maize germplasm containing the gene, and CIMMYT began to develop IR (imidazolinone-resistant) maize varieties suitable for conditions in Western Kenya. Three IR maize hybrids have passed Kenya's variety approval tests. IR maize is one of the first projects for the newly formed African Agricultural Technology Foundation (AATF), which has taken responsibility for regulatory and commercial arrangements for IR maize. BASF initially granted access to the IR gene for research purposes. An agreement is being negotiated to allow its use in commercial varieties for Kenya. AATF has agreements with three seed companies in Kenya to produce the IR varieties, and royalty payments are likely to be managed by AATF (rather than CIMMYT or KARI). One IR hybrid underwent extensive field testing and demonstration in 2005. The IR varieties will be subject to PVP in Kenya; it is not clear how the IR gene itself would be protected, if this were seen to be desirable.

Source: Authors.

commodity-focused IARCs have extensive biotechnology research programs. Many of the tools and genes they use are patented in the North. Some are specifically licensed for research purposes, but there is little experience on how to proceed with products based on such research (box 6.5). CIAT believes that a transgenic, virus-resistant rice variety it has developed is nearly ready for diffusion and has commissioned a freedom to operate (FtO) search, which identified the principal intellectual property holders with whom CIAT needs to negotiate. CIAT admits, however, that it is poorly prepared for such negotiations. Similarly, CIMMYT commissioned an FtO search for its Bt maize varieties for Africa, but the next steps are still unclear. ICRISAT has developed a number of transformed crop lines but has yet to do an FtO for commercializing any of them.

The IARCs also have little experience in patenting their germplasm-related innovations. CIAT has filed one patent jointly with Embrapa for a Brachiaria transformation method, and another for a tissue culture technique (for guanabana), but these have yet to be granted. ICRISAT has yet to patent any technologies, although there are several candidates. Most IARCs are developing their staff to identify which research streams might result in patentable products and hence require different management.

Recently initiated CGIAR Global Challenge Programs are expected to yield a wide range of patentable technologies through collaboration between IARCs and institutes in developing and industrialized countries. The Challenge Programs aim at making all protected technologies and materials available on a nonexclusive basis to all who aim at using them to develop products for the resource-poor. The Generation Challenge Program intends to include a humanitarian license clause in its consortium agreement to avoid the negotiation of individual licenses. Such a clause would require clear definitions for such terms as "resource-poor" (Barry and Louwaars 2005).

7 Lessons

The pressures to strengthen IPRs in plant breeding in developing countries present both immediate and long-term challenges to policy makers and donors. The immediate challenges are related to framing and implementing appropriate legislation that is consistent with TRIPS and that supports national agricultural development goals. As part of meeting these challenges, countries will need to develop suitable responses to pressure exerted in negotiations of bilateral trade and investment agreements to go beyond the minimum requirements of TRIPS. The longer-term challenges are derived from the fact that an IPR regime, on its own, is not likely to provide the incentives that elicit the emergence of a robust plant breeding and seed sector. Attention to other institutions and the provision of an enabling environment are also necessary.

This chapter examines ways of addressing these two sets of challenges. Because most of the responsibility is with stakeholders themselves, the first part of the chapter outlines priorities for policy makers. The chapter concludes with a summary of possible interventions that the World Bank (or other donors) might undertake to help support the establishment of an appropriate legal framework and the development of requisite institutions.

CHALLENGES FOR NATIONAL POLICY MAKERS

PVP legislation

IPR regimes for plant breeding in developing countries demand urgent attention. Policy makers need to ensure that they have an IPR regime that is relevant to national conditions and thus supports the growth of the seed sector, but the regime must not be so restrictive that it limits future development options or proves unenforceable. Although TRIPS allows for the possibility of patents for plant varieties, patents are not a suitable alternative for developing countries, which should focus on establishing a *sui generis* system of PVP.

The design of a suitable PVP regime will necessarily represent a dialogue and a series of compromises among various stakeholders, including the commercial seed industry, public agricultural research, and farmers. To be effective, the PVP system must elicit broad-based support, implying that the formulation of supporting legislation and regulations should be the product of open public debate. Even if legislation is already in place, many developing countries will find that

there are sufficient options for interpretation and application to warrant a thorough review of procedures and priorities.

Because PVP legislation must respond to the circumstances of a particular country and represent consensus among a range of stakeholders, it is not possible to provide a blueprint that policy makers can follow. Models are available (particularly the UPOV Conventions), but even these include a number of options that demand the careful attention of policy makers. The provisions of the 1978 UPOV Convention generally meet the TRIPS requirements, yet now UPOV requires that new members join under the 1991 Convention. Several options, discussed below, deserve careful consideration before a decision is made to use UPOV 1991 as a model for national legislation. They include the levels of seed saving and seed exchange, the scope of protection, the breadth of coverage, and the relation of PVP legislation to the concerns of Farmers' Rights (for further details, see Appendix C).

Seed saving. UPOV 1978 places no restrictions on farmer seed saving, while UPOV 1991 prohibits seed saving but allows countries to introduce specific exemptions, "taking into account the legitimate interests of the breeder" (see table 2.1 for a comparison between UPOV 1978 and 1991). The political repercussions and enforcement requirements of a seed saving restriction make it a candidate for consideration in only a small minority of cases in developing countries. In cases where industrialized countries prohibit seed saving (for example, in the EU), there is usually a small-farm exemption, and even so the experience has been that royalty payments on farm-saved seed are often difficult to enforce. Thus when a developing country frames its PVP legislation, rather than allowing a blanket prohibition on seed saving, it must be able to defend—and demonstrate how it will enforce—any restrictions on seed saving in specific instances (for example, export horticulture or particular field crops grown by large-scale commercial farmers).

Seed exchange. Seed exchange is less amenable to precise definition than seed saving. Although UPOV 1978 is interpreted to allow seed exchange as part of the farmer's privilege, UPOV 1991 explicitly forbids the practice and offers no possibilities for exemption. The term "seed exchange" covers an exceptionally wide range of practices. At one end of the scale, resource-poor farmers who find themselves without seed at planting time may beg or borrow seed from a neighbor; legislating against such a practice is both inappropriate and pointless. At the other end of the scale, larger-scale farmers may earn considerable income through informal sales of saved seed, threatening the viability of local seed enterprises. For these reasons, national PVP legislation needs to be very careful in respecting local customs of seed provision while guarding against the possibility of large-scale seed production in competition with legitimate seed companies. In many cases, conventional seed law (which requires registration of seed companies or mandates seed certification) is a better way to address this problem than trying to restrict seed exchange through PVP.

Scope of protection. National PVP legislation consistent with UPOV should have little difficulty ensuring that protected varieties are available for research and further breeding. UPOV 1991 includes additional rights on EDVs and extends protection to the harvested product of a protected variety, but these modifications need not cause significant problems for IPR legislation. It is more important that policy makers are aware of the current debate in which some MNCs are proposing further restrictions on the use of protected varieties in breeding programs. These positions may be translated (for example, through bilateral trade negotiations) into pressure for corresponding provisions in PVP legislation in developing countries. Developing country policy makers must ensure that such pressures are not used as an excuse for establishing excessive restrictions on plant breeding and should defend researchers' access to protected germplasm in a manner consistent with UPOV 1991.

Breadth of coverage. The coverage of PVP legislation also needs to be considered. Although UPOV provides for the eventual protection of all species, the Conventions allow coverage to be introduced incrementally. Policy makers should take advantage of this flexibility when introducing PVP. It makes sense to begin with crops for which the seed industry or agricultural markets will benefit most from PVP, building experience and gradually expanding the coverage to other crops. The treatment of extant varieties also deserves attention. Attempts to extend excessive protection to varieties already in farmers' fields (especially if their ownership might be contested) may unnecessarily complicate the implementation of PVP legislation.

Farmers' Rights. There is no provision in the TRIPS Agreement for issues such as benefit sharing

(which forms part of the concept of Farmers' Rights under the IT PGRFA) or the widely discussed protection of farmer-bred varieties. The inclusion of these issues in PVP legislation or in national laws on biodiversity is controversial but must be addressed. Whether or not the concept is included in PVP legislation, it is important to ensure that various types of legislation are consistent. The concept of Farmers' Rights should not create any major confusion with regard to seed exchange or sale or the novelty requirement for a new variety. A compulsory declaration of the source of the materials in applications for PVP and patents is considered a good link between IPRs and genetic resource rights by providing important information that is needed to encourage benefit sharing. On the other hand, the establishment of rights to a local variety may hamper broader access to useful local germplasm, which critics of PVP argue is the case for protected modern varieties.

Models for PVP legislation. An IPR system for plant breeding must chart a careful course between providing sufficient incentives for investment in research and seed production while protecting seed security for resource-poor farmers. There is no need to establish an exceptionally rigid or comprehensive IPR regime in the early stages of seed system development. Commercial seed systems usually begin with products that are difficult for farmers to save (hybrids, vegetables) and that generally require little intellectual property protection. As the seed industry matures and farmers recognize the value of commercial seed, companies offer a wider range of products, some of which may require attention to IPRs. Seed industry development usually parallels the growth of agribusiness, and markets for particular commodities may demand specific attention to IPRs.

There is considerable pressure on countries to establish legislation that is consistent with a UPOV Convention, and there are a number of strong arguments for following this advice, including the advantages of participating in a harmonized system for characterizing new varieties and being able to take advantage of the considerable technical advice and expertise that UPOV and its members can offer to developing countries. However, given that the 1991 UPOV Convention is now the only option available to further entrants, policy makers must carefully consider the costs and benefits, as well as the remaining flexibility, of this system. For instance, policy makers must recognize that legislation consistent with UPOV 1991 prohibits farmers from providing seed of protected varieties to their neighbors under any circumstances. On the other hand, carefully designed legislation can exempt specific crops (and/or types of farmers) from restrictions on seed saving, providing the possibility for a more targeted approach relevant to the circumstances of smallholder farmers. The major parameters in the design of a PVP system and their relation to UPOV 1991 are summarized in table 7.1.

Even within countries, different seed systems have different requirements for protection. Legal options may be considered for tailoring IPR systems to such complex conditions. Strong protection may be provided for export agriculture, and weak or no protection to noncommercial sectors that primarily cater for subsistence farmers. When agricultural development proceeds, certain crops or conditions may gradually be brought under strengthened regimes.

The administration of PVP

Although many developing countries have drafted legislation to address PVP requirements, relatively few have begun to implement PVP, and little guidance on appropriate strategies is available. This section looks at some of the key decisions facing agricultural policy makers in the implementation of PVP. No matter what model of PVP is adopted, policy makers also need to consider the costs and enforcement of the system.

The costs of PVP. The establishment of an effective PVP system goes well beyond drafting and passing legislation. A PVP system requires the creation of an administrative office and possibly variety testing facilities, which entail considerable investments of financial and human resources. Some countries will find it difficult to identify staff with sufficient scientific and legal skills for such tasks, and the opportunity cost of redeploying trained personnel (for example, the release of experienced plant breeders for variety testing) must be considered. Policy makers must carefully examine how the costs of establishing a PVP administration can be minimized. Several areas deserve attention.

- Cost considerations strengthen the argument for a targeted approach to PVP coverage that concentrates first on priority crops and areas, gradually develops competence, and extends the breadth of crops eligible for protection.

Table 7.1 Key Parameters in the Design of a PVP System

Parameter	Arguments for a restrictive interpretation	Arguments for a less restrictive interpretation	Relation to UPOV 1991
Seed saving	A country may not attract high-value export crops, such as flowers, if seed saving for these species is not restricted.	Saving seed of field crops is part of farming practice. It is very difficult to enforce seed saving restrictions in these cases.	If a crop is not specifically exempted in national legislation, UPOV 1991 imposes seed saving restrictions.
Seed exchange	Widespread informal sale of seed of protected varieties (especially by large-scale commercial farmers) is a disincentive to commercial seed activity.	Seed exchange and informal sales among small-scale farmers is customary and difficult to control. Large-scale informal seed sales can be controlled by appropriate seed regulation.	Legislation consistent with UPOV 1991 does not allow any type of seed exchange of protected varieties among farmers.
Scope of protection of germplasm for breeding	Restrictions on EDVs discourage copy-cat or cosmetic breeding. (Some MNCs wish to limit any use of protected varieties in breeding programs.)	Both public and private plant breeding in developing countries can make effective use of protected germplasm, and undue restrictions would hamper their productivity.	The use of protected varieties in further breeding is supported, with the exception of EDVs.
Breadth of coverage: number of species	TRIPS expects that all species will be eligible for protection.	A gradual introduction of protection allows PVP authorities to address priorities and gain experience.	UPOV 1991 requires initial protection of at least 3 genera or species, with phased expansion to at least 24 in an 8-year period.
Breadth of coverage: extant varieties	Providing protection to extant (usually public) varieties may serve as a reward for past plant breeding efforts, allow NARIs to arrange for private seed production, and provide income for NARIs.	Excessive privilege assigned to old public varieties may actually be a disincentive to further breeding.	UPOV 1991 makes no distinction for extant varieties but allows their protection.
Farmers' Rights	There are arguments for including Farmers' Rights within a single piece of legislation.	Farmers' Rights can be covered in separate legislation. There are no examples to date of successful PVP-type rights for farmer varieties, and enforcement problems would be considerable.	UPOV 1991 makes no provision for Farmers' Rights.

Source: Authors.

- It is important to explore opportunities for harmonization and cooperation, which can reduce costs for both the PVP authority and the applicants. Using standard criteria for protection (such as the UPOV criteria) and uniform test guidelines could offer significant advantages, particularly for countries with relatively small plant breeding sectors. Test reports from other countries could be used, DUS testing can be assigned to particular countries in a region, or regional PVP certificates can be issued. All of these options could represent a significant savings and would promote a more effective PVP application system, irrespective of the type of protection system that is adopted.
- A PVP authority can also assign part of the responsibility for testing varieties (DUS) to breeders themselves, which will save some costs. However, this alternative may put smaller domestic plant breeding firms at a disadvantage, and thus some flexibility must be maintained.
- Attention should be given to establishing an appropriate fee structure for PVP. Unfortunately, no comprehensive guidance exists for

doing so. While cost recovery is certainly a worthwhile goal, it must also be balanced against the dangers of excluding applications for crops with relatively small seed markets or varieties from companies or institutes that cannot afford large fees. Many PVP systems establish a uniform fee schedule for all crops, but this is not the only possibility. Fees may be based on the actual cost of evaluation (which may vary between crops), the value of the protection (higher fees for crops with larger commercial seed markets), or the type of applicant (with discounts for crops and varieties directed towards resource-poor farmers). Subsidies could be also be considered, at least initially, to promote particular types of plant breeding, but policy makers must be able to justify such use of public funds. See table 4.3 for examples of costs of PVP applications and maintenance.

Enforcement. Often the enforcement of PVP entails considerable problems, which is another reason to introduce PVP in a gradual manner. Private companies and public institutes that lobby for the establishment of PVP must be made aware that most enforcement responsibilities will fall on their shoulders. Experience to date indicates that enforcement difficulties can undermine confidence in a PVP system. The difficulty (and political sensitivity) of enforcing rules on the saving or local exchange of seed, for instance, provide an important argument for caution in the initial stages of PVP. Even in cases involving competing commercial firms, courts are often unprepared to interpret the infringement, particularly because of the biological nature of the protected subject matter. Implementation of IPR regimes must therefore include attention to strengthening the judicial system's knowledge of IPRs in plant breeding. Attention is also required for promoting a business environment in which contracts are expected to be enforced. Private firms will need to develop their own capacity to monitor the market and to seek legal recourse when infringements are detected, and public research institutes that hope to earn royalties from their protected technologies must be prepared to invest in monitoring and legal resources.

A PVP system will not meet its goals if it is not supported by the full range of stakeholders. Breeders, seed producers, traders, and farmers need to understand the objectives of the system in order to comply with the rights and obligations associated with it. The development of a PVP system should thus include an extensive information campaign involving all stakeholders, including the legal profession. Developing judicial experience in PVP may take some time.

Protecting biotechnology

Patents. Although plant variety patents are not a reasonable option for developing countries, a number of issues related to IPRs in biotechnology justify attention to national patent regimes and their implementation. Many developing countries have well-established patent offices, but only a few have the experience and human resources to deal with patents related to plant breeding and biotechnology. Most national patent offices will need to build their capacities to deal with patents related to agricultural biotechnology, to provide clear guidelines about what can be patented, and to define the scope of the protection. If a country hopes to introduce transgenic varieties, it will need to establish legislation that provides adequate protection, although this protection does not necessarily have to depend on the patent system. Several possibilities exist, such as allowing patents on classes of transgenic varieties without establishing patent rights on individual plant varieties, which is the approach taken by the EU. (In several EU countries, the farmer's privilege and breeder's exemption for transgenic varieties are valid, even when the scope of a patent would normally disallow them.) In many cases, however, providing credible enforcement for the right combination of biosafety regulation, seed laws, and PVP may offer adequate protection for transgenic varieties, at least in their early stages of diffusion in developing countries.

Biosafety. Biosafety regulation can help limit the misappropriation of transgenic germplasm, but it is unwise to expect that biosafety authorities will assume responsibility for enforcing IPRs. Although the establishment of a competent biosafety authority is a priority for countries that wish to use transgenic crops, it is equally important to identify a clear division of responsibilities between biosafety authorities, seed regulators, and IPR agencies.

Other incentives for seed system development

Policy makers must recognize that the development of a commercial seed sector depends on a

range of factors that extend well beyond IPR regimes. These factors cannot substitute completely for an IPR regime, but they need to be exploited as policy makers consider how to structure incentives for seed sector development. India, for instance, has had a thriving and diverse commercial seed sector for more than two decades but has only recently implemented PVP legislation. Uganda's commercial seed sector is developing through a partnership between public research and private seed production, without the help of IPRs.

Seed regulation. Other regulatory capacities can contribute to the performance of IPR regimes for plant breeding. In particular, it will be difficult to institute an effective PVP system without an adequate seed regulatory framework, including clear rules and procedures for variety registration and seed quality control. A well-administered procedure for releasing varieties and an adequate system to control seed quality can limit many instances of the misappropriation of plant varieties or genetic resources. The effectiveness of seed regulation depends on competent management, reasonable standards (consistent with enforcement capabilities), and strong industry participation. It is important that policy makers concerned with IPRs ensure that an appropriate national seed regulatory system is in place.

Commercial seed markets. Initial seed market development is usually based on seed types that are difficult for farmers to save, such as hybrid or vegetable crop seed. Once companies are producing and selling high-value seed, they will have the experience and infrastructure to expand into other types of seed, and once farmers have experience with using good quality commercial seed, they will be more likely to broaden their seed demands. An IPR regime should develop in parallel with this evolution in seed markets, and policy makers need to ensure that the enabling environment (characterized by contract enforcement, the availability of credit, and so forth) is adequate for the growth of the domestic seed industry

Agribusiness development. In many cases when policy makers want to support high-value export crops, they will need to ensure that adequate IPRs are in place. More restrictive PVP may be applied selectively in particular cases when commercial incentives justify additional protection, such as in cut flowers.

Public sector breeding. Many NARIs are uncertain about whether to complement or compete with the private sector and hence are confused about how to take advantage of PVP. Policy makers need to set clear guidelines in this area to ensure that NARIs fulfill their public service mandate. NARIs need to distinguish between using PVP in order to stimulate the use and delivery of their varieties on the one hand and seeing PVP as a contributor to their budgets through the collection of royalties on the other. In addition, policy makers must recognize that systems of international germplasm exchange are being threatened by an almost exclusive focus on the possible financial advantages accruing to the control of germplasm, with little appreciation of the importance of equitable access. In biotechnology research, most NARIs are not organized to use their own assets, such as varieties, breeding lines, and basic research capacities; to assess their freedom to operate when they make use of protected techniques and tools; and to acquire access to complementary technology on equitable terms.

Protection may facilitate the development of public-private partnerships in research, yet this report highlights a number of examples of how public research has cooperated effectively with the private seed sector without IPRs.

CHALLENGES FOR TRADE NEGOTIATORS

IPRs have become a topic on the international trade agenda ever since the Agreement on TRIPS was negotiated and adopted of as part of the overall package of agreements leading to the creation of the WTO. TRIPS obliges all WTO members to offer specified minimum standards of intellectual property protection in a wide range of sectors, although the TRIPS Agreement also leaves developing countries a certain amount of flexibility in how they fulfill their obligations. This flexibility allows countries to design IPR regimes that suit their specific circumstances.

IPRs are a tool that can support agricultural development, if IPRs are tailored to the conditions within each country. Developing countries, with their diversity of farmers and seed systems, present special challenges for designing a supportive IPR system. The goal should be to provide incentives for seed sector development through IPRs such as trademarks, trade secrets, and PVP, without creating unnecessary or unrealistic limitations on the practices and livelihoods of smallholder farmers. Meeting this goal requires a careful balancing of rights and obligations, which may imply adapting,

as opposed to simply adopting, the standard models available.

The agricultural sector, and in particular plant breeding, is one area where the flexibility offered by TRIPS is quite broad. Yet pressures exist for developing countries to go further than required by TRIPS, notably in bilateral trade negotiations and discussions in the framework of WIPO. Trade negotiators need to realize that IPRs are primarily meant to support innovation, and that the trade aspect is secondary. Strengthened IPRs in breeding thus need to be justified on the basis of careful assessment of the national breeding and farming sectors if they are to play a positive role in agricultural development by providing incentives for both domestic and foreign investments.

Accepting patent protection for plant varieties or a *sui generis* system that complies with UPOV 1991 as a bargaining chip in trade negotiations may not be very helpful. While it is not essential for the initial development of a commercial seed sector, a properly balanced combination of PVP, trademarks, and patents may contribute to a fair and competitive business environment that stimulates innovation and provides transparency for farmers. The use of the UPOV guidelines for testing new varieties, however, offers clear advantages. It opens the door to accepting test reports from other countries and to initiating regional collaboration on testing. These alternatives can lower costs for PVP agencies and applicants, shorten the approval process, and facilitate seed trade. The harmonization of criteria for granting protection does not have to go hand-in-hand with uniform scope or coverage of protection; in fact, it maintains the option to refine and adjust the system as the seed sector develops further.

Care should be taken that trade considerations do not dictate development pathways for national seed systems. If IPR systems are overambitious relative to local needs and capacities, then they are likely to lead to missed opportunities in seed sector development, to create implementation problems that undermine the system's credibility, and to divert resources and attention from more important priorities. Admittedly the negotiation of international agreements has become a daunting task, given the range of issues put on the table at once. Governments need to find ways to ensure appropriate consultation—for example, between different ministries. IPRs are typically under the jurisdiction of an economic ministry, but in the case of plant breeding, the MoA will be an equally important partner for consultation. It is also important that consultation and debate involve other stakeholders, perhaps first and foremost farmers, who should be the principal beneficiaries of the development of a commercial seed sector. A wider debate on such decisions should improve understanding and commitment in what is often seen to be a controversial field.

CHALLENGES FOR RESEARCH MANAGERS IN PUBLIC INSTITUTIONS

Before giving their unconditional support to IPRs in plant breeding and their use in public agricultural research, research managers and policy makers responsible for public research at the national and the international level must consider the potential impact on breeding strategies and on costs and benefits.

There are three main reasons for public research institutes to embrace IPRs: recognition, technology access and transfer, and revenue. IPRs formally link a variety to a research institute and individual breeders, thereby conferring recognition of their achievement. With respect to technology transfer, the advent of IPRs may facilitate seed production if only an exclusive license will entice a commercial seed producer to take a new variety into its product range. There may also be expectations that technology will be acquired more easily if patents can be traded. Finally, IPRs can serve to recoup research investments by providing a legal basis for license contracts between breeders and seed producers, which would commonly include a royalty payment. In public research, variety development is supported through public funds, and research managers tend to emphasize other research objectives in addition to variety development (see the next section). However, given the declining public funding of agricultural research in many countries, revenue generation is an attractive option for many public institutions. Income from IPRs can support the institute as a whole and help managers provide financial support for particularly productive researchers or research groups.

Impact on breeding strategies

The introduction of the concept of revenue generation in public plant breeding is likely to have an

impact on the distribution of funds within the NARI and on the breeding strategies applied. Since IPRs can be generated relatively easily in plant breeding compared to other sciences, the pursuit of revenue could cause other important disciplines to be marginalized, such as soil science, social sciences, and plant pathology. Revenue generation will focus breeding on commercial farmers and hybrids rather than on resource-poor farmers and OPVs, which are unlikely to generate profits for seed companies or royalties for breeding institutions.

The shift to commercial crops and farmers may be consistent with recent changes in national agricultural policy and trends of commercialization of public entities in some countries. In other countries, however, the public task of NARIs is based on supporting both equity and national agricultural production. The trend towards crop diversification and breeding for low-input agriculture may be reversed with a public research focus on using IPRs for revenue generation. Another strategy for NARIs may be to secure a choice of varieties for farmers in a market that may otherwise be dominated by large commercial firms because of IPRs. However, this latter strategy may shift research priorities away from smallholder farmers' needs.

Policy makers and research managers need to take care in assessing the prospective impact of IPRs in public breeding before including protection in their research strategies. If NARIs are not supposed to protect their inventions, governments will have to provide the necessary funds for research.

Impact on public research organizations

Protecting own intellectual property. When a NARI intends to commercialize its varieties using IPRs, it has to realize that it needs the capacity to design commercialization strategies and license contracts, as well as to follow up on these contracts. Usually NARIs are unaccustomed to employing marketing staff and intellectual property specialists. Their focus on research means they have little experience in attracting or administering appropriate personnel to manage their intellectual property portfolio.

Research managers also tend to look at the benefits derived from IPRs rather than the costs. Aside from the cost of additional personnel, the direct costs of acquiring and implementing IPRs may be substantial. Application and maintenance fees can be considerable, and commercial decisions have to be made to determine which rights to apply for and which to surrender. An even more significant cost can arise when rights have to be defended, especially when the public sector confronts experienced negotiators from commercial companies with significant resources. NARIs must be prepared to spend money on protecting intellectual property.

Managing third-party intellectual property. Even when a NARI does not intend to protect its inventions, the introduction of IPRs may have a significant impact on the institute. NARIs will need to develop ways and means to determine their potential risks and freedom to operate with respect to technologies that they use but which are patented by others. The rights of the patent holder have to be recognized and consent sought in the research stage or when research is leading to a product. Thus NARIs should develop an intellectual property plan for each project to decide when and how contact will be established with the technology provider—that is, whether to ask for a research license or wait until a product is developed; whether to protect their own inventions; and how to commercialize their innovations. This plan starts with a patent search to establish rights over the technologies that are being used. Although most biotechnologies are not protected in developing countries, this situation is changing rapidly for large countries such as China, India, and Brazil. NARIs will require the capacity to develop intellectual property plans and the negotiation skills to gain access to technologies on favorable terms. This capacity not only requires access to lawyers, intellectual property specialists, negotiators, and marketers, but more importantly calls for an important shift in culture among researchers, who commonly prefer to concentrate on their science and not be bothered by "administrative rules."

Impact on IARCs

Strategies for protecting inventions by the IARCs concentrate on the technology transfer argument on the one hand and the original objective to develop international public goods on the other. Several IARCs are developing agribusiness parks or other mechanisms to link directly with the private sector and provide additional pathways for technology transfer. Another challenge for IARCs is to get access to protected technologies without incriminating their primary aim of poverty alleviation. A less debated challenge for IARCs is the

impact of the commercialization of some NARIs (owing to the introduction of IPRs) on IARCs' abilities to reach the resource-poor. Early experience in using IPRs as a bargaining chip to get access to commercial intellectual property held abroad shows that this argument for patenting inventions is weak.

CHALLENGES FOR FARMERS AND THEIR ASSOCIATIONS

Farmers' organizations and NGOs that represent farmers' interests need to be prepared to participate in debates about appropriate IPRs. The immediate link between IPRs and investment in plant breeding may not always be strong, but farmers have an interest in creating incentives for the development of better planting materials, even if they may have to pay a bit more for seed. Exceptions such as the farmer's privilege may create a useful balance between the rights of breeders and those of farmers. In developing countries, a major difficulty for farmers' organizations in adopting an appropriate position on IPRs in plant breeding is that different farmers have different interests. The interests of commercial farmers quite closely resemble those of farmers in industrialized countries, and strong protection for flower varieties, for example, may be very conducive for the export horticulture sector. The interests of smallholders may be quite different, and a strict IPR regime may reduce their access to potentially good varieties.

The concept of Farmers' Rights is often linked to the IPR discussion, but even though the IT PGRFA specified this concept, there is little agreement as to whether Farmers' Rights should include the right to save and use seed on-farm or to exchange or sell farm-saved seed in all circumstances (given the addition of the words "as appropriate and subject to national law").

In some countries, the right of farmers to protect their own local varieties is included in national IPR legislation. This right is not in conflict with conventional IPR systems, but several points deserve attention. If this right is to be implemented by relaxing the standards for application (especially uniformity standards for a variety), then there is a risk that relaxed standards can be misused to protect broader genepools rather than individual varieties. Others argue that IPR on varieties conflicts with the moral values of farming communities, which have always relied on free exchange of materials, and that such protection should not be promoted for farmers' varieties. Finally, protection itself serves a purpose only when the variety is commercialized on a sufficiently large scale to cover at least the cost of protection. At the very least, an IPR system should avoid granting protection for farmers' varieties without the consent of the community that developed them.

Farmers' associations and NGOs that represent farmers need to be involved in the national debate on agricultural IPRs. Organizations that represent farmers need to develop consultation mechanisms with their members on this issue and to develop a well-informed capacity to involve them in decision-making processes. At the same time, national political systems need to ensure adequate opportunities for open debate about IPR legislation.

The yes-or-no discussion on IPRs that can be observed in many countries today is not very productive. Instead efforts should concentrate on balancing the different interests. The five-country study concluded that there is no reason for developing countries to adopt overly restrictive PVP systems: the adoption of such systems to acquire trade benefits reduces the options for broader support to rural development objectives.

It is possible to serve the interests of different groups of farmers by providing different levels of protection within one legal framework. This objective can be achieved either by providing a minimum level of protection and adding additional rules for specific crops or farmers (for example, export crops can be protected according to the UPOV 1991 model and subsistence crops by a less restrictive system) or by designing a stronger IPR system but carefully delimiting exceptions. For instance, smallholder farmers should be free to save their own seed of protected varieties, whereas commercial farmers should not (as is the case in the EU both for seed protected by plant breeder's rights and patents). In cases where the rights are weaker, it is important to recognize that private sector incentives for investment will be correspondingly lower and that public sector plant breeding will need to be well financed to provide the necessary support.

POTENTIAL ROLE FOR THE WORLD BANK

The World Bank can assist developing countries by providing immediate support to national efforts at developing and implementing PVP legislation as

well instituting longer-term strategies that foster the development of seed sector institutions.

Immediate support for appropriate IPR legislation

Discussion forums. The framing of PVP legislation must be an open process that considers the interests of all stakeholders. Even in countries where legislation is already established, usually many aspects of implementation and interpretation deserve careful review. The Bank can support opportunities for national (or, where relevant, regional) forums that promote debate and discussion about the shape of PVP legislation and its implementation. Although the Bank cannot offer specific blueprints, it can encourage stakeholders to take into account both poverty reduction strategies and the trade dimension of IPRs. Stakeholders should recognize (1) the possibility of providing different levels of protection for different types of crops, (2) the necessity of structuring IPR regimes to evolve in concert with national seed systems, and (3) the importance of key parameters in PVP legislation (table 7.1). The Bank can also sponsor meetings and other activities that explore possibilities for regional collaboration in the administration and management of PVP, as well as encourage stronger regional mechanisms for patent applications, including those in biotechnology.

Research. Because there is so little experience with PVP in developing countries, further analysis is needed to offer more precise advice to policy makers. In a few years, it would be useful to conduct a follow-up study, similar to the present one, to monitor progress and synthesize what will surely be a considerable amount of new experience as many more countries institute PVP systems and begin to gain experience with patents in biotechnology. Analysis as part of sector strategies can allow the Bank to help countries identify situations in which inappropriate or ineffective IPRs may restrain the development of specific crop sectors or market segments. Furthermore, there are specific instances of research that might be undertaken, such as an examination of how to structure fee rates for PVP, how IPRs and Farmers' Rights may effectively be combined, and how to support modalities such as patent pools and clearinghouses to ensure that excessive restrictions imposed by biotechnology patents do not limit the development of a competitive seed industry.

Bilateral trade negotiations. Although the TRIPS requirements for the protection of plant varieties allow countries considerable flexibility, bilateral trade negotiations with industrialized countries may include proposals to adopt more restrictive IPRs, such as plant variety patents. Wherever the Bank can use its influence, it should encourage both partners in such negotiations to carefully consider possible impacts on equitable agricultural development and to recall that IPRs can be differentiated by crop and allowed to evolve.

Additional opportunities for strengthening seed sector institutions

This report argues that the potential contribution of IPRs to strengthening national seed sectors depends on a range of other factors, including the business environment, the nature of the agricultural economy, and public agricultural research capacities. Contributions from a donor like the World Bank to relevant institution building in a particular country should be based on a long-term strategy. IPR regimes in plant breeding will make a stronger contribution to seed system development through complementary attention by the World Bank to institution building. Examples include IPR institutions themselves, seed regulation, the commercial seed industry and agribusiness, and public agricultural research and extension.

IPR institutions. Many countries will require assistance in the design and development of the IPR institutions (for both PVP and patents) needed to support agricultural innovation and development. This assistance may include support to ensure that IPR systems are transparent and efficient, encouragement for exploring regional and international harmonization, and opportunities for supporting human resource development. Capacity building may also be supported for breeders, seed producers, traders, and farmers to understand the objectives of the system in order to support compliance with the rights and obligations associated with it. The development of a PVP system should thus include an extensive information campaign involving all stakeholders. Support could also include the following:

- In some countries, the PVP system may not have access to adequate technical capacity in conducting or interpreting DUS tests, and short-term training courses would be useful.

- As more PVP systems are put into practice, officials and technicians from PVP offices would profit from occasional opportunities to meet with their counterparts, exchange experiences and learn about new developments; the Bank could provide a suitably neutral aegis for such workshops.
- Examiners from national patent offices could profit from short-term training related to the protection of biotechnology innovations, and they could learn from the experience of the European Patent Office (EPO) or USPTO.
- The judicial systems of developing countries will need to gain experience in PVP and patents in plant science, and suitable training activities would be very useful.
- Countries may require assistance in providing information to stakeholders in the seed system regarding the rights and obligations associated with national IPR regimes for plant varieties and biotechnology.

Seed regulation. As responsibilities for seed production in developing countries shift from the public to the private sector, the management and responsibilities of national seed regulatory agencies must be reconsidered. Various donors (including the World Bank) have encouraged the rationalization and harmonization of seed regulations (for example, in Sub-Saharan Africa). Because competent seed regulation is needed to support an IPR regime for plant varieties, further attention to seed regulatory reform, at both the national and regional levels, would have high payoffs. Areas that might be considered for donor attention include:

- Training and advice that allows seed regulatory agencies to tailor regulatory procedures and requirements to their financial resources.
- Further support to regional collaboration and harmonization.
- Building competence in seed companies so that the private sector can assume greater regulatory responsibilities.
- Shifting some public regulatory investment towards consumer (farmer) education and consumer protection.

The seed industry and agribusiness. The World Bank can also support the growth of the private sector, including the commercial seed industry and agribusiness development. An appropriate PVP system should encourage the growth of the domestic private seed sector. The Bank may find opportunities to stimulate the sector through, for instance, support for seed industry associations. Agribusiness projects also have relevance to PVP, especially if they require the use of high-quality seed or planting material. Bank assistance to such projects should include a thorough review of the IPR implications:

- Are IPRs relevant for the success of the proposed project (how, what type)?
- Do stakeholders participating in the project have access to sufficient intellectual property protection?
- Are complementary or supporting actions required to ensure that intellectual property protection is not a constraint to project success?
- Is it clear that the relatively strict types of IPRs required for agribusiness do not interfere with the provision of seed for subsistence agriculture?

Public agricultural research and extension. Because the establishment of IPR regimes for plant varieties may have a significant impact on NARI strategies, the Bank should consider how to include this theme in its support for agricultural research, both at the national and international level. One priority is to assist NARIs in developing their IPR strategies and policies to take advantage of national IPR regimes. In many cases NARIs also need advice on using the private seed sector to promote public varieties. This includes advice on developing skills in contracting with seed companies, ensuring that a source seed production system is in place, and building competencies in promoting new varieties and monitoring their uptake. In addition, NARIs may need assistance in developing the capacity to assess their freedom to operate with protected technology. NARIs need assistance to formulate intellectual property policies and strengthen their legal and negotiation capacities.

References

Almekinders, C.J.M., and N.P. Louwaars. 1999. *Farmers' Seed Production: New Approaches and Practices.* London: Intermediate Technology Publications.

Almekinders, C.J.M., and N.P. Louwaars. 2002. The importance of the Farmers' Seed Systems in a functional national seed sector. In N.P. Louwaars (ed.), *Seed Policy, Legislation and Law: Widening a Narrow Focus.* Binghamton: Food Products Press (The Haworth Press Inc.).

Alston, J.M., and R.J. Venner. 2002. The effects of the U.S. Plant Variety Protection Act on wheat genetic improvement. *Research Policy* 31(4): 527-542.

Atanassov, A., B. Bahieldin, J. Brink, M. Burachik, J.I. Cohen, V. Dhawan, R.V. Ebora, J. Falck-Zepeda, L. Herrera-Estrella, J. Komen, F.C. Low, E. Omaliko, B. Odhiambo, H. Quemada, Y. Peng, M.J. Sampaio, I. Sithole-Niang, A. Sittenfeld, M. Smale, Sutrisno, R. Valyasevi, Y. Zafar, and P. Zambrano. 2004. To Reach the Poor: Results from the ISNAR-IFPRI *Next Harvest* Study on Genetically Modified Crops, Public Research, and Policy Implications. EPTD Discussion Paper No. 116. Washington, DC: IFPRI (International Food Policy Research Institute).

Barry, G., and N. Louwaars. 2005. Humanitarian licences. In N. Louwaars (ed.), *Genetic Resource Policies and the Generation Challenge Programme*. Mexico City: Generation Challenge Programme. Pp. 23-34.

Barton, J.H. 2000. Reforming the patent system. *Science* 287: 1933-1934.

Binenbaum, E., C. Nottenburg, P.G. Pardey, B.D. Right, and P. Zambrano. 2003. South-North trade, intellectual property jurisdictions, and freedom to operate in agricultural research on staple crops. *Economic Development and Cultural Change* 51(2): 309-336.

Broothaerts, W., H.J. Mitchell, B. Weir, S. Kaines, L.M.A. Smith, W. Yang, J.E. Mayer, C. Roa-Rodríguez and R.A. Jefferson. 2005. Gene transfer to plants by diverse species of bacteria. *Nature* 433(7026): 629-633.

Butler, L.J. 1996. Plant breeders' rights in the US: Update of a 1983 study. In J. van Wijk and W. Jaffé (eds.), *Proceedings of a Seminar on the Impact of Plant Breeders' Rights in Developing Countries, held at Santa Fe de Bogota, Colombia, March 7-8*. Amsterdam: University of Amsterdam.

Butler, L.J., and B.W. Marion. 1985. Impacts of patent protection in the U.S. seed industry and public plant breeding. *North Central Regional Research Bulletin* No. 304. Madison: University of Wisconsin.

Byerlee, D., and K. Fischer. 2002. Accessing modern science: Policy and institutional options for agricultural biotechnology in developing countries. *World Development* 30: 931-948.

Diez, M.C.F. 2002. The impact of plant breeders' rights on research: The case of Spain. *Food Policy* 27: 399-415.

Dreher, K., M. Morris, M. Khairallah, J.M. Ribaut, S. Pandey, and G. Srinivasan. 2002. Is marker-assisted selection cost-effective compared with conventional plant breeding methods? The case of quality protein maize. In R.E. Evenson, V. Santaniello, and D. Zilberman (eds.), *Economic and Social Issues in Agricultural Biotechnology*. Wallingford, U.K.: CABI.

Eaton, D.J.F. 2002. TRIPS and plant varietal protection: Economic analysis and policy choices. Report number 7.02.01. The Hague: Agricultural Economics Research Institute (LEI).

Eaton, D.J.F., and F.W. van Tongeren. 2006. Patents versus plant varietal protection. In R.E. Evenson and V. Santaniello (eds.), *International Trade and Policies for Genetically Modified Products*. Wallingford, U.K.: CABI.

ESA (European Seed Association). 2004. Plant Variety Protection based on the UPOV Convention and Protection of Biotechnological Inventions based on Directive 98/44/EC. ESA Access to Plant Genetic Resources and Intellectual Property Discussion Paper. 13 May.

EC (European Commission). 1998. Commission Regulation No 2605/98 of 3 December 1998 amending Regulation (EC) No 1768/95 implementing rules on the agricultural exemption provided for in Article 14(3) of Council Regulation (EC) No 2100/94 on Community Plant Variety Rights.

Evenson, D.D. 2000. Patent and other private legal rights for biotechnology inventions. In V. Santaniello, R.E. Evenson, D. Zilberman and G.A. Carlson (eds.), *Agriculture and Intellectual Property Rights: Economic, Institutional and Implementation Issues in Biotechnology.* Wallingford, UK: CABI.

Fernandez-Cornejo, J. 2004. The Seed Industry in U.S. Agriculture: An Exploration of Data and Information on Crop Seed Markets, Regulation, Industry Structure, and Research and Development. Economic Research Service Agriculture Information Bulletin Number 786. Washington, DC: USDA (United States Department of Agriculture).

Frey, K.J. 1996. National Plant Breeding Study I: Human and Financial Resource Devoted to Plant Breeding Research and Development in the United States in 1994. Special Report 98. Ames: Iowa State University, Iowa Agriculture and Home Economics Experiment Station.

Fulton, M., and K. Giannakas. 2001. Agricultural biotechnology and industry structure. *AgBioForum* 4(2): 137-151.

Garcia, J.C. 1998. Brazil. In M.L. Morris (ed.), *Maize Seed Industries in Developing Countries*. Boulder: Lynne Rienner.

Helfer, L.R. 2002. Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments. FAO Legal Papers #31. Rome: FAO (Food and Agriculture Organization).

Hu, R. 1998. Seed Technology Management Science (Chinese). Beijing: China Science Press.

Huang, J., and R. Hu. 2000. Agricultural R&D investment system and pattern: Current situation and international comparison. *Management World* 3: 170-179.

Huang, J., R. Hu, and S. Rozelle. 2003. *Agricultural Research Investment in China: Challenges and Prospects.* Beijing: China's Finance and Economy Press.

ISF (International Seed Federation). 2003. "ISF View on Intellectual Property." International Seed Federation (ISF) Position Paper, June 2003. http://www.worldseed.org/pdf/ISF_View_on_Intellectual_Property.pdf.

———. 2004. *Protection of Intellectual Property and Access to Plant Genetic Resources.* Proceedings of an international seminar, 27-28 May, 2004, Berlin. CD-ROM.

———. 2005. "Essential Derivation from a Not-yet Protected Variety and Dependency." ISF Position Paper, June 2005. http://www.worldseed.org/Position_papers/ED&Dependency.htm.

Jaffé, W., and J. van Wijk. 1995. *The Impact of Plant Breeders' Rights in Developing Countries.* The Hague: DGIS (Directorate-General for International Cooperation, Netherlands Ministry of Foreign Affairs).

James, C. 2003. Global review of commercialized transgenic crops. *ISAAA Newsletter*.

———. 2004. Global Status of Commercialized Biotech/GM Crops: 2004. ISAAA Briefs No. 32-2004. Ithaca, NY: ISAAA (International Service for the Acquisition of Agri-Biotech Applications).

Kalton, R.R., P.A. Richardson, and N.M. Frey. 1989. Inputs in private sector plant breeding and biotechnology research programs in the United States. *Diversity* 5(4): 22-25.

King, J.L. 2001. Concentration and Technology in Agricultural Input Industries. Economic Research Service Agriculture Information Bulletin Number 763. Washington DC: USDA (United States Department of Agriculture).

Koo, B., C. Nottenburg, and P. Pardey. 2004. Plants and intellectual property: An international appraisal. *Science* 306: 1295-1297.

Koo, B., P.G. Pardey, K. Qian, and Y. Zhang. 2003. The Economics of Generating and Maintaining Plant Variety Rights in China. EPTD Discussion Paper No. 100. Washington, DC: IFPRI (International Food Policy Research Institute).

Krattiger, A. 2004. Editor's introduction: PVP and agricultural productivity. *IP Strategy Today* 9: ii-vi.

Le Buanec, B. 2004. Protection of plant-related innovations: Evolution and current discussion. *IP Strategy Today* 9: 1-18.

Lesser, W.H. 1997. Assessing the implications of intellectual property rights on plant and animal agriculture. *American Journal of Agricultural Economics* 79: 1584-1591.

———. 1998. Intellectual property rights and concentration in agricultural biotechnology. *AgBioForum* 1(2): 56-61.

Louwaars, N.P. (ed.) 2002. *Seed Policy, Legislation, and Law: Widening a Narrow Focus.* Binghamton: Food Products Press (The Haworth Press Inc.).

Louwaars, N., D. Eaton, and A. van Wijk. 2003. Framework for the Introduction of Plant Variety Protection in Developing Countries. North-South Policy Brief 2003-2. Wageningen: Wageningen University Research Centre.

Louwaars, N.P., R. Tripp, D. Eaton, V. Henson-Apollonio, R. Hu, M. Mendoza, F. Muhuku, S. Pal, and J. Wekundah. 2005. *Impacts of Strengthened Intellectual Property Rights Regimes on the Plant Breeding Industry in Developing Countries: A Synthesis of Five Case Studies.* Wageningen: Centre for Genetic Resources, The Netherlands.

Louwaars, N.P., B. Visser, D. Eaton, J. Beekwilder, and I. van der Meer. 2002. Policy response to technological developments: The case of GURTs. In N.P. Louwaars (ed.), *Seed Policy, Legislation, and Law: Widening a Narrow Focus.* Binghamton: Food Products Press (The Haworth Press Inc.).

Mooney, P.R. 2000. The parts of life: Agricultural biodiversity, indigenous knowledge, and the role of the third system. *Development Dialogue Special Issue*. Uppsala: Dag Hammarskjöld Foundation.

Pal, S., and D.Byerlee. 2003. The Funding and Organization of Agricultural Research in India: Evolution and Emerging Policy Issues. Policy Paper 16. New Delhi: National Centre for Agricultural Economics and Policy Research.

Pal, S., R. Tripp, and A. Janaiah. 2000. Public-Private Interface and Information Flow in the Rice Seed System of Andhra Pradesh (India). Policy Paper 12. New Delhi: National Centre for Agricultural Economics and Policy Research.

Penna, A.L.D.R. 1994. An Analysis of the Impact of Plant Breeders' Rights Legislation on the Introduction of New Varieties in UK Horticulture. PhD dissertation, Wye College, U.K.

Perrin, R.K., K.A. Hunnings, and L.A. Ihnen. 1983. Some Effects of the U.S. Plant Variety Protection Act of 1970. Economics Research Report No. 46. Raleigh: North Carolina State University, Department of Economics and Business.

Pray, C., J. Huang, R. Hu, and S. Rozelle. 2002. Five years of Bt cotton in China: The benefits continue. *The Plant Journal* 31(4): 423-30.

Ramanna, A. 2003. India's Plant Variety and Farmers Rights' Legislation: Potential Impact on Stakeholders' Access to Genetic Resources. EPTD Discussion Paper No. 96. Washington, DC: IFPRI (International Food Policy Research Institute).

Ramanna, A., and M. Smale. 2004. Rights and access to plant genetic resources under India's new law. *Development Policy Review* 22(4): 423-442.

Salazar, S., C. Falconi, J. Komen, and J.I. Cohen. 2000. The Use of Proprietary Biotechnology Research Inputs at Selected Latin American NAROs. Briefing Paper 44. The Hague: ISNAR (International Service for National Agricultural Research).

Sampaio, M.J.A. 1999. Brazil. In U. Lele, W. Lesser, and G. Horstkotte-Wesseler (eds.), *Intellectual Property Rights in Agriculture: The World Bank's Role in Assisting Borrower and Member Countries*. Washington, DC: World Bank.

Sperling, L., J.A. Ashby, M.E. Smith, E. Weltzien, and S. McGuire. 2001. A framework for analyzing participatory plant breeding approaches and results. *Euphytica* 122 (3): 439–450.

Srinivasan, C.S. 2001. International Experience of Plant Variety Protection: Lessons for India. PhD dissertation, University of Reading, U.K.

———. 2003. Exploring the feasibility of farmers' rights. *Development Policy Review* 21(4): 419-447.

———. 2004. International trends in plant variety protection. Presented at the 85th EAAE Seminar on Agricultural Development and Rural Poverty Under Globalization: Asymmetric Processes and Differentiated Outcomes, 8-11 September 2004, Florence, Italy.

Supreme Court of the United States. 2001. J.E.M. Ag Supply Inc. DBA Farm Advantage, Inc., et al. v. Pioneer Hi-Bred International, Inc. Opinion of the Court No. 99, 1996. Delivered 10 December 2001.

Thirtle, C., L. Beyers, Y. Ismael, and J. Piesse. 2003. Can GM-technologies help the poor? The impact of Bt cotton in Makhathini Flats, KwaZulu-Natal. *World Development* 31: 717-732.

Traxler, G., S. Godoy-Avila, J. Falck-Zepeda, and J. Espinoza-Arellano. 2001. Transgenic cotton in Mexico: Economic and environmental impacts. Presented at the 5th Conference of the International Consortium on Agricultural Biotechnology Research, Ravello, Italy.

Traynor, P.L., and J. Komen. 2002. Regulating genetically-modified seeds in emerging economies. In N.P. Louwaars (ed.), *Seed Policy, Legislation, and Law: Widening a Narrow Focus.* Binghamton: Food Products Press (The Haworth Press Inc.).

Tripp, R. (ed.). 1997. *New Seed and Old Laws: Regulatory Reform and the Diversification of National Seed Systems.* London: Intermediate Technology Publications.

van Wijk, A.J.P., N.P. Louwaars, and D.J.F. Eaton. 2004. *Framework for the Introduction of Plant Variety Protection in Developing Countries.* Wageningen: Centre for Genetic Resources, The Netherlands.

Wallø Tvet, M.W. 2005. How will a Substantive Patent Law Treaty affect the public domain for genetic resources and biological material? *Journal of World Intellectual Property* 8(3): 311-344.

Appendix A. Patents on Biotechnologies

GENES AND DNA SEQUENCES

Transgenic crops are distinguished by the presence of several types of "foreign" genetic material. These include functional genes (that is, genes that code for insect resistance, herbicide tolerance, or other desired characteristics); selectable marker genes (which have characteristics easily identifiable in the laboratory and, when linked to a functional gene, facilitate the detection of transformed cells); promoters (which regulate the timing and location of the expression of functional or marker genes); and end sequences (portions of DNA that terminate transcription). These different types of genes and sequences (and their combination in a "construct") are all candidates for patenting, and most industrialized countries allow patents on genes and sequences.

The situation in developing countries is more complex. Some countries specifically prohibit gene patents (for example, the Andean Pact countries); others, such as China, allow gene patents; and most have yet to formulate a clear policy. In general, claims on plants are not allowed in developing countries. On the one hand, this policy provides freedom to operate for research; on the other, it hampers investment in biotechnology for agriculture.

It is important to recognize that patents on plant genes affect more than just the production of transgenic varieties. It is possible to identify and protect genes that are used in more conventional breeding procedures. For instance, several herbicide-tolerant crop varieties commercially available in North America incorporate patented genes that have been identified through techniques such as mutagenesis or whole cell selection and then incorporated in new crop varieties through conventional breeding. Another example is IR maize, which is being tested in Kenya. The key to patent protection in these cases is the definition of novelty—that is, some countries prohibit patent protection on substances found in nature, which are considered to be discoveries rather than innovations. In most cases, a discovery must be further developed in order to be considered an innovation and eventually gain a patent that may effectively include the discovery. Genes discovered and developed in the course of conventional breeding can be patented in several countries, however. A good example is the resistance to aphid (*Nasonovia ribisnigri*) in lettuce, patented by Rijk Zwaan (a breeding company in the Netherlands) in the USA and Europe. The European patent is, however, under appeal from various sides, including some important vegetable seed companies.

Although the possibility of patenting genes is controversial, the concept itself seems straightforward. Even so, several issues contribute to making this area a particularly complex one for patent law. One problem is related to broad patent claims, which may cut a swath as wide as "all genetically engineered cotton plants." Although such comprehensive claims may be more difficult to make now than in the early years of biotechnology, the issue of broad patents remains a concern for many areas of research, including the plant breeding industry (Barton 2000). Another issue that affects gene patenting is the degree to which claims are allowed for genetic material whose functions are incompletely understood. For instance, the Human Genome Project witnessed a rush towards patents for a wide range of DNA sequences without any corresponding characterization, and although such practices are more prevalent in the pharmaceutical industry than in plant breeding, they illustrate that there is not yet a widely accepted definition of how genetic material qualifies for a patent. This issue is related to a third issue, which concerns the type of genes or DNA sequences that might be patented. Claims have been made for protecting DNA that does not constitute a complete gene, including promoters, nucleic acid probes (used to identify DNA

sequences), and polymorphisms. On the other hand, patents have been sought for collections of genes, from bacterial cloning vectors to entire genomes. Both EPO and USPTO now have stronger guidelines concerning claims on genes: there must be a good knowledge and description of the gene's function.

A fourth issue that complicates the granting and defense of gene patents is the variable nature of the genes themselves. A good example of the difficulties in identifying what precisely is eligible for protection is provided by the Bt genes that are used for insect resistance in cotton, maize, and other crops. The Bt bacterium produces certain insecticidal proteins and has been used as a source of "natural" insecticide for many years. The techniques of biotechnology have allowed the identification and transfer of the genes that code for these crystalline ("Cry") proteins; the nomenclature describes a series of different cry genes (found in different strains of the bacterium), each coding for a distinct Cry protein that is effective against specific insects. (Thus the cry 1Ac gene codes for the Cry 1Ac protein that is effective against the cotton bollworm and is the basis of most versions of Bt cotton.) Not only are there various claims on genes that code for specific Cry proteins; the cry genes that are used in transgenic plants are synthetic and significantly different from the original "wild" genes found in the bacterium. In most cases, the Bt genes are "codon modified" because part of the code that functions in a bacterium must be changed to be more effective in a plant. So although the insecticidal protein that is produced by the transgenic plant may be essentially identical to that produced by the bacterium, the governing gene may look somewhat different, and patent claims can be made on the modified gene and the techniques used for its modification. A cry gene may be further altered by eliminating certain portions to produce a truncated form of the gene (which may prove more effective), and research has also created "fusion" genes that code for novel proteins combining parts of two different Cry proteins. The various types of cry genes must be linked with specific promoters as well. The potential patent claims on various aspects of the process and disputes over definitions of novelty explain why Bt technology causes considerable uncertainty among scientists in developing countries and is the subject of continuing legal disputes among the major biotechnology MNCs. One of the main cases was recently won by Dow after almost two decades of dispute. Although the Bt example is particularly complex, it illustrates that genetic modification is rarely a case of simply identifying and moving a gene from one organism to another and demonstrates how patent claims on genes may cover a range of issues.

TRANSFORMATION METHODS

The possession of appropriate genes and sequences is obviously not sufficient to produce a transgenic plant variety. There are two major techniques for introducing foreign genetic material into an organism. One is based on *Agrobacterium tumefaciens*, a bacterium that is able to insert its own or other genes into a plant genome. This transformation is accomplished through a plasmid (an autonomous piece of DNA) from the bacterium. The plasmid is used as the basis to construct a vector that incorporates the genes that are to be transferred to the plant. Tissue of the target plant is incubated in a culture of *Agrobacterium* that includes the transformation vector, and the modified plant cells are then regenerated to develop viable transformed plants. The second type of transformation technique is based on the direct, physical transfer of foreign genes into target plant cells. The most common example is particle bombardment (biolistics), in which metal particles are used as carriers of plasmids containing transgenes and are introduced into target plant tissue at high velocity. The plant cells are tested for successful transformation and then regenerated. Both *Agrobacterium* and biolistic transformation techniques are complex procedures characterized by a wide range of modifications and improvements. For instance, the *Agrobacterium* methodology was initially unsuccessful at transforming monocotyledons (such as cereals), but several recent advances have overcome this limitation. Similarly, the success of biolistics depends on a number of engineering considerations governing particle delivery. Hence both technologies are subject to a large number of broad and specific patent claims that make their utilization (and any claims on the resulting varieties) far from straightforward. The particle gun technique was developed by Cornell University and licensed exclusively to Dupont, thus providing an exclusive right to use and sublicense the technique. A development that may address restricted access to transformation methodology is the recent announcement by CAMBIA of the discovery of transformation methods based on several genera of bacteria other than

Agrobacterium and the establishment of an "open source" licensing facility for these techniques (Broothaerts et al. 2005). Whether this methodology proves as efficient as the older methods remains to be seen.

REGENERATION METHODS

The transformed plant cells (the products of *Agrobacterium* or biolistic methods) must be regenerated to produce whole (genetically modified) plants. Various techniques, part of the science of tissue culture, are used to accomplish this goal, and each regeneration protocol is appropriate to particular species or even varieties. The majority of these transformation methods are described in the published literature and hence are available to all researchers, but modifications that provide higher efficiency or that are appropriate to specific species may be kept secret by individual laboratories, because it is impossible to detect their utilization in the final product.

DIAGNOSTIC TECHNIQUES

The other major area of biotechnology relevant to the plant breeding industry is diagnostic techniques that allow the identification of genes or sequences associated with particular functions or characteristics. Many of these methods are known as marker systems, and their application in breeding is referred to as "marker assisted selection" (MAS). The application of these methods can enhance the efficiency of plant breeding by accelerating the identification of desired plant types, but the end result of the process is usually a conventional (nontransgenic) variety. Although private firms rarely discuss their breeding techniques, MAS techniques have already contributed to a certain proportion of the varieties that are commercially available. Many public breeding programs in developing countries also use MAS, and a few products are beginning to appear (such as a downy mildew-resistant variety of pearl millet released recently in India). The potential applications for MAS continue to grow, but because the costs of these breeding techniques are usually higher, careful decisions must be made regarding when to invest in these techniques (Dreher et al. 2002).

The different MAS techniques are all based on the ability to detect differences in DNA sequences between selected plants. In some cases, the DNA is digested with restriction enzymes that cut it into segments of different lengths; the patterns of DNA fragments are compared, and the pattern associated with the desired genotype is identified. An early example of this method is restriction fragment length polymorphism (RFLP). In other cases, specific short nucleotide sequences in DNA are identified and multiplied ("amplified") through the polymerase chain reaction (PCR); differences in the resulting patterns are correlated with different plant functions or characteristics. The most important techniques include random amplified polymorphic DNA (RAPD), amplified fragment length polymorphisms (AFLPs), and microsatellites. By identifying a close linkage between the marker and a preferred gene (allele), MAS provides an effective method to screen large numbers of plants to determine if the gene is present. The elements of these MAS techniques are subject to varying degrees of protection. They rely on DNA sequences and probes, some of which may be available publicly whereas others are covered by patents. The AFLP technology is recognized as being particularly powerful. It is available in commercial kit form, but its components are subject to a number of patents.

Although MAS techniques are used in conventional plant breeding and no foreign DNA sequences become part of any resulting variety, the use of patented diagnostic technology may have implications for a plant breeder's ability to claim ownership of the final product. The exact situation will depend on the conditions under which the technology was acquired and the wording of any contract with the supplier. So-called "reach through claims" have not seemed to play a significant role in this area to date. Patent offices have also become aware of the negative effect of these claims and are very critical in granting wide claims.

Appendix B. The Breeding and Seed Sectors in the Case Study Countries

PUBLIC SECTOR RESEARCH IN CASE STUDY COUNTRIES

China

China's public agricultural research system includes more than 1,600 research institutes. Approximately 10 percent of the research is carried out at the national level, while 90 percent takes place in provincial and prefectural institutes. The total budget for agricultural research was US$ 1,025 million in 2002. About 73 percent is for crop-based research, of which 40 percent is devoted to crop breeding. China has invested heavily in agricultural biotechnology research—an estimated US$ 112 million in 1999 and a staff of more than 2,000 (Huang and Hu 2000).

Agricultural research at the national level is the responsibility of the Chinese Academy of Agricultural Sciences (CAAS), which comprises numerous institutes concentrating on specific crops, such as the CRI and IVF, as well as the BRI, with its focus on biotechnology. The BRI undertakes a wide range of agricultural biotechnology research and has developed its own Bt gene. This general institutional structure is replicated at the provincial level. Thus in Hunan, a major rice-producing province, the Hunan Academy of Agricultural Sciences has a Hunan Hybrid Rice Research Center as well as a Hunan Rice Research Institute.

The public agricultural research system in China has undergone a number of changes (Huang et al. 2003), including a shift from core funding to a competitive grant basis and assigning responsibility to research institutes for raising their own funds. Increased commercialization of the public agricultural research system is leading to overlapping roles and a shifting away from goals of food security, poverty reduction, and environmental sustainability. Thus despite the system's impressive achievements, it faces many challenges, particularly given the projected growth in China's population, income, and associated food needs.

Colombia

Public agricultural research in Colombia was formerly in the hands of ICA, but the government introduced an initiative to privatize research in the early 1990s with the creation of an independent research corporation, CORPOICA. ICA remained as a regulatory entity while all research functions were transferred to CORPOICA. In theory CORPOICA is supposed to be supported by contract research from producer organizations and private industry, but in fact the Ministry of Agriculture and Rural Development still provides most of CORPOICA's budget by "outsourcing" research tasks. CORPOICA is responsible for research on most of the agricultural crops in Colombia, but research for important cash crops is in the hands of a number of semipublic institutes supported in part by grower associations (for coffee, sugarcane, and palm oil, for example). CORPOICA's budget for 2004 was US$ 13.8 million and it employed about 300 researchers (compared to about 500 employed 10 years ago). CORPOICA has a biotechnology department, although it has not done any transformations.

India

Responsibilities for public agricultural research in India are divided between the ICAR institutes and the state agricultural university system. ICAR coordinates 89 research institutes, most of them specializing in particular commodities or disciplines. ICAR employs about 4,100 scientists. Much of the responsibility for agriculture in India is left to individual states, and 34 state agricultural universities (and 120 affiliated zonal research stations)

carry out research and outreach (with partial support from ICAR). The total research expenditure in 2000 was estimated to be US$ 625 million, equivalent to 0.42 percent of agricultural GDP (Pal and Byerlee 2003), with about 55 percent contributed by the central government and 45 percent by the states. It is estimated that approximately US$ 25 million is spent on biotechnology research.

Kenya

The major responsibility for agricultural research is with KARI, although some public agricultural research is also conducted by Kenyan universities. KARI is one of the stronger NARIs in Sub-Saharan Africa, but even so its operations are severely limited by its budget. The KARI budget for 2004/05 was nearly US$ 40 million, a sharp increase from the previous year (US$ 25.5 million), mostly owing to a significant expansion of donor funding, which covers slightly more than half the total budget. KARI has long experience in plant breeding and has been particularly successful in producing maize hybrids for the highland regions that constitute the major maize growing area. KARI has invested in biotechnology and has inaugurated a biotechnology facility that will support work on transgenic insect-resistant maize and other projects.

Uganda

Uganda's public agricultural research is managed by NARO, which is also responsible for livestock, fisheries, and forestry research. Its budget for 2004/05 was US$ 11.1 million, 70 percent of which is provided by donors. NARO is currently reorganizing to accommodate the Plan for the Modernization of Agriculture (PMA). NARO is expected to contribute to the PMA by conducting research that is demand driven and market responsive. Future funding for

Table B.1 Variety Release in the Case Study Countries

Country	Rice	Maize	Beans	Cotton
China[a]	1996-1999: 237 public and 3 private	1996-1999: 170 public and 4 private		1996-1999: 107 public and 10 private
	2000-2002: 189 public and 28 private (54% of releases hybrid)	2000-2002: 105 public and 34 private (all releases hybrid)		2000-2002: 85 public and 15 private (8% of releases hybrid)
Colombia	1992-2003: 25 varieties (5 public)	1990-2003: 80 varieties (11 public)	1950-1989: 33 varieties 1990-2003: 20 varieties (all public)	1990-2003: 29 varieties (6 public)
India	1995: 14 2000: 33 2001: 20 2002: 22 (all public)	1960-1999: 120 public hybrids and OPVs, plus an approximately equal number of unnotified private hybrids		1995: 5 2000: 6 2001: 7 2002: 9 (mostly public) plus many unnotified private hybrids
Kenya		1960-1999: 17 hybrids and 5 OPVs (all public) 2000-2003: 43 private hybrids and 4 private OPVs; 8 public hybrids	1982-2003: 15 varieties (7 since 1999) (all public)	
Uganda		2000-2003: 12 varieties (all public)	1995-2003: 12 varieties (all public)	

Source: Louwaars et al. (2004).
a. In China, a "private variety" is one marketed by, but not necessarily bred by, a private firm.

research will come not only from central government and donor contributions but also from private contracts and local governments. It is thus expected that NARO will generate a significant amount of its own funding, although the Research Act leaves open the question of NARO's control over any funds it generates. The new policy envisions research funding rising from its current 0.6 percent of agricultural GDP to 2 percent.

Variety Release

Trends in the release of varieties developed by the public and private sector in the case study countries are summarized in table B.1.

THE SEED SECTOR IN THE CASE STUDY COUNTRIES

China

Until recently, seed in China was supplied primarily by public seed production organizations. Their monopoly on sales was removed with a new seed law in 2000. This law permits private companies, research institutes, or individuals to produce and market seed provided they obtain the necessary certification from the provincial agricultural administrative department. In addition, public seed companies and research institutes are allowed to retain some of the profits from seed sales. The new law strengthened a number of trends already visible in the seed sector in the 1990s. While public institutes could already license their varieties and some private seed companies had appeared, local markets were still in the hands of the public seed companies operating at the county level. This has now changed. Many of the public seed companies at both the county and prefectural levels have gone bankrupt or have become cooperative companies, selling primarily nonhybrid or unprotected hybrid seed. In 2002, there may have been as many as 20,000 seed companies in China, including individuals selling only small amounts at the local level. A certain amount of consolidation has been taking place since then, underlining the current unsettled climate for the sector.

Many research institutes are extending their traditional breeding activities to include production and marketing. Some private seed companies have also begun investing in breeding activities. Although foreign companies began marketing wheat and maize seed in the 1990s through Chinese partners, direct foreign investments in joint ventures (as minority shareholders) in seed production and marketing have been permitted since 2002 only. The most notable example is a joint venture for production and marketing of Bt cotton between Monsanto/DPL and two provincial seed companies. The government's role has been less pronounced in regulating the vegetable seed sector, and private companies, including joint ventures with foreign companies, have been selling vegetable seed in China since at least the early 1990s.

Colombia

In the 1970s and 1980s, the Colombian government was involved heavily in the seed sector, operating a state seed company and offering subsidized credit to support the use of certified seed. The state company marketed mostly ICA varieties and a few imported commercial hybrids of maize and sorghum. Government policy encouraged private firms to replace the state seed company, and these firms thrived under a regime of support prices and government grain purchasing until 1990, when government policy changed. At one point there were 25 domestic seed companies, but the current number is less than half that; these are complemented by several MNCs. The domestic seed companies do most of their business in rice seed (6 companies have their own rice breeding capacity). The largest player in the market is FEDEARROZ, the national rice growers' association, which has moved from simply marketing inputs to breeding rice varieties and selling its own seed. Several small local companies breed and sell their own maize hybrids, but the market is dominated by hybrids from the MNCs. The MNCs have the majority of the cotton seed market as well. A range of public programs and producer organizations is responsible for seed production of many other crops, including wheat, barley, beans, and potatoes.

India

One of the contributors to India's Green Revolution was the development of state and national seed corporations, which provided seed of the new rice and wheat varieties as well as other public crop varieties. With the exception of some vegetable seed production and imports, the private seed sector did not have a significant presence in India until

the mid-1980s. Policy changes in the 1980s opened the doors to domestic private plant breeding and seed production and also allowed the participation of foreign seed companies. The economy-wide reforms of 1991 further liberalized the seed sector, particularly for the participation of MNCs. The initial expansion was based on hybrid seed, beginning with hybrid sorghum, pearl millet, and maize. Public research had developed cotton hybrids by the early 1980s, and private companies quickly adopted the technology, making India the world's leading producer of hybrid cotton seed. The prospect of hybrid rice drew a number of private companies into this area, although hybrids still account for a tiny fraction of India's rice seed market. Vegetable seed production is also mostly in the hands of the private sector, which largely produces proprietary hybrids (including some imported seed) but also some public hybrids and OPVs. Most of the public seed corporations survive, although their performance and financial stability vary widely between states. The public corporations are relied upon mostly for producing nonhybrid seed of major crops such as wheat, rice, and pulses. The participants in the private seed sector range in size from large, diversified national firms (some with MNC participation) to tiny local operations that may specialize in the multiplication and distribution of seed of a single crop.

Kenya

Until recently, all seed production in Kenya was the responsibility of the parastatal KSC, and no other commercial seed operations were allowed. The KSC had exclusive rights to all KARI varieties and also established its own breeding program, principally for maize (although work was also done on wheat, pasture grasses, and sorghum). A policy shift in the early 1990s allowed MNCs (including some from South Africa and Zimbabwe) to sell hybrid maize (and to a lesser extent sorghum and sunflower) seed. The policy change also encouraged a domestic seed industry to develop. There are currently three seed companies (besides KSC) with their own breeding programs, and several other small companies produce and market seed of public varieties. KARI and KSC signed an agreement awarding royalties to KARI for the use of varieties currently under KSC production, although some details of that agreement are still in doubt, including the degree to which KSC has exclusive access.

Uganda

Uganda has never had a very strong seed sector, but its new policies for agriculture have encouraged an expansion of activity. Earlier, virtually all seed (of public varieties) was produced and marketed by the parastatal Uganda Seed Project, which had several production facilities. This operation was recently converted to Uganda Seed Ltd., which has been a candidate for divestiture since 1998. Uganda Seed Ltd. continues to produce a small amount of seed, but it is now challenged by five local companies that have emerged in the past few years, mostly based on experience in grain trading and participation in seed acquisition for regional emergency seed operations. Only one of these companies has its own plant breeding capacity (it relies on IARC germplasm); most companies multiply and sell NARO varieties. Several multinational and regional companies produce seed in Uganda for export and some also market seed in Uganda (mostly hybrid maize seed).

SEED REGULATION IN THE CASE STUDY COUNTRIES

China

China's first seed law was decreed in 1989, followed in 2000 by the "Seed Law of the People's Republic of China." Previous regulations required that new varieties of the major crops must pass two to three years of trials and be approved at the state or the provincial level before being extended and used. Currently this requirement applies to rice, wheat, maize, cotton, soybean, and one or two other crops determined by the agricultural administration department at the state council and the people's government of the provinces, autonomous regions, and municipalities. The criteria for new varieties are established by the MoA or at the provincial level. The new seed law has not stipulated any approval mechanisms for less important crops.

There are rules for seed production and management, including a licensing system for seed producers and traders. Based on "The Regulation of Crops Seed Production and Operation Licenses Approval," decreed by the MoA, there are four types of licensed seed companies. The first type is permitted to produce and market seed of conventional crops. The second can also deal with hybrids. The third type of seed company can be involved in foreign seed trade in addition to

producing and marketing any kind of seed locally. The fourth type of seed company can have its own breeding program. All seed companies have the right to carry their own trademarks and have their own seed packages according to their respective licenses. Although Chinese seed regulation is relatively comprehensive, resources dedicated to enforcement are far from adequate.

Colombia

All crop varieties offered for sale in Colombia must be tested for agronomic performance and officially released. The testing process involves trials in one or more of five agroecological zones in the country (varieties are released for specific zones). Until recently, these trials were run by ICA, but a new regulation (Resolution 2046, which aimed to adjust Colombian seed legislation to "the evolution in the domestic seed industry and to bring it in line with international norms") allows companies with their own plant breeding capacity to conduct these tests and submit the results to ICA. All seed of agricultural crops sold in Colombia must be certified, and ICA is the official certification agency. Some seed companies complain that ICA does not have the capacity to fulfill this function efficiently, and there is pressure from the industry for ICA to license companies to certify their own seed. ICA is also responsible for monitoring seed sales and detecting violations of regulations.

India

All public crop varieties must be officially released and notified through a process that includes performance tests at either the state or national level and notification by the Central Seed Committee. The national level performance testing is managed through the extensive All-India Coordinated Crop Improvement Programs (AICCIP). Private varieties do not require release or notification in order to be sold. Private varieties may be entered in the AICCIP trials, although the fees for the private companies are currently quite high. In practice, only a minority of private hybrids are officially notified, although companies acknowledge that data from the tests is useful and that notification is an aid to promoting a variety in the market. Seed certification is managed by state seed certification agencies, and only notified varieties may be certified. Certification is not compulsory, even for notified varieties, although various agricultural programs and subsidies require that farmers use certified seed. Most private seed, and a substantial minority of public sector seed, is sold as "truthfully labeled," requiring the name of the variety and minimum germination and purity standards. Officers of the state departments of agriculture are assigned to monitor seed sales and collect samples of commercial seed to test for conformity with certification tags or truthful labels. The seed regulations are being reviewed, partly in light of recent IPR legislation, and a revised Seed Act (which took effect in 2005) makes some form of variety testing and registration compulsory and provides for optional seed certification, involving possibilities for self-certification by companies.

Kenya

Variety approval and release in Kenya was reorganized recently and placed under the auspices of KEPHIS. All varieties of field crops (public and private) must be entered in National Performance Trials, which are divided into agroecological zones. All varieties must be registered, including DUS testing, and this testing takes two years. Seed of most field crops also must be certified. The responsibility for seed certification lies with KEPHIS and is managed from several regional stations. There is some pressure from seed companies for possible accreditation to certify their own seed, but no action has been taken. The certification requirement has been enforced even for small-scale, formal seed production (by donor-supported producer groups, for example) for crops such as beans and sorghum. However, KEPHIS has indicated that in the future small-scale seed producers will be able to sell seed for some crops (but not maize) as "standard seed," which requires only seed quality testing. Kenya, Tanzania, and Uganda recently concluded a harmonization of seed regulations for Eastern Africa. The new accord includes an agreement that varieties released in any one of these countries will have a "fast track" in variety testing in the others. The accord also adopts common certification requirements, including a short list of crops with mandatory certification.

Uganda

Variety release in Uganda still follows the system established for public plant breeding. Candidate

varieties (public or private) must undergo a series of field trials that take at least three seasons and include at least seven sites; the trials are managed by NARO. If a variety progresses to the most advanced stage, DUS testing begins, managed by the National Seed Certification Service (NSCS). Performance and DUS data are presented to a committee that is in charge of official variety release; NSCS maintains a national variety list. Seed of major field crops must be certified by NSCS, although the agency is underfunded and the industry is anxious to see a system in which companies can be accredited for certification. Uganda participated in the recent Eastern African harmonization of seed policies and regulations.

PVP legislation in the case study countries

Table B.2 provides details on the coverage, length of protection, and other parameters of PVP legislation in the case study countries.

SEED USE IN THE CASE STUDY COUNTRIES

China

In China, farmers' sources of seed vary by region and crop. Marketed rice seed is divided roughly equally between OPVs (214,000 tons in 2002) and hybrid seed (250,000 tons). Over 90 percent of the area sown to hybrids is sown to seed purchased each year, whereas the corresponding area figure for OPVs is estimated to be 30 percent. Hybrid rice seed has gained considerable market share since 1980, despite its higher cost for farmers, and now accounts for almost half of the area planted to rice. On the other hand, approximately 35-40 percent of the rice area is sown with farm-saved or informally acquired seed. The cotton seed market is dominated more heavily by OPVs: hybrid seed accounts for only about 15 percent of the estimated annual sale of 78,000 tons. Purchased cotton seed from formal sources is estimated to account for 35 percent of the total seed requirement, highlighting the importance of saved and exchanged seed. In 2003, approximately 56 percent of the cotton area was planted to Bt cotton (James 2003), and sales of Bt cotton seed are 58 percent of total sales. Since its release, Bt cotton has been absorbed into farmers' seed systems, with a considerable amount of seed saving and crossing taking place. The situation in vegetable seed is quite different, given the extent of development of hybrid varieties. Replacement rates are estimated to be almost 100 percent for most major vegetable crops, such as Chinese cabbage, tomato, chili, and cucumber (Hu 1998; Koo et al. 2003).

Colombia

Colombia's dualistic agriculture is reflected in patterns of seed use. For rice, approximately half of the area is sown with purchased seed each year. Seed purchase is quite high in this largely commercial enterprise, although the industry is concerned about the amount of unauthorized seed sales by farmers. Maize is much more of a small-farm crop, and the proportion of purchased seed is much lower than for rice. However, the commercial maize sector, which grows maize mostly for feed, depends heavily on purchased hybrid seed. Currently three MNCs account for about 80 percent of the hybrid maize seed market. Cotton is also dominated by MNCs, but official statistics indicate that the degree of seed saving varies widely from year to year. Although beans are an important crop in Colombia, local varieties account for the vast majority of production, and there is little formal seed sale.

India

Seed use in India also varies by crop and by region. Nearly 90 percent of rice seed is still farm saved or locally acquired, but important regional differences prevail. Very little commercial seed is sold in some states, whereas in others, such as Andhra Pradesh, more than one-quarter of rice farmers buy commercial seed in a given season. The situation for maize is even more variable, depending in part on the farming system. In some states, hybrids account for less than 10 percent of seed use, while in others, where maize is more of a cash crop, hybrids account for more than three-quarters of maize seed use. Proprietary hybrids constitute the vast majority of maize seed sales, although state seed corporations and some small companies sell public hybrids and OPVs. Most vegetable growers purchase seed from the private sector. Vegetable hybrids are important for many species; these may be products of domestic private plant breeding or imported, but some public hybrids and OPVs are also on the market. For cotton, there are distinct regional patterns of seed use. Northern India relies

Table B.2 PVP Legislation in the Case Study Countries

Parameter	China	Colombia	India	Kenya	Uganda
Legislation	Regulations of the People's Republic of China on the Protection of New Varieties of Plants (1999). Member of UPOV (1978) since 2000.	Law 243 of 1995 establishes PBR. Resolution 2046 (2003) defines limitations on seed saving. Member of UPOV (1978) since 1996.	Protection of Plant Varieties and Farmers' Rights Act (2001) establishes PBR. India has applied to join UPOV.	Seed and Plant Varieties Act (Cap 326) amended in 1991 and 1994 to establish PBR. Kenya joined UPOV (1978) in 1999.	A draft Plant Variety Protection Act, debated in Parliament in 2004, defines PBR as well as farmer and community rights.
Scope of coverage	41 crops currently eligible. Certificates issued for 15 species to date; cotton not eligible for protection.	All crops eligible. In practice certificates issued for 7 agricultural crops and 15 horticultural crops.	No crops excluded, but exemption for varieties whose commercial exploitation would be a danger to public order, public health, and so forth.	No crops excluded; to date applications have been accepted for 31 agricultural crops and 23 horticultural crops.	No crops excluded.
Length of protection	20 years for vines, fruits, and ornamentals; 15 years for all other crops.	25 years for trees and horticultural crops; 20 years for field crops.	18 years for trees and vines; 15 years for other crops.	18 years for trees and vines; 15 years for other crops.	25 years for trees and vines; 20 years for annual crops
Farmer seed saving and exchange	Seed saving and exchange are permitted. (Local and informal seed sales are regulated by seed law.)	Farmers with more than 5 ha not allowed to save seed of protected varieties. No farmer's privilege for horticultural or tree crops or transgenic varieties.	Seed saving, exchange, and sale by farmers are permitted, but not sale of "branded seed."	Seed saving currently permitted, but moving towards UPOV 1991. (Local seed sale restricted by certification requirements)	Farmers have the right to use, exchange, and sell farm-saved seed of protected varieties but not "on a commercial scale."
Breeder's exemption	Protected varieties may be used for breeding. (No special rules for EDVs.)	Protected varieties may be used for breeding.	Protected varieties may be used for breeding. Protection of EDV depends on rights of original breeder.	Protected varieties may be used for breeding, but moving towards UPOV 1991.	Protected varieties may be used for breeding.
Protection of extant varieties	Protection offered for varieties that were in China up to 4 years before a species/genus becomes eligible for protection (application to be made within 1 or 2 years, woody and agricultural species resp.)	Amnesty for 1 year when PVP was introduced for officially released varieties. Protection period based on remaining period, counting from year of release.	Varieties already released and notified will be eligible for protection (from date of original notification).	Public varieties already released eligible for protection (from date of filing), but decision contested.	Extant varieties not eligible for protection.
Plant variety patents	Hybrids can fall under the scope of a patent for a "breeding methodology."	Genetically modified organisms may be patented because not found in nature.	No patents of plant varieties.	No patents of plant varieties.	No patents of plant varieties.

Source: Louwaars et al. (2004).

Table B.3 Seed Use for Major Field Crops in the Case Study Countries

	Rice		Maize		Cotton	
Country	Area planted (000 ha)	Area sown with purchased seed (%)	Area planted (000 ha)	Area sown with purchased seed (%)	Area planted (000 ha)	Area sown with purchased seed (%)
China	30,000	30 (OPV) 90 (hybrid)	23,000	96	3,200	35
Colombia	470	50-60	550	15	44	35-65
India	45,000	11	6,100	25	8,500	65
Kenya			1,600	45		
Uganda			540	20-35	160	-

Source: Louwaars et al. (2004).

to a large extent on OPV cotton (in large part because suitable hybrids have not yet been developed for this region); these are largely public varieties, produced by both private and public seed companies. In central and southern India, in contrast, most of the cotton sown is hybrids (mostly private), produced almost exclusively by private firms.

Kenya

The star performer of the Kenyan seed sector continues to be hybrid maize. Kenya was one of the first countries in Sub-Saharan Africa to produce hybrid maize, and many farmers have long experience with relying on hybrid seed. Most of these farmers are in the more productive highlands, the center of commercial maize production in Kenya. Nationwide, annual purchase of commercial maize seed accounts for about 45 percent of maize area; the vast majority of this is hybrid seed, with some OPVs (public and private) being sold in more marginal production areas. Maize seed sales are still dominated by KSC, which accounts for roughly 90 percent of the market; the remainder is divided among six other companies. Little seed of other crops is sold, although a few companies sell a small amount of seed of KARI bean varieties, and some MNCs market sunflower hybrids. Virtually all vegetable seed is imported. Most seed of crops for dryland areas (sorghum, millet, pigeon pea, and so forth) is produced only through special donor- or government-supported projects.

Uganda

Although seed production and sales are increasing in Uganda, the majority of the industry's business is still through special projects or NGOs rather than over-the-counter sales. The major product is maize seed; sales in recent years were under 2,000 tons but jumped to nearly 5,000 tons in 2003. Beans are in second place, with roughly 800 tons sold annually. Smaller amounts of seed of sorghum, groundnuts, and several other food crops are also sold.

Summary data on the use of purchase seed

Table B.3 presents comparative data on the use of purchased seed for major field crops in the case study countries.

Appendix C. Major Issues in Current IPR Systems for Plant Varieties

For historic background and general policy issues related to IPR systems, please refer to chapter 3. This appendix provides an analysis of the differences between existing protection systems under the UPOV Conventions of 1978 and 1991, and the US utility patent system. (Plant patents have not been included, because they cover a very limited range of crops in one country only.) This appendix also provides a brief introduction to Farmers' Rights and the protection of biotechnological inventions.

FARMER'S PRIVILEGE

The traditional right of farmers to save seed from their harvests to plant the following season is an important aspect of *sui generis* systems and is one of the most contentious aspects of IPRs in plant breeding. Although this practice is often described as a "farmer's right," it is referred to here by the UPOV term of "farmer's privilege" to distinguish it from the broader concept of "Farmers' Rights," discussed below.

The 1978 UPOV Convention assumed that farmers were permitted to save and reuse seed of protected varieties as part of "private and noncommercial use." However, article 15(2) of the 1991 UPOV Convention rules that on-farm seed saving is not permitted without the consent of the breeder, although it allows member states to specify crops for which the use of farm-saved seed is permitted, "taking into account the legitimate interests of the breeder." In the EU, this provision is interpreted as the right of smallholder farmers to save seed for specific crops and the right of the breeder to collect royalties on farm-saved seed used on larger farms. The 1991 Convention also prohibits any transfer of seed of protected varieties (through sale, barter, or gift) between farmers. Utility patents on plant varieties are even more rigid, and a patented variety normally cannot be saved for subsequent use as seed on the farm or traded or exchanged with other farmers.

Various interpretations of farmer's privilege have favored the adoption of laws based on the more liberal 1978 UPOV Convention in many developing countries. In most cases in these countries, restrictions on saving seed of food crops on the farm are neither administratively feasible nor politically acceptable. Making the transfer of seed from farmer to farmer illegal is widely considered incompatible with the traditions of small-scale farming.

The issue of seed saving is a good example of how IPRs in plant breeding must be tailored to the conditions of national seed systems. Even within a single country, the requirements and conditions of different crop production systems are not uniform, and countries could consider legal options that address this variability. For instance, earlier seed law in the Netherlands included severe restrictions on saving planting materials for ornamental crops, while field crops were regulated on the basis of the more liberal UPOV 1978 Convention. Many vegetatively propagated commercial flower species can be multiplied very rapidly by farmers, which would considerably reduce revenues for breeders and provide inadequate incentives for innovation in a sector that is very important for Dutch agriculture. Thus an amendment to the law made the farm-level propagation of such species illegal. This example emphasizes that countries need to design appropriate levels of protection for different types of commodities, in accord with the domestic agricultural economy and plant breeding capacities.

BREEDER'S EXEMPTION

The breeder's exemption is the right of a breeder to use a protected variety for developing new varieties. This exemption stems from the traditionally unrestricted use of seed by farmers and breeders.

It is seen as a way of promoting the development of the best varieties for farmers, limiting the development of long-term commercial advantages, improving opportunities for smaller breeding companies, and thus promoting competition in the sector. Unlike the farmer's privilege, the breeder's exemption has not dramatically changed in later UPOV Conventions, prompting some companies in the USA to look to the patent system for protecting their germplasm (box C.1). The only modification in the 1991 Convention is the limitation on EDVs, which may fall under the rights of the original breeder. The EDV provision is meant to limit the possibility of "cosmetic breeding," which produces a variety that is only slightly different from the original through techniques such as mutation breeding, repeated backcrossing, or genetic transformation (for example, simply inserting a transgene in a protected variety). The EDV concept is susceptible to different interpretations, however, and is the subject of an ongoing debate among breeders (ISF 2004). An EDV can be protected when it is DUS and new, but to commercialize the variety, the breeder of the EDV must have the consent of the person or entity that holds the rights to the original variety. Some larger companies would like to introduce the concept of "genetic distance" in the definition of an EDV, but others fear that this step could lead to the monopolization of certain gene pools. After much debate, seed company representatives recently agreed upon arbitration rules for EDV disputes (ISF 2005).

OTHER ISSUES RELATED TO PLANT VARIETY PROTECTION

Regardless of whether they want to follow UPOV, countries face several additional important IPR issues that require attention. These issues include the choice of crops eligible for protection, the protection of harvested materials, and the requirements for variety registration.

Although it is expected that a country's IPR regime for plant breeding eventually will provide some type of protection for all cultivated species, both the 1978 and 1991 UPOV Conventions provide guidelines for phasing in this protection.

Box C.1 Breeder's Exemption and the Patent System

For seed companies in the USA, one of the attractions of patents for plant varieties is the absence of a breeder's exemption: patented varieties cannot be used to develop new varieties without the consent of the patent holder. The research exemption available under patents in the USA is much narrower than in many other countries, essentially eliminating the possibility of using a patented variety in a research program, and some US seed companies would like to see this as a pathway for eliminating the breeder's exemption for protected varieties. Although most other countries do not grant patents on plant varieties, there is a danger that biotechnology patents could effectively remove the breeder's exemption where, for instance, a PVP-protected variety contains a patented gene.

The EU has attempted to resolve this conflict between patents and PVP by providing a farmer's privilege, where applicable, in the patent system, and the option of compulsory cross-licensing, in the spirit of the breeder's exemption (EC 1998). But the conditions for granting such licenses imply a limitation of the breeder's exemption, compared to the freedom available under PVP (Eaton and van Tongeren 2006). The seed industry association, representing majority opinion among its members, has stated that it would prefer to see an unencumbered breeder's exemption remain (ISF 2003), without the complications posed by cross-licensing (ESA 2004). The breeder's exemption on varieties that also include patented components is currently maintained through a "gentlemen's agreement" among companies, but it is not clear now how long this situation will last. A workable legal solution to maintaining the breeder's exemption while at the same time respecting patents for plant components has yet to be developed. Controversial discussions, however, have started recently in certain sectors of the seed industry to delay access to the breeder's exemption under the UPOV system. Such an action would significantly reduce the difference between patents and PVP.

Source: Authors

The 1991 Convention expects initial coverage of 3 genera or species with a phased expansion to 24 over an 8-year period. There is debate over whether this phased expansion is compliant with the TRIPS Agreement, which specifies that countries have to provide for the protection of varieties of (any) crop species. Countries must also decide how to treat varieties that are already in commercial seed production, the majority of which are likely to be publicly released varieties. Such extant varieties may be given a full term of protection, be protected for the requisite period beginning from their original release date, or be excluded from protection.

One of the innovations of the 1991 UPOV Convention is the possibility of expanding protection to harvested materials. This regulation allows the breeder to protect his or her rights not only in the seed market but also in the market of the harvested product, if the breeder has not had the "reasonable opportunity to exercise his right" on the propagating material. The principal application of this regulation occurs where access to seed or planting material cannot be controlled (for example, in production areas in countries that do not have an operational PVP system) and the product enters markets where the variety is protected. This rule is used particularly in the flower industry when flowers are produced in developing countries and shipped to Europe and the USA. Now that the most important flower producing countries in the South are members of UPOV, there is a debate whether breeders should still claim rights on the harvested products, but shipments from these countries have occasionally been seized in the importing countries.

The establishment of a PVP system also requires decisions regarding the nature of the variety registration process. UPOV provides detailed guidelines on descriptors for variety registration. In theory, an application must be compared with all varieties of common knowledge, but the great worldwide increase in variety registration is making it more difficult to assess the uniqueness of a variety. There are calls for greater collaboration among PVP offices and the establishment of an effective reference collection, but problems will remain for some time (Le Buanec 2004). The responsibility for data collection must also be determined. In some cases, breeders are responsible for providing the data required for a DUS application; in other instances, a national PVP office does the examination, or it contracts DUS testing to independent research institutions or purchases DUS reports from other authorities. Decisions also need to be made regarding the registration of hybrids (and/or inbreds) and the provision or deposit of germplasm, especially in the case of hybrids, which are often treated as trade secrets.

FARMERS' RIGHTS

An issue that falls outside of the TRIPS requirements for IPRs in plant breeding but which elicits considerable debate is the concept of Farmers' Rights, which has several aspects, such as the right of farmers to save (and use, exchange, and sell) seed derived from their own harvests. The IT PGRFA brought three basic concepts under the scope of Farmers' Rights: (1) the right of benefit sharing, which gives farmers the right to be compensated for their contributions to the development and maintenance of genetic resources and for making them available for use in breeding; (2) the right to be involved in the development of national policies; and (3) rights related to the protection of traditional knowledge relevant to genetic resources. As a corollary, farmers may also claim ownership over their local varieties and apply for PVP. There is controversy over whether some of these aspects of Farmers' Rights should be included in PVP legislation to allow countries to comply with TRIPS, CBD, and IT PGRFA through one piece of legislation. Many national PVP laws make no mention of these issues, but India recently enacted "The Protection of Plant Varieties and Farmers' Rights Act," and the Organization of African Unity produced model legislation for "The Protection of the Rights of Local Communities, Farmers, and Breeders, and for the Regulation of Access to Biological Resources." In a given country, decisions on how to treat Farmers' Rights will need to be based on an assessment of the major sources of innovation in plant breeding in the country, the aspirations of farming communities, and possibilities for administering and enforcing the wider aspects of Farmers' Rights.

The right of benefit sharing would seem to offer attractive possibilities for ensuring that farmers' ingenuity and experience are fairly rewarded. As a number of observers have pointed out, however, there is virtually no experience in the actual implementation or management of such rights in agricultural crops. The CBD would require a direct link between the benefit sharing and the use of a

particular genetic resource. However, the extent to which particular local varieties (with identifiable "owners") may be used in the development of new crop varieties, and the problems in calculating the exact contribution of such a variety, monitoring seed sales, and collecting the appropriate royalties, make the management of such compensation mechanism hugely problematic (see, for example, Srinivasan 2003). A declaration of source is currently discussed in the framework of the CBD. A multilateral approach to benefit sharing is included in the IT PGRFA for a number of important crops, but the implementation rules have yet to be designed. Similarly, the degree to which farmer-bred varieties can be identified, registered, and marketed has yet to be tested (see, for example, Ramanna and Smale 2004).

PATENTS AND BIOTECHNOLOGY

In the past two decades, the contributions of biotechnology have transformed the science of plant breeding. The most visible (and controversial) aspect of plant biotechnology is the ability to transfer segments of DNA from one organism to another, resulting in transgenic varieties. The range of commercial transgenic crop varieties is still quite narrow (the majority feature herbicide tolerance or insect resistance), and about one-third of the global area planted to transgenic crops is in developing countries (the majority in Argentina, Brazil, China, India, and South Africa) (James 2004). Nevertheless, a recent review demonstrates considerable progress in research capacity for genetic transformation in the South (although concentrated in relatively few countries), including a range of crops and characteristics well beyond current commercial offerings (Atanassov et al. 2004). A less publicized but equally important contribution of biotechnology to plant breeding is the development of a range of tools and processes that allow plant breeders to link particular functions to specific genes or sequences of DNA and to track their presence during the course of conventional plant breeding. The genes and techniques used in developing transgenic crops, as well as the diagnostic tools and processes of marker-assisted breeding used to produce conventional plant varieties, are all candidates for patent protection (see Appendix A).

National patent systems have been unable to keep pace with the rapid development of plant biotechnology, leaving many areas of uncertainty and dispute. In developing countries, only a small minority of patent offices have begun to consider applications related to plant biotechnology, while in several industrialized countries a number of claims to basic technologies are still the subjects of complex court cases. It is therefore impossible to chart an unambiguous course for the development of effective IPR regimes for biotechnology, but it is important to recognize the major parameters and to identify the issues that will affect IPR policy in the coming years. Areas of particular concern include the protection of genes and other sequences, the methods used for genetic transformation, information in bioinformatics databases, and the diagnostic techniques that biotechnology offers conventional plant breeding.

IPRs for biotechnology thus present a complex set of issues that will challenge policy makers, researchers, and the commercial sector for many years to come. Developing countries need to strengthen their capacity to understand the issues and to develop appropriate policies regarding the patentability of various biotechnologies and their products in order to support domestic development of biotechnology and promote access to foreign technologies.

If biotechnology is to contribute to poverty alleviation and rural food security, a greater effort must be made to place technologies in the public domain. The promotion by CAMBIA of an open-source model for biotechnology innovations is a challenging example. Although some important technologies are in the public domain, most of the key elements of plant biotechnology are controlled by a small number of MNCs. Important court cases are in progress to define the boundaries of some of these claims, but the results will merely assign rights to one firm or another, or result in further cross-licensing that keeps most of the technology in the hands of a few large firms.

Agricultural research in developing countries needs better access to this technology. Certainly there are instances in which these firms are willing to provide humanitarian licenses for some of the technology; the example of "Golden Rice" is the most highly publicized case. Such licenses may focus on segmented markets (particular countries or classes of farmers) and on public-private partnerships in which NARIs can trade access to some of their own technology (Byerlee and Fischer 2002). One recent example is the PIPRA initiative of major

U.S. universities, foundations, and nonprofit research institutions to make agricultural technologies more easily available for breeding varieties of subsistence crops in the developing world, partly through humanitarian licensing. In addition, researchers can use technologies that are not patented in their own countries without fear of immediate sanction from the patent holder, as long as the products do not enter into international trade (Binenbaum et al. 2003). However, some argue that such use could impede future negotiation of legitimate licensing agreements for new technologies.

In most cases, developing country researchers will need to do a thorough FtO analysis to understand the ownership implications of the tools, materials, or processes that contribute to a particular research project. The technology they use may have been acquired through nonofficial channels, by means of an MTA that may allow only research use, or through commercial purchase that includes other types of contractual restrictions. As biotechnology research in developing countries moves from theory to practice, an explicit understanding of the nature and implications of access to protected technology becomes increasingly important if products are to be delivered into farmers' hands.

A point of equal importance is that national patent offices must be prepared for a growing number of applications in plant biotechnology. They will have to define the types of claims that may apply for protection, given the details of the national law, and establish guidelines for determining the novelty of particular biotechnology inventions.